MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

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9:48 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

MR. HACKBARTH: Welcome to those of you in the audience. Having completed the work on our March report to Congress at the last meeting, we are now taking up topics, many of much of which will be addressed in our June report. You will notice that we have somewhat fewer sessions but longer sessions in recognition of the complexity of some of the topics that we are wrestling with.

This morning, we have two sessions, one on accountable care organizations and the second on physician resource use measurement.

David, are you going to lead on accountable care?

MR. GLASS: Yes. Good morning. Today, Jeff and I will bring you up to speed our work on accountable care organizations. I will briefly review the rationale for ACOs, what characteristics our analysis shows they would need to have, and some of the implications of those characteristics. Jeff will then introduce an illustrative payment design, an outline two passed ACOs might follow, and raise some issues that will have to be addressed.

Medicare needs a way to control cost growth. Current spending growth is unsustainable. Constraining

fee-for-service rates in conjunction with other policies the Commission has recommended may improve policy and slow growth, but it's unlikely to be sufficient. ACOs could provide the Congress an additional lever by tying bonuses and penalties directly to the rate of growth in overall medical spending, which is ultimately what we want to control. Being able to control volume growth, not just price, is important and could create the trade-off between constraining fee-for-service rates and constraining ACO targets. For the same level of Medicare spending, stronger incentives for ACOs would mean fee-for-service rates could be higher and vice-versa, as we will explain a little later.

The objectives for an ACO policy are, first, at the highest level, to provide a path to delivery system reform that would improve care coordination and collaboration among providers.

Second, the ACO will tie physician and hospital payments to quality and resource use to help assure beneficiaries get high-quality care.

And third, it should achieve a sustainable Medicare spending growth rate. It can do so by creating an incentive to reduce unnecessary services. Data on regional

variation show it is possible to reduce unnecessary services and still maintain quality.

Finally, physicians and hospitals will have the common incentive to coordinate care and reduce unnecessary services because they will share in the efficiency gains.

The basic thrust of our ACO design is to give physicians and hospitals joint responsibility for the quality and cost of care delivered to a population of patients. Physicians and patients could be assigned based on Medicare claims, as Elliott Fisher has demonstrated in his work. We think there would be bonuses for high quality and low cost growth, penalties for low quality and high cost growth, and penalties would create more potential for Medicare savings. Some designs that been proposed are bonus only and depend on behavioral changes producing savings, but that weakens incentives and Medicare could end up spending more money for the status quo if providers continue to grow their volume at the current rate, which is why we include penalties in our design.

We are defining cost growth as the rate of increase in overall Medicare spending for beneficiaries assigned to the ACO. Overall spending would include

Medicare services patients receive outside of the ACO, as well. Under this design, ACOs would need to have the following characteristics.

We analyzed data from the Dartmouth group and found that ACOs would have to have at least 5,000 patients to tell the difference between real improvement and random variation. Even at the size, multi-year averaging would be required to reduce the random variation to low enough levels.

Several implications follow from making ACOs this size. First, the problem is ACO incentives for an individual to take actions that restrain volume may be too small to overcome fee-for-service incentives. That is, the individual provider will still have a greater incentive to do a procedure that to not do it. The tragedy of the common problem still exists. The bonus or penalty is shared by many; profit from the additional procedure all goes to one.

But there is also an opportunity here. Incentives for joint actions could be large enough to overcome fee-for-service incentives. An ACO jointly could change patterns of care and capacity. Actions that all members of the ACO take could make a difference. This, in turn, means

that successive ACOs will have to have the capability to make joint decisions, which means they will need organization and information. If savings come from constraining capacity, it will take time to see the effect and evaluations might have to take that into account.

An example of the difference between an individual action and a joint decision is as follows. This is from the perspective of the practice and what we are looking at is the decision to order the additional MRI. So the logic of the individual decision to order an additional MRI image, given the practice already owns an MRI, is as follows. The revenues would be $500. The marginal cost for assuming is $100, meaning a $400 profit. So Medicare spending will go up by $500. If you look at the effect that would have on the ACO bonus that they might get for restraining resource use, that is a negative-$500 times 0.5, which we're saying have a 50-50 chance of reaching their bonus, and their share of the savings is 0.8. So there's a negative-$200 there net. So the net incentive of $400 profit and the minus-$200 effect on the ACO bonus is a net incentive of plus-$200. So they would go ahead and order the additional MRI.

Now let's move from the first column we just

discussed to the second that is shown in yellow on the slide. So we're looking at the incentive under a ACO for the practice to lease an additional MRI machine. We assume revenue would be $500,000, which would come from both Medicare and non-Medicare patients. The annual profit after a cost of $450,000 is $50,000 for the practice. But Medicare spending would increase by $250,000. We're assuming here half the revenue is for Medicare patients. The bonus would go down by $100,000. So the net incentive would be a negative-$50,000 and the practice would not lease the additional machine. They would reach a joint decision not to increase capacity.

So the point of this slide is to show that once a practice has invested in a piece of machinery, they will use it. It will be difficult for ACO incentives to be large enough to give the practice an incentive to not use the machine. However, the ACO incentives could alter the initial decision to purchase a machine, and in general, to increase or not increase capacity.

Other examples of not increasing capacity would be not recruiting an additional cardiologist perhaps, or not building additional ICU beds. The other joint actions that

might arise are changing practice protocols. For example, when or when not to admit a patient.

One question is that the other payers don't follow the same approach, the power of the incentive will be diminished. I think this came up in yesterday's session, John.

Jeff will now explain how these incentives could be embodied in an illustrative ACO payment design.

DR. STENSLAND: Clearly, there's more than one reasonable way to determine bonuses and penalties, so here I'm just going to present one possibility. The idea is just to try to bring this down to a more concrete level for discussion.

In this system, physicians and hospitals would continue to receive fee-for-service payments less a withhold, and I'm going to walk into one method for deciding which ACOs lose their withhold and which ACOs get bonuses.

First, let's look at that far right-hand column. These are ACOs that lose the withhold. They lose it because they fail to meet the quality targets and they fail to meet them for three straight years.

In the middle column, we have ACOs that meet the

quality standards in one or two of the three years. They get their withhold back unless they fail to meet the cost benchmark for three straight years. For those that are mixed on quality and fail on costs for three straight years, they would get one-half of their withhold back.

Finally, let's look at the first column. These are ACOs that meet the quality target for three straight years, high-quality ACOs. These hospitals all get their withhold back. In addition, if the ACO meets the cost target for three straight years, they will get a bonus. So the bonus is for ACOs that consistently meet both their quality and their cost targets.

In the system of bonuses and withholds, Medicare would have some control over the growth rate of Medicare spending. If spending is growing too fast, Medicare could set more aggressive spending and quality targets. If Medicare spending growth is reduced to a sustainable level, Medicare could set easier spending growth and quality targets.

Now, the bonuses I just talked about depend on meeting targets. So how targets are set will be an important consideration.

Here we present one possibility of how we could set resource use targets. Our goal is to set fair targets that allow good providers to achieve bonuses in both historically high and historically low resource use markets. Medicare could do this by allowing a fixed dollar increase in spending per capita for each ACO in the country.

For example, let's start looking at the first column. It shows the national average spending of $10,000 per year per beneficiary, a target growth amount of $500. This is equivalent to a national spending target of $10,500 per capita. Now, you may ask, why do we set a target of $500 and not simply 5 percent. The reason is that if we used a 5 percent target, we would be rewarding providers that have historically had the highest level of utilization and this would not be fair to providers in areas of the country that have done a good job restraining resource use growth.

Now let's look at that second column. Here we have a low-spending ACO. For this ACO, a $500 spending growth target is equivalent to a 6.3 percent increase in spending. We can contrast this to the last column. Here we have a high-spending ACO that has historically spent $12,000

per capita. That high level of spending and the same target of $500 results in a percentage growth target of 4.2 percent.

The bottom line is that we want quality providers to be able to achieve a bonus whether they are in a historically high-spending area or historically low-spending area. The spending growth target of $500 would be adjusted for regional wages, but it wouldn't be adjusted for any regional difference in utilization. So you won't get a higher target just because you happen to have a lot of imaging or a lot of visits in your market that other markets don't have.

Now let's look a little bit about how this would be used to compute payments. In this example, I contrast two ACOs. First, look at the left-hand column. The top line shows us one of these ACOs has high quality and the bottom line shows us the other ACO has low quality. The second column tells us that both of these ACOs have historically spent $7,000 per capita per year. Due to equal historical levels of spending, they both have a spending target of $7,500.

In this example, the high-quality ACO keeps its

spending level constant at $7,000. The low-quality ACO increases its spending to $8,000. The high-quality low-cost growth ACO is rewarded with a bonus. We see this in the last column. They are paid $7,400 in total for the year. This consists of $7,000 fee-for-service payments, having their withhold returned, and getting a $400 bonus. The providers in the ACO benefit from the $400 bonus per patient. The taxpayers benefit from a reduction in the growth rate of Medicare spending. Even after paying the $400 bonus, the taxpayers still spend $100 less than the target.

In contrast, let's look at the second row. Here, we have a low-quality, high-cost growth provider with $8,000 in billings, but it loses withhold and fails to get a bonus. The net result is despite providing more services per beneficiary, the low-quality provider receives a lower level of Medicare compensation. That's the $7,200 in the lower right-hand column.

Now, here we have the high-value ACO in this example that was only paid $200 more than the low-value ACO. But keep in mind that the high-value ACO would also have incurred lower costs due to providing a lower volume of

services. So the providers in the high-value ACO should be generating a significantly higher level of net income on Medicare patients due to having higher Medicare revenue and lower costs of care.

A key decision is whether ACOs should be voluntary or mandatory. Under a voluntary ACO model, the system of bonuses and penalties would have to be attractive enough to bring providers into the ACO, because under a voluntary system the providers could always opt out. If they opt out, they would not be held accountable for increases in utilization.

In contrast, mandatory ACOs hold all providers responsible for changes in utilization. Because the system is mandatory, Medicare could set the reward system up so that ACOs with very high utilization could lose under this method. This would not be possible under the voluntary model. The stronger incentives in the mandatory ACO could result in better constraint of service volume. The model would also create strong incentives for providers to join together into organizations that can cooperate to control volume.

It is important to remember that the current

Medicare spending growth rate is unsustainable. What unsustainable means is that it will change. Because spending is equal to prices times volume, either the volume will decline or the rate of increase in Medicare prices per unit of service will have to decline. Voluntary ACOs are limited to weak incentives so that they can attract volunteers. Mandatory ACOs could have stronger incentives to reduce volume, so they could be accompanied with softer restraints on fee-for-service rates. Remember, providers in the ACO are still all paid the same fee-for-service rates. With strong incentives to restrain volume, there would be less of a need to constrain fee-for-service rates.

The main point here is that there is a trade-off between reducing volume and reducing rates and the mandatory ACOs could have a stronger effect on volume.

The physician group practice demonstration is one example of how a voluntary ACO program could be designed. In this demonstration, physician group practices agree to be held accountable for meeting certain quality goals and constraining risk-adjusted annual Medicare spending for a group of beneficiaries assigned to their practice. The program provides bonuses for meeting targets but does not

have any penalties for failing to meet targets.

The good news in the PGP demonstration is that most sites improve their quality metrics. In fact, all did. The frustrating news is that Medicare costs at the PGP sites grew just as fast or faster than the comparison sites in most cases. Some PGP sites did get bonuses for their level of risk-adjusted costs, but this appears to be due to better coding at these PGP sites and not a reduction in the actual cost of care. In other words, it appears that the PGP demonstration has resulted in the coding of more conditions, but the PGP demonstration has failed to slow Medicare cost growth. While the PGP demonstration has not yet delivered savings, that does not mean it does not have long-term potential or that savings could not be generated if the incentives and processes were improved.

There are several design decisions that could be made to enhance the probability that the ACOs could generate savings. First, ACOs could be given spending targets in advance, and this is not the case in the PGP demonstration.

Second, CMS could speed the flow of information to ACOs. For example, ACOs could be alerted when patients are admitted to a hospital outside of the ACO to help the ACO

coordinate care and do discharge planning.

Third, if the ACO program was permanent, the group practices and the hospitals would have a stronger incentives to make long-term changes to restrain the growth in Medicare spending while improving quality.

For example, if we are asking an ACO to reduce its capacity by either not buying a new MRI machine or not hiring that additional interventional cardiologist, they're basically agreeing to reduce the growth of their long-term -- reduce the long-term growth in their revenue stream and they would say, well, if you're going to have me reduce the long-term growth in my revenue stream, you better have a permanent system of bonuses so I could have some long-term potential for bonuses from the ACO as opposed to a three- or four-year demonstration.

Fourth, private payers in Medicare could encourage ACOs to bring in other payers. If you had other payers involved, this would enhance the incentive to constrain capacity. Providers have told us that they basically treat all their patients the same, so if they change their heart failure protocols, it's going to affect all of their patients. If they don't buy an MRI, it's going to affect

their revenue stream from all their payers. So if you want them to be willing to reduce the revenue stream from all payers, they tell us they need to get bonuses from at least a majority of their payers to help make up for that lost revenues stream.

Fifth, we have discussed using both withholds and penalties to strengthen the magnitude of the incentives.

And finally, measuring performance over three years would reduce the volatility in performance and reduce the incentive to drop high-cost patients.

And finally, it would also help Medicare differentiate between truly good performance -- meaning consistently good performance -- and random variation in costs from one year to the next.

So now this brings us to our discussion questions. The first question for discussion is the big one, and that's whether Medicare should use ACOs as a mechanism to try to constrain volume growth.

If so, the next question is what would happen -- what should happen to ACO providers if there was no change in volume? Basically, what should happen to providers if these incentives don't work? Should there be penalties?

The third question is how should bonuses and penalties be structured? We've offered just one potential design and that's in this paper, but we'd like to hear your comments and suggestions.

And finally, if you include the ACOs should be pursued, the next question is whether they should be voluntary or whether providers should be able to opt out, and providers should be able to opt out or whether they should be mandatory. If they are voluntary, we risk not affecting the behavior of providers in the highest-growth areas. That's because they may decline to join the system.

We now turn this over to your discussion. There's certainly plenty of issues to talk about.

MR. HACKBARTH: That's an understatement.

[Laughter.]

MR. HACKBARTH: Nice job. This is a very clear presentation and paper, as well.

So we will have our usual three rounds. The first is strictly clarifying comments. What did ACO mean, for example. Hopefully a little more honed in than that. But clarifying comments. Then the second round will give people an opportunity to make either an initial statement of

affirmation -- I think this looks good and we ought to go in this direction, or a statement of reservation. And then based on those two rounds, we will try to have a focused third round of discussion that really starts to hone in on the major issues that seem to be on people's minds.

So let me see heads for clarifying questions, round one. We will start over here with George, Nancy, Ron.

MR. GEORGE MILLER: Just one clarifying question. Again, I thought this was an excellent job, as the Chairman said. But I didn't see anything in here about beneficiaries' choice. In putting this together, what does a beneficiary -- what input does a beneficiary have with the choice of either a physician or health care organization?

DR. STENSLAND: In the example we've laid out so far is the beneficiary is still free to choose their doctor.

MR. GEORGE MILLER: Okay.

DR. STENSLAND: So if they think their doctor is not doing a good job, they could go ahead and try to visit another specialist, even if that specialist is outside the ACO. So it really puts pressure on that primary care doctor to have their patient think they are doing a good job and to keep those patients satisfied with the services that are

within the ACO, because a satisfied patient will stay in the ACO, a dissatisfied patient will leave the ACO. And if the patient leaves the ACO, the way this is modeled, you are still responsible for those costs.

MR. GEORGE MILLER: The same thing for the hospital?

DR. STENSLAND: The same thing for the hospital.

MR. GEORGE MILLER: Thank you.

DR. KANE: On page nine of your slides, you have an example of a bonus penalty calculation. So if actually billing was target for the good guy, the high-quality, $7,500, the net payment would be 705 guys? And so they would get better revenue out of this if they ignored your volume incentive?

MR. GLASS: But their cost of delivering the services would go up.

DR. KANE: Yes -- well, yes, so the marginal --

MR. GLASS: The marginal -- yes.

DR. KANE: So I think that as soon as Medicare takes some of the lower volume reward, you create an incentive not to do it. I'm just trying to see if I understand this right. So if they actually spent the target

level, they would get more revenue?

DR. STENSLAND: [off microphone] Yes.

DR. KANE: So I guess what would be helpful is what your marginal cost assumptions are here, to understand better what the incentive really is.

DR. STENSLAND: I think this gets back to the other example that we showed with the MRI machine of saying, generally, the ACO incentive probably is not going to be big enough to overcome the marginal profit you're going to get from just running the machine more. But it might be big enough to overcome the average profit. So it might be big enough to convince you not to buy the machine because then you get the bonus, you don't have the cost of the machine, and maybe the combination of not having the cost of the machine plus the bonus overcomes that profit you would have -- the revenue you would have generated from the machine. It all depends on the magnitude of the marginal cost and the marginal revenues.

MR. HACKBARTH: So a corollary of that would be that to the extent that this works through creating systems thinking, thinking about investment in equipment or a mix of specialties and the like, you would expect the effects to be

greater over time, that you might have smaller effects in the short run than you could see in the long run. Is that a fair inference?

MR. GLASS: Right, and part of the logic behind that is the observation that in areas with a large supply of specialists and ICU beds and that sort of thing the use of supply-sensitive services is much greater, and that seems to be driving a lot of the variation in resource use.

MR. HACKBARTH: The existing PGP demo has lots of other issues, design issues that are different than what we have described here, but that also could be a reason why you're not seeing cost effects in the short run with the PGP demo. The system impulses is still developing.

DR. STENSLAND: I think that the PGP people who spoken to us or spoken publicly on this, they have said, well, this is a temporary program and it only affects a small part of our total payers so we're not fully invested in this thing because we can make long-term decisions because it might end in four years and then we're going to have this long-term revenue stream go away in exchange for a short stream of bonuses and that makes them reluctant to make big changes.

DR. CASTELLANOS: First of all, good job and I like this concept very well. Being a physician, my real interest is the patient and the patient's care. George has started the questions on, but what's the incentive for the patient? I don't see any incentive for the patient? We're not sure about quality. We're not sure about cost savings. And I'm supposed to, as a physician, cajole or talk these patients into staying because I'm going to be responsible no matter what for three years, whether they stay with me or not. So what's the advantage to the patient?

MR. GLASS: Well, I guess one advantage to the patient would be if high-quality ACOs were encouraged, the quality would go up. The quality of care would increase. And I suppose they could choose between -- if this was publicized, they could choose between a high-quality and a low-quality ACO. So they would know which one was delivering high-quality care.

DR. CASTELLANOS: But you won't know that for several years. I agree, there is a value of quality --

MR. GLASS: Well, you could do it retrospectively, I suppose. You could look retrospectively to see what this group has produced in the past.

DR. CASTELLANOS: Not an ACO that is just starting up.

DR. STENSLAND: So not at one that's just starting out. You'd have to kind of promise something. But there is an example of one of the ACOs brought up the other day at the conference that John was talking about and they improved their heart failure regimen. They would have people communicate every day with the system. And what they found out was they were able to dramatically reduce admissions for the heart failure, and if they are able to reduce the admissions for heart failure, they have got something you could sell to the patient. You say, you want to be in this ACO system because we have a system for monitoring you. And if you look at the chance of you having to go into the hospital, it's better than other systems. There is also a big incentive the ACO system to reduce readmissions, because readmissions are a big cost. And like I say, we want you to stay in this ACO system because one of the things we work hard on is to get right the first time so you don't have to come back into the hospital. If you could show that they actually have lower readmission rates, that might be a selling point to the patient.

I think part of the function of the ACO is to say, now when the system does those good things, when they reduce remission rates and they reduce their revenue because they're doing it, when they reduce admission rates and they reduce their revenue because they're doing it, they get some compensation for that through the ACO bonus.

MR. BERTKO: First, David and Jeff, nice report here and good presentation for clearing this up. As both David and Jeff have indicated, I've been part of the Elliott Fisher team looking at this, so we've done some thinking about it.

The one clarification comment I would have is we've looked at ACOs as being a big tent, and that while I would agree with you that a hospital physician group is probably the most likely one in there, I would see if you guys would agree that perhaps a large multi-specialty group by itself could be an ACO, and perhaps several other variations?

DR. STENSLAND: That's certainly an option and I think at some of our other ACO discussions over the last couple of years we brought up that option. The one thing for you all to decide is whether it's fair to leave the

hospital out. The reason that you might think it's not fair is that if you look at a lot of the savings that the ACO hopes to generate, a lot of is going to be due to things like reduced admissions, reduced readmissions. So the hospital's revenue might be the revenue that's shrinking the most, and if the hospital's revenue is the one that's shrinking, you might think they should have an opportunity to share in the bonuses.

The other factors, what we've gathered from you, is there's a lot of you that have suggested that it's very important for hospitals and physicians to work together, and so having them both in the ACO might make it easier for them to work together as opposed to if the hospital has a different set of incentives from the physician, which could create some discord.

MR. GLASS: Yes, and the other consideration was that we've kind of shown that they have to be able to make joint decisions and have some form of organization and the hospital may be the only one with enough assets to convene everyone and provide HID or whatever. So in our paper, we've been assuming hospitals are in. But that's clearly something the Commission could decide otherwise on.

MR. HACKBARTH: Could I just ask a follow-up question about the PGP demo. It's labeled physician group practice, but don't all of them include a hospital in the configuration?

MR. GLASS: I think there's one that does not.

MR. HACKBARTH: One that does not?

MR. GLASS: Middlesex, I think.

MR. HACKBARTH: You know, that's a big hunk of the dollars, 30 or 40 percent of the dollars are in the hospitals, so to the extent that you are trying to change that and having a hospital involved would seem logical to me.

DR. CROSSON: Glenn, excuse me. On that point, my understanding, and actually, I think Middlesex does have a hospital. That is the hospital. But my understanding is that although the savings available in the demonstration project come from both savings on the office side and the hospital side, that the hospital itself is not included in the potential for gain. I could be wrong, but I think that is the design element. It is the group practice that stands to gain.

DR. STENSLAND: I think that's correct, but I

think the point is that a lot of these group practices are part of a bigger system, so that if you give --

DR. CROSSON: Some are, but some are not.

DR. MARK MILLER: Let me just make one quick comment as to why this issue is -- you just made the set of arguments for inclusion, which I tend to agree with. I think the argument that the physician-only people make, and I don't whether you are in that camp or not, is that the more you include providers who potentially lose revenue, the more resistant they are to change. And this is probably a religious question in the end, but that's kind of the underlying discussion here.

MS. BEHROOZI: This is just the round one clarifying question, so I don't mean to sound skeptical because it all sounds -- you're putting out a lot of great information and it's great directionally, but it's really on the issue of involvement of other payers which you identify as sort of a principal point that would strengthen ACO design. In the paper, you make the comment, therefore, ACOs should be structured so that private insurers could also have an incentive to set up a bonus system similar to Medicare. The clarifying question is whether you have

thought about what that means, what that means in terms of the structure, which then also goes, I think, to the voluntary-mandatory question a little bit, or whether that's yet to be explored. That's the question.

DR. STENSLAND: We haven't done any serious thinking on that. The people in Vermont are trying to structure it that way, where they will have three main insurers, Medicaid and -- and they're hoping to get Medicare, they don't have Medicare in yet -- in the whole program, so we haven't done much work but there's others who are working in that direction.

DR. CROSSON: My question is sort of on the same topic, on slide nine again, which we still have up there. This assumes that -- I assume it assumes that the physicians and the hospitals are part of this ACO. So this gain here or the difference in the net Medicare payment example, as simple as it is, is actually more complicated because it assumes that that money, that gain, is going to be in some way shared between physicians and hospitals. So this is a combination of an increase in payments under Part B and Part A and then make some assumptions that there is some organizational entity and some process on the other end to

receive that in an equitable manner.

MR. GLASS: You could make it kind of mechanical and have Medicare do it if you wanted to, as a percent of -- look at last year's spending, what percent of it was the hospitals, what percent was the physicians, and return it that way. So you could do a mechanically, virtually kind of if you wanted to. Or you could just give the $400 to this organization and say, split it up however you guys like.

DR. CHERNEW: I have a question about slides five and six. Go to six, because it includes both. My question is, the big difference is that on the right in the yellow, you have the fixed costs included. On the left, you don't. Is that -- so what I think is misleading -- my question is, there has to be -- the right question seems to be what would happen under an ACO system versus not? But in either system, someone has to invest in the MRI. So the right comparison isn't what would happen if the MRI was free, which is sort of the marginal one on the left.

What seems to be missing on the left, or my question is, who bought the MRI on the left and what was their incentives to do it under the -- in the non-ACO world? Because the question you're trying to answer is if we put in

an ACO, how does that affect the incentives for investing in an MRI. But I don't think -- and correct me if I'm wrong -- I don't think that is what's on the left here. I think the left here is just if the MRIs were free, the ACOs won't stop use.

DR. STENSLAND: I think you could think of this as, okay, we set up an ACO and it starts tomorrow and you have your own ACO. Do we really think you are going to start doing fewer MRIs on that machine you already have, and the probable answer is no.

DR. CHERNEW: Right.

DR. STENSLAND: But maybe you might not buy another machine to expand your capacity.

DR. CHERNEW: But the question for that, and this is what I'm sort of asking is, the issue is so maybe that's true. That's the column on the right. But what I don't understand is that has to be compared to what your incentive was to buy the MRI machine without the ACO, and that's not the column on the left.

DR. STENSLAND: No.

DR. CHERNEW: Right. So I'm trying to figure out how the ACO changes the incentive to buy the machine. I

agree with your point that the ACO won't affect the marginal incentive to use it. That I agree with. But I don't see on this how the ACO influences the incentive to buy the MRI machine because I don't see the non-ACO version of what that incentive was.

MR. GLASS: Well, there's no ACO - the effect on the ACO bonus goes away.

DR. CHERNEW: I know, but there was some other organization that was deciding to buy the MRI machine without the ACO and that had a set of marginal costs and fixed costs and whatever it was, and so that seems to me to be the comparison.

DR. STENSLAND: Yes. The comparison is just the first three rows in that upper right-hand column. So of there was no ACO, you would spend $500 -- you would get $500,000 in revenue, you have $450,000 in costs, and your net profit would be $50,000. And that's without an ACO, you have $50,000 in profit and that's why you do it.

DR. CHERNEW: So the fixed costs are basically in the $400,000.

DR. STENSLAND: Four-hundred-and-fifty, right.

DR. CHERNEW: In the $450,000, yes. We set it up

as a --

MR. GLASS: It is $400,000 is the fixed cost and the marginal is $50,000 or something like that.

DR. CHERNEW: Four-hundred-and-fifty thousand would be your annual cost.

MR. GLASS: It is marginal and --

DR. STENSLAND: Annual costs of operation. So in the paper, we set this up as if you leased the machine annually so that your annual costs of leasing, maintenance, and operation is $450,000.

DR. CHERNEW: So now given that, I'm sure it will take hours to get back to here. I will think about that again. But that helps.

[Laughter.]

MS. HANSEN: Just to follow up on the question of quality, I think, as well as post-acute care, not only hospital, in terms of quality, the worry sometimes of stinting, that still comes up. So is that taken care of by the fact that the accountability will still follow the primary care physician if the beneficiary goes someplace else? So there's a little bit of an incentive there that the accountability will still trail, and that's part of -

MR. GLASS: Because the quality would be assessed of the population, so that would be true.

MS. HANSEN: And then the second clarification is in the ACO, we're talking about the physician and the hospital, but so much about the outcome is also related to the post-acute care. So would that include places like home health agencies as part of that? Or is that just kind of a contract of provider consideration?

MR. GLASS: The spending on it would be included, but they wouldn't have to be officially part of the ACO. Presumably, the hospital and the physicians, when they make a discharge decision, would pay a lot of attention to where they were sending them and choose the SNF with high quality and low cost and less likelihood of readmission.

MS. HANSEN: Okay. So the payment would go to the ACO they would contract --

MR. GLASS: No, the fee-for-service payment would still go to, say, the SNF, but the hospital and physician would have a large incentive to make sure they were sending the patient to a good SNF.

MS. HANSEN: Thank you.

MR. HACKBARTH: Okay. Let's move on to round two.

Let me see, since Mike needs more time to think, I've got to start over here again. Peter, do you want to go ahead?

MR. BUTLER: Several comments. I'll answer the questions first as best I can, if you could put those back up. I favor mandatory over voluntary, but the devil is in the details obviously. But I think you will get more teeth out of this if you go on the mandatory versus the voluntary side.

The second question related to do you think it should be used to constrain growth. I have a problem with the way the question is framed. I think it should be, do you think it should be used to achieve appropriate care for the patients, which by the way is probably less utilization. But I think we should frame it in the context of the overall goals of the metrics we're trying to hit for the patient population. But having said that, I do think it should be used.

And then the way I would frame then the rest of my comments is if you look at the way we could intervene in the system from just on one end informing physicians of utilization patterns to the other end of the spectrum having competitive Medicare Advantage bids, I like this one almost

the best because it comes the farthest along the food chain, if you will, to kind of align the whole utilization question. It retains the Medicare rate, so you don't have to go through that nonsense, and helps -- I wouldn't call it nonsense, but administratively it is easier to kind of just pull it off. You've got great data. And I very much like the integration of the physician and the hospital activity, because frankly, not only is it positive, but all of the other payment reforms -- episode of illness, episode of care, and that kind of bundling -- is going to encourage the same kinds of things anyway.

I would say that there are some both large systems and small hospitals that have come an awful long way in terms of working with their physicians on all of the quality metrics, on readmission rates, and they're positioned far differently, I think, than they were maybe in the first round of managed care to accommodate all of this.

Not really stated in here, but you say, why is it different? I think also IT is not a small factor in this. A lot of big systems now are being able to measure this across the physicians and hospitals in ways they haven't been before, and often those investment decisions are also

bringing hospitals and doctors closer together, much better able to deal with this than maybe they were in the early 90s when capitation was first rolled out. So I like all of those aspects of this.

I do worry about the logistics. I do worry about revisiting the toxic impacts of handing out bonuses. It's not just between hospitals and doctors, it's within groups, between the primary care and the specialist.

On a positive note, I would say we have one of these PHOs. We do have quality and pay-for-performance now. We do hand out bonuses to both the hospitals and doctors and it works very well, so we would be anxious to participate in something like this.

My final point would be on the -- it's kind of referenced, but it's a very important point. If you have, say, 5,0000 of your so-called enrollees in a quasi-capitated system and maybe you have 95,000 that aren't, you don't exactly have the cultural tipping point in the organization to fundamentally do things differently. And that was a big roadblock, I think, in getting through the first round of all this. And so this by itself, I wouldn't say is going to flip over behavior, but I don't think we can ignore it and I

don't think it's an excuse not to try to do it, because if others were to jump on this, I think it's absolutely the right direction to go.

MR. HACKBARTH: I had promised Jack -- he assured me he was going to say something that is so profound as to alter the course of our --

MR. EBELER: Unfortunately, the profound here is I don't understand, and I have worked at this -- this is a part of health care that I come out of in a lot of ways. The statistical analysis has been, I think, the most powerful tool we have had in health care, this whole idea of looking at geographic contiguous units. It is a fabulous unit of analysis and we're trying to turn it into a unit of intervention. There's a part of this that -- and magic happens, step here. The statistics at the front end work and then your statistics at the back end work and it's sort of the thing. So I don't quite know what an ACO is.

The descriptions that we have sound like the discussions we used to have years ago about why it wouldn't be smart to start some type of an organized delivery system organized health plan, the kind of world I come out of. You say, gee, let's do that. The difficulty is -- and we talk

about it as though it's an exclusive organization. But as Peter says, the truth is this is a statistical construct nested within another statistical construct which is Medicare. So I don't quite understand how it works. I think there's possibly -- I think I hear two potential paths. One is we need to define what "it" is, and again, maybe this is my not getting it. And then figure out how to pay it. I mean, if Peter was to do this, let's figure it out. My personal guess is that we may be talking about a radical redesign of Medicare Advantage, because this is what Medicare Advantage was supposed to do.

And the other possibility I think I hear is people talking about implicitly geographic-specific budget caps in Medicare fee-for-service, sort of an SGR across all Medicare payment in the local area in fee-for-service, and then you opt out of that to be an ACO. I mean, those are two potential paths.

But you've got to help me --

MR. GLASS: Okay. Let's address why it isn't a MA plan first.

MR. EBELER: Tell me what it is. I can't tell what it is.

MR. GLASS: Let's take a really concrete example. In Vermont, they're talking about -- apparently, I'm not sure of the facts, but it's something like there's 13 hospitals there and they exist quite in distinct markets. They tend not to have a lot of overlap among their patients. And they've started a medical home sort of thing where they have several -- and the idea is to bring several of the medical homes together with the hospital in the area and form a ACO out of that. So that would be, I think, the most concrete, simple to understand definition of an ACO. So it would be that hospital in that area, and it has a market area to itself, and it's got these medical homes that feed into it, and the combination of those things becomes an ACO. They cannot take insurance risk.

MR. HACKBARTH: Let me just leap in for a second. Arnie is going to have to step out briefly, so I wanted to give him a chance to get his comment in before he leaves, and then we can pick up with this. Arnie?

DR. MILSTEIN: Thanks, Glenn. I have been for the last several years with foundation support been trying to understand the, I'll call it the architecture of delivery systems that are achieving good quality of care with a much

lower level of resource use, both for Medicare and other chronic illness populations. And boiling it down, if one were to essentially draw conclusions based on, I'll call it these favorable outliers, one would have to come down very strongly in favor of allowing primary care groups to be ACOs, because they have, by far and away, the best leverage point on total spending in so-called supply-sensitive services. It's their success that affects whether people even need specialists and hospital services, and they are also in a wonderful position at the margin to direct patients toward higher-quality, lower-spending hospitals and specialists.

So if our goal is -- if we want to heavily weight the goal of sustainability of Medicare, my observations would suggest that we want to make sure that primary care groups are allowed to participate in this program, because I think they are by far best positioned to achieve the objectives of both Medicare's sustainability and quality.

The second comment I would make is in some ways derivative of that and it has to do with underlying all of this -- and I think it refers to, was it Mark or Glenn's comment about this is primarily a religious question.

Another way of framing the religious question, it's an equity question, because how you design this program, if one says that my primary goal is to improve affordability of health care, including Medicare health benefits, for low-middle-income Medicare beneficiaries and especially for service workers who are increasingly the nature of the American workforce, and shielding them from increases in what have to pay in Medicare taxes, then you come down very strongly in favor of tilting this program in some ways towards primary care groups and allowing in some communities some a pretty severe effects on hospitals and specialists, especially in those geographies where the suggestion is that there's a lot of supply-sensitive services going on, at least benchmarked against other geographies.

And so in some ways underneath all of this is a question of values and where you want to place your pain relief priorities. If the priority is toward Medicare sustainability and quality, then I think the evidence suggests you want to tilt ACO management and leadership towards primary care physician groups. And if you want to weight in the other direction toward limiting financial distress and acute pain for hospitals and specialists who

perhaps due to no fault of their own happen to find themselves in a practice environment in which there's a lot of supply-sensitive services going on, then you tilt in the direction of allowing specialists and hospitals to participate in the gains.

MR. HACKBARTH: Arnie, is an implication of that, the tilting towards primary care that you're advocating, well maybe you don't even need to do ACOs. You do medical homes on -- as you put it, I think, in one of our discussions on medical homes, medical homes on steroids with very strong performance incentives for total costs.

DR. MILSTEIN: Or at least allow them to -- yes. I think the point here that this paper makes is that if you want confidence in your savings numbers, you need at least 5,000 enrollees and that obviously tilts in the direction of group aggregation of primary care practices.

MR. HACKBARTH: That was going to be my next point, is one of the issues with building the accountability for total cost performance on primary care is the small numbers problems. And so for total cost accountability, you are almost by definition talking about aggregations of primary care physicians, whether they're in a formal group

or some sort of virtual group.

Thank you.

MR. EBELER: I understood that "it."

[Laughter.]

MR. BERTKO: Let me go to one of the questions that was maybe answered, the difference particularly between MA and an ACO, and that is attribution of seniors at least into this. I think that was in the paper. MA has to have an active enrollment. This would attribute it, so, and I'll pick Peter, your hospital. You guys serve a ton of seniors, so you probably more likely have 50,000 seniors attributed to the physicians that work with your facility. That part of it can come into place instantly because that's a huge advantage over the whole roll-up of an MA enrollment.

Secondly, though, David made a very good point earlier about -- I think you used the word "convener" for the hospital. So convener and contracts are very important. I will come back to that with other comments, but that's an argument in my mind for voluntary in the short run as opposed to mandatory, because you need to have organizations and contracts in place to make it work.

MR. GLASS: But the other distinction, an MA plan

takes the full insurance risk. It gets full capitated payment, full insurance risk. This is still mainly fee-for-service.

MR. EBELER: This attribution issue, and to go back to Peter's, he said, I've got 5,000 in the ACO and I treat another 90,000. There's two "its" there and I can't tell exactly --

MR. GLASS: Well, if you went with the attribution model then -- go ahead.

MR. HACKBARTH: This is important. It didn't fully meet my expectations for profound.

[Laughter.]

MR. HACKBARTH: But we have a lot of people in the queue and we're running out of time, so I want to get back to people who have been waiting patiently. George?

MR. GEORGE MILLER: My follow-up second-round question has to do with the rural America and how they fit into this. I saw a little bit in the chapter, but I need a little more explanation because I'm concerned about distance. Although you're talking about 5,000 people, in rural West Texas, for example, 5,000 people could be hundreds of miles apart. I'm not sure how that works, and

let me lay the other issue on the table as you think about that.

Also, a high-quality low-resource -- I'm not sure I understand their incentive because the fact that they are lower resource users means they've already gotten all the low-hanging fruit. And to get more cost out of the system, they may have to affect staffing, as an example, since that's the largest piece of -- certainly a health care organization's piece. So I'm not sure I understand the incentive there. There are a high-quality provider, low-resource user. How do they figure into the bonus calculation? I'm not sure I follow that logic.

MR. BERTKO: Let me -- again, we've got all kinds of statistics, but I'll go back. Even in our measurements -- this is Elliott Fisher and John Skinner -- of low-cost places, and I'm thinking of the Dakotas here in particular, there is still enormous variation within places that, on average, are very low cost. That's the opportunity, I think.

MR. GLASS: Well, also, we set up the bonus as a set dollar target and that's why that low resource use ACO you were talking about gets a 6.3 percent target growth. So

we realize that they have taken some of the fat out of the system already, so they're given a higher -- their target growth is 6.3 percent whereas national it's 5 percent, and for the high resource use guy it's only 4.2 percent.

DR. STENSLAND: The advantage is that you're in North Dakota, even adjusting for wages, that $500 is going to probably go farther because people just don't do as much high-tech stuff. All the distance acts like a giant co-pay, and so they might be able to do well because they're given that $500 and they can do more with that than a big urban area.

MR. GEORGE MILLER: [off microphone] [inaudible]

DR. STENSLAND: Yes, I think that is an issue, and really to get up -- when we looked at some rural areas, like North Dakota, you would have to conglomerate a lot of small little towns into a big entity and that would be something you'd have to probably work out in more detail than we have already. But to get to 5,000 people, it would have to be something like all the CAHs in North Dakota would be an ACO or something like that. And how you would structure the bonuses and penalties to not make them too much at risk would be part of the factor. Also, maybe some of the

littlest towns wouldn't be that interested it the hospital is already getting cost as a CAH and the doctors are getting rural health clinic payments or costs as a community health center. They might be that interested in this kind of model.

MR. GEORGE MILLER: The voluntary versus mandatory issue question you asked at the end of the chapter.

DR. STENSLAND: Yes. So if it was mandatory, there would have to be some working through all those specific rural issues.

MR. GEORGE MILLER: Okay. Then it's hard to answer that question, because I'd like to know how many rural hospitals would fit in that category, so how do you make that mandatory if it wouldn't be a benefit?

MR. GLASS: Well, you could say that -- and you'll have to correct me -- I think it's North Dakota has a relatively small number of hospital systems that many of these small hospitals are affiliated with. So you could conceivably take the entire hospital system, which is, you know, a main hospital and several smaller hospitals, together as -

MR. GEORGE MILLER: In West Texas, as an example.

MR. HACKBARTH: Potentially, George, you could also cut it another way. You could say it is mandatory in certain parts of the country and voluntary in places like these where the nature of care delivery is different and more distant, less organized. It's not an absolute yes or no decision. It could be yes in some places.

DR. MARK MILLER: I know we're out of time, but I just want to say something quickly. I don't think we should just assume that these things can't work in rural areas. Geisinger is one of the biggest systems and it is in a rural area. These connections can be made. But that's not to say that your comments aren't valid.

MR. HACKBARTH: And Intermountain Health Care. They have an urban base, but then they've got 23 very small hospitals in very remote locations connected to the system.

Nancy?

DR. KANE: I think we just need a set of principles to establish a context in which this could possibly operate. I think it is what we are -- and I think the goal is really to set up something that is really quite temporary to force organizations into bigger systems in rural areas and to -- I mean, I think that is what this is

really for, is to get organizations that have traditionally operated in silos to start talking to each other.

So in thinking about some of the principles that I would subscribe to or think we should at least consider talking about, one is that this will work best in an all-payer environment, and we've talked about it and kind of hinted at it. And I think in order to get to an all-payer environment, we need to talk about the role of States and whether or not we can create collaborations with States to create all-payer environments. And in bringing in States, we could also help tailor any of these ACO models to the local State situation rather than trying to create at the national level some cookie cutter approach that doesn't fit a lot of local environments.

So I think even though Medicare is a Federal program, now more than ever we need to consider how do we get to all-payer and how do we get States to help us design locally relevant payment methods. So that's my first principle, is how do we articulate a role for the States and encourage all-payer environments for any of these payment innovations.

The second principle, I think, is that we need a

geographically-based clinical information system. The biggest obstacle for an ACO is that the beneficiary can go anywhere, and at least have a way to notify the people who are on the hook for it that the patient has gone to the emergency room or has just gone to see a specialist outside the ACO.

There are increasingly better information systems and EMRs out there, but so far, they still don't talk to each other and they don't talk across systems, and yet the patient is still able to go over the place. I think we really at the Federal level, one of the real value added and one of the important contexts for this is you really need some type of interoperability that really works and that captures key pieces of information and that people who are care providers have access to.

I think related to what I think Ron was saying is you can't leave the beneficiary out of this. They do need some incentive to stay in the ACO or to notify the ACO of where they're going. You can't just drop this on the provider without any support for the beneficiaries' incentive. It's just not realistic if you think about the potential -- some of these systems have 60 -- I think even

Geisinger, 60 percent out-of-network use. You really have to think about how do you get the beneficiary to be a part of the solution here.

And then finally, I think -- well, actually I have two more. I'm sorry, but this is a long session, right? It does have to be long term. It can't go away because you are talking about massive system change, massive changes in the way organizations and providers relate to each other, and a three-year window is chump change. They can wait it out. They can lose money for a while, just wait it out, make it go away politically. You can't just put something up that's got a three-year window.

And I think the ACOs should really just be the temporary payment method that leads towards either unbearable withhold increases on the poor performers or a much more rewarding bundled payment, increasingly bundled payment for those who do well, and therefore they're better able to capture those benefits. So this fee-for-service ACO thing should really be seen as a vehicle to push organizations towards wanting to take at least episode-based payment or A and B bundled payments, at least on segments of their business as they began to learn how to collaborate

together. There has to be a constant forward motion to this. This should not be viewed as a static, can stay in place forever. It has to be viewed as pushing people out of it and into more bundled payments, because I think the inertia here is huge and if we can't get everybody rowing in the same direction, as soon as there's a break in the economy or a window of opportunity, this will collapse.

I guess my final comment is, in the meantime, if one of the purposes of this ACO is to not have organizations add MRIs and excess capacity, there are perhaps better and more direct ways to do that and we should consider them. That would include reviewing certificate of need and other types of planning mechanisms at a regional or geographic level. Again, here's where collaborating with the States might really help, and creating a context for which these might work effectively and encouraging or rewarding States that actually set up real controls on the proliferation of high-cost, high-fixed-cost technology.

So I just think we need a set of context principles that we say, if you're going to do this, this will work best under these principles, and the closer we can get to it, the more likely you'll see some real benefit from

it.

DR. MARK MILLER: A really quick informational point just in case anybody else misunderstands. We are not speaking of this as a three-year process. It's continuous. It's just you're evaluated on a three-year --

DR. KANE: I still think it needs to have other things that are better that is pushing toward, not just it.

MR. HACKBARTH: You could imagine that over time, this might evolve towards a global capitation and maybe not with full risk assumed by the ACO, but some sort of risk sharing, risk corridors with the government which would increase the power of the incentives significantly. As groups get more confident that, hey, we can manage this, they may welcome that as opposed to resist it.

DR. CASTELLANOS: First of all, I strongly support the direction we are going. We need to work together, all of this, primary care, specialists, physicians, hospitals. We need to work together and this is a great step. I agree with Nancy. I think we need to push on that because there's a great amount of inertia there.

I'd like to talk about MRI. It's not the MRI that's the problem. It's the person that's using the MRI or

the person that's ordering the test. There's no question ownership does have a role as being excess usage. But I think there's been some studies in Health Affairs and, in fact, Glenn and myself talked about one from Seattle where they really showed the big difference here is the practice pattern of the physician.

I think in our next topic, when we talk about physician resource use, this is intimately related to the issue of whether we can control growth on volume. We need to control growth in volume. It's way out of control. But I think one of the ways we need to do it is not just limiting the ownership, but limiting the use of it and the practicality and appropriateness of it.

Now, the question is should we do with voluntary or mandatory, well, mandatory, you will get it done but you are going to have so much resistance and so much static from every provider that I would certainly say start voluntarily.

DR. STUART: I have Jack's question in mind. I read this twice and I couldn't figure out what "it" is, and it seems to me that it really cries for some system examples. There's one sentence in here about Vermont doing something, and maybe you could tell us a little bit about

what Vermont is doing. One of my particular concerns in this is, is everybody covered in this? They are 13 hospitals in Vermont. Are all the physicians and all the hospitals then going to be part of these things? Maybe that will help me figure out what "it" is.

MR. HACKBARTH: One thing -- I am very eager to get through the rest of the group and we're quickly running out of time. But one thing that we may consider, want to consider, is how to bring some more life to this. The example, as I said to Jack, that keeps coming to mind for me is my former employer, Intermountain Health Care. We had Brent James here a number of years ago, before many of you were on the Commission, and Brent, a highly regarded physician and one of their leaders in trying to improve quality and reduce costs, explained in some detail about how perverse the incentives are in the existing Medicare program for an organization like theirs. They are always fighting the incentives. Doing the right thing is costing them money.

So when I think of this, just because of my personal connection with them, I'm always thinking, how do we alter the program so that there starts to be some reward

for the Intermountain Health Cares of the world, the Geisingers, the Mayo Clinics, organizations for a variety of reasons have some Medicare Advantage business, and may actually want more Medicare Advantage business, but because of their patient choices, patients have chosen to remain in traditional Medicare. Not all of their activity is in Medicare Advantage. And so they still want to do the right thing, but we're penalizing them at every turn. How do we help them out, to me is sort of the basic question.

DR. REISCHAUER: Not to pile on here. The challenge that we have is bending the cost growth curve significantly sometime over the next ten years. I am very skeptical in the political environment we're in and the institutional environment we're in that ACOs are going to be a significant component of that answer. ACO-like things exist here and there, and of course the question is, is it just the incentives? Or is it something else that has kept them from spreading more robustly around the country? I suspect it's something else, as well as the lack of financial incentives.

I think one might make a success out of this if you really thought bonus payments could be quite large, ten

percent or 15 percent, and penalties could be ten percent or 15 percent. But realistically, I don't think that's going to happen in my lifetime. Maybe my lifetime will be short and I will prove to be wrong.

[Laughter.]

DR. REISCHAUER: We have sort of imagined these things and talked about little examples of the cost, but nowhere in there is the costs of organization management keeping these things going, which is -- especially when they're loosey-goosey is a very complicated thing to do with components, hospitals, physicians who can go in and out depending on what their whim is or things like that. If I had to do this it would be mandatory because I don't think we would tolerate the kind of incentives necessary to make a voluntary system grow over time.

So I think we have to define something that has practical feet on the ground, and maybe there's a version of ACOs that might with a set of incentives that do, but I am unconvinced by where we are right now.

MR. EBELER: When he said it, he sounded profound.

[Laughter.]

MR. BERTKO: Sorry Bob, you've got two or three

years left to live.

[Laughter.]

MR. BERTKO: Now let me make a couple of comments.

DR. REISCHAUER: When an actuary says that, you know, you're really nervous.

[Laughter.]

MR. BERTKO: Good. I'm glad you picked up on that.

A couple of comments here. First of all, on the multi-payer aspect of it, absolutely true, the project where we're trying to recruit sites to become ACOs is we are pushing the multi-payer activity. The good news is, in virtually every market that I was in, you have a dominant two or maybe three payers. So if you have Medicare Plus, you're the local Blue, or in some markets, for example, the company I was with, you own 50 to 70 percent of the bodies that would be in there. You guys say it right, but I just want to reemphasize that, because it does require enough people under a change in management to get there.

I would follow up on a couple of people's comments on suggesting -- and this is kind of my opinions but I think reflecting the opinions of our whole team at Dartmouth and

Brookings -- that to start with, this ought to be a voluntary system, and I'll go back to the comments I made earlier.

You can get the attribution and the people in, but to make it be effective, you really need to have some form of organization and possibly some contracts, and -- I think it was your comment, Bob -- you need to have an infrastructure there.

We have been talking to enough people to say, yes, here's a hospital system that has 250 primary care physicians associated with it. We could probably turn that on 1/1/10 with everything, and so there are local groups there.

The next part is bonus versus penalties. I would be a bonus person for now because one of the things preventing this, at least with capitation for both PHOs and a variety of PSOs, if you remember that term, Glenn, the downside penalty is fairly big for groups that are worrying about this, and the hospitals in particular that we have talked to have recognized they're going to lose revenue. The lost revenue is offset by A, some bonus potential, but B, locking people into systems, and then C, they're going to

raid their competitors across the street because they are going to be higher quality, lower cost, and recognized as such. So it's a complicated one.

I could see going to a mandatory environment down the road after this was up and running and five years out, we learned a whole bunch of lessons to say, here's the book. Now it's mandatory. Get the book and follow it out. But I don't think it would begin to try to impose it in North Dakota or South Dakota today or tomorrow. I mean, that's just too soon. Thank you.

DR. CROSSON: I guess to start, I agree with Peter. It probably comes as no surprise from prior comments that I have made at the Commission that I think this is one of the more important ideas that we've talked about and will talk about.

I think I also agree with Bob that this is not easy. This kind of change that we are talking about is probably as difficult a change as we've envisioned in all of the times that we've talked here because it fundamentally involves changing eventually not only the structure of health care delivery, but the way it's paid.

I also agree that the kind of change that's

envisioned here and the kind of change in costs that are needed to take the country to are not going to be brought about by two or 3 percent bonuses. It has to be more substantial than that or it won't work.

I have some of the same concerns that Jack raised, and that has to do with the issue of taking a research model that Elliott has used which attempts to assign by a preponderance of claims a certain number of individuals to a certain delivery system or collection of hospitals and doctors and operationalizing that. I'm not quite sure how that works because if you're going to eventually morph this to the level of accountability that I think Bob was talking about, you just can't have open access. You just can't have people going out and taking a flight to the Mayo Clinic and recharging to the accountable care organization a $250,000 bill. It just won't work that way.

Now, there may be some stepwise process to get from that model to something which is more robust and perhaps has more of a defined population and more control over the use of resources. But I think that has yet to be described.

I think in addition to the question of voluntary

versus non-voluntary for the providers, there is the question of voluntary or non-voluntary for the beneficiaries. I think George touched a little bit on that. And I think as we think this through, we might want to think about something that Jack was referring to, which is essentially Medicare Advantage for provider organizations, where, in fact, perhaps incentives that the Medicare program could create, individuals could, in fact, voluntarily enroll for a period of time into one of these delivery systems, which would fix some of the attribution issues. I'd like to see us think about that.

With respect to the question of whether the accountable care organization should be just a physician delivery system or a collection of delivery systems versus physicians linked to a hospital, I have to come down very strongly on the latter. The reason is I think most of the savings that could eventually be used to create incentives really come from the physicians' impact on the hospitalization process. And you really, I don't think, could have a successful system if all of the incentive to manage the appropriateness of care was on the physician side and the hospitals only stood to lose. You'd have complete

malalignment of incentives in that process.

So I agree with Peter that I think it implies in some way that these work together, and in fact, I think there are many downstream advantages from having that kind of coordination.

I would raise again the question of whether we want to look at the issue of cumulative incentives as opposed to simply annual incentives, so that in order to strengthen the incentive here in this process, one could provide annual bonuses. One could also use the performance year over year to change the update process to both the hospital and physician component, and by creating a cumulative incentive, you create more power even though you don't move all that much money from one year to the next.

And then I will throw in one other really annoying thing, and that is the question of whether or not to actually, if we can take Part A and Part B on together, why not consider Part D in this? Because again, there is a significant amount of incentive power created by the physician pen with respect to the use of pharmaceuticals. Now, I realize that it's really complicated, but it might be worth taking a look at.

In the end, I do think that this is important. I think this is an evolutionary thing. It is going to take a long time because we are dealing with a system that doesn't work right now, both the payment system, and to my mind anyway, the disaggregation of the delivery system. Changing that is going to take a long time. But I do think I have, and many of us have, an intuitive sense that there is a place that we could go to which is better than where we are now, even though we are, as they say, looking through a glass darkly at the moment.

MR. HACKBARTH: Following up on Jay's comment, something that might be useful background for our next conversation on this is under Medicare Advantage, my recollection is that there was a provision introduced to allow provider sponsored plans, I forget the --

DR. CROSSON: MA-PSOs.

MR. HACKBARTH: PSO, which hasn't taken off. Just understanding why that -- and why is that? Are there modifications that could be made in that that might make it more attractive as sort of another door into this set of issues. That might be worth some studying.

MS. HANSEN: I just have a short comment related

to that. I think one of the things that people were talking about, the difficulty of the structure and the payment -- and Jay, you just said that it takes a long time for this to occur. I think a large piece that just has to be elevated, just to acknowledge the ability to have it happen, is the delivery behavior that actually has to occur. That's a body of work by itself. We were informally talking about it as just the execution process of it. So one is knowing where the bones are and you know what the money is. But making that squishy middle really happen is one of the things that makes the biggest difference, to have something aligned all of the way through.

So it's really not our role technically on a policy commission, but I think the acknowledgment of why things take so long to really come about, because they're not fully aligned because the belly of it is so difficult. And it is about practice, behavior, relationship changes that are always messy but really are necessary for a real change to occur.

DR. CHERNEW: I think one of the reasons why there is some confusion about what the "it" is is because there are different "it"s. I don't think there is one "it" that

we are trying to identify, what is it, but there's different versions in different people's mind.

The one version that I have, and John, I will look to as sort of the authority, is sort of a virtual version of this. In other words, people get assigned in a sort of claims way to of these organizations. Of course, that means the beneficiaries just are where they are. It's totally virtual to them.

In that model, though, there's no organization change needed at all. Depending on how you set it up, it may encourage organizational change in the way we're talking about, but that's going to be really sensitive to the actual parameters that you use. And we can't in the level of detail that we're discussing now figure out whether the "it" that would like it to be is the "it" that it will become, because that's going to depend on all of the parameters that we set up for what these things are.

So if I understand sort of the easiest version of this, which is I think this virtual we assign people and claims to an ACO and make them responsible in one way or another, but we do it weakly because there's a lot of noise floating around in the system. There's evidence on

withholds from years back. I'm not an expert now on exactly what that evidence on having withholds and stuff are, but the evidence isn't overwhelming that withholds were that useful. I think the reason you get the math that you guys got in the slides five and six -- and again, I could be wrong -- is basically this is a way to lower prices to people and lower prices more for people that do high volumes of stuff, because you have your price, they take away the withhold. So then you just have a lower price. For everything you do, you get a lower price. If you keep volume down, you get some of that but not all of it back.

So the reason in your example it is not profitable to buy the MRI is you have lowered the revenue associated with that and you've lowered it particularly if you've done a lot of stuff. So it's harder to make that MRI profitable. It is just keeping prices down for things and it's bundled in a whole lot of fluff, but I think in the end -- I'm sorry John, it's wonderfully crafted --

[Laughter.]

DR. CHERNEW: -- but I think in the end, it just works out because prices have gone down.

So I'm not inherently opposed to that one way or

another. I think what we really need to think through is the details. I work a lot that it ends up being a distraction. So the chapter has a whole set of things on how this could work with existing initiatives, things we've done, and it goes through medical homes and other types of things, all of which is very good.

But again, I'm so glad I don't have your jobs because it must be really hard to write given you don't know the details of a lot of these different parameters and you're trying to write how this -- so I agree with the tone of the chapter that this could work with medical homes. But I fear in sort of my gut that we have so many things floating around that it's going to be a big distraction, that we're going to end up having a whole thing on medical homes.

And I agree, we could craft a health care system with medical homes, episode payment, and ACOs. We could work them in a way that might fit in a virtual way voluntarily that worked also in North Dakota. That's hard.

[Laughter.]

DR. CHERNEW: So I guess where I come down on all of this is I just personally feel it's just way too early.

My earlier comment that I made was elevating this to a chapter of where ACOs would fit into a broad system of health care reform in that sense, for me -- I personally am just not there yet because I have a lot of concerns about what it is. I have a lot of concerns that the literature that suggests the mechanisms by which I see this working might not be as optimistic as one would think, and the most optimistic -- if I keep talking, he'll be back for the other conversation -- but I might be amongst the more pessimistic, giving me a shorter lifespan, but I'm not so sure that we know enough. We can aspire to have this be a building block on an evolutionary path to having the health care system that will aspire to, which I would be 100 percent for. I am just not there yet based on the evidence and what I see that we know where this is.

So in the cases where there's a provider system that we think would be integrated now and great and we could find an incentive system to let them reap some of the gains from doing good stuff, I am again completely for that. I'm not sure you need a ACO proposal necessarily to get there, but that's a sort of separate question. And I think we need to step back and think about where this fits into the broad

set of things.

MR. HACKBARTH: So let me ask you this, Mike. So a possible implication of what you're saying, if I understand you correctly, is an approach that bears some consideration is increase uniprice pressure, use a mechanism that doesn't require as much complexity, like maybe the MA-PSO, modify that a little bit as the refuge, the opportunity for truly integrated organizations that want to get out of fee-for-service payment and don't necessarily want to just do it through a standard insurer. And so push real hard on uniprices and create an escape opportunity that's simpler than this.

DR. CHERNEW: I would be --

MR. HACKBARTH: And also has stronger incentives.

DR. CHERNEW: I wouldn't want to see them sort of side by side, but if you ask me right now, I would probably be leaning a shade toward something like that, because I understand it better.

MR. HACKBARTH: Okay. Bill is going to have the last comment. We are well behind schedule here.

DR. SCANLON: It relates to something that Mike said and to the voluntary/mandatory issue, and it's very

easy to understand, sort of the interest in mandatory, because if something is going to work and if you can make it work universally, it's a lot more powerful.

But I think, and consistent with Mike, is that the mandatory idea which would involve virtual ACOs needs more development. There's the issue of governance. The incentives need to be at the provider level. And if the providers are not linked to an organization, and in the voluntary world, they will be. I mean, they're going to be there because they want to be there. But in the mandatory world where we've created them virtually, if I am the outlier and my bad behavior benefits me but harms the organization, I may not change my behavior. This is kind of the classic thinking about this in economic terms is the externalities. If I'm the factory that pollutes, how does the community get me to stop polluting? Does it pay me or does it outlaw my pollution? What's going to be the leverage that an organization is going to have over this provider that is going to, in some respects, go against sort of the community's good?

This is critical, because I think that we are not going to learn if we demonstrate this with voluntary

organizations. What is going to happen if we try to make it mandatory and create these virtual organizations, because we haven't prepared for this critical difference, which is the people that are participating are not there because they want to be. They are there because we force them to operate as a group. But we've still allowed them, because it's going to still be a fee-for-service world, to operate independently while they're, quote, "part of a group.". So I think that needs a lot more development before we could think about a mandatory world.

MR. HACKBARTH: Okay. In the interest of time, I'm not going to try to summarize right now, but I did hear some fairly consistent themes that I think we can use to focus the discussion next time. So this was very helpful to me. Good work, guys, on the paper and the presentation.

Our next agenda item is physician resource use measurement. We have got to get a new term.

MS. PODULKA: I don't want it to trip off your tongue.

MR. HACKBARTH: Right. We are right now about 20 to 25 minutes behind schedule for anybody keeping score. I guess it occurs to me we may want to give the lunch people a

heads up that we're going to be running late. I don't envision we are going to make up a whole lot of time in this conversation.

Jennifer, whenever you're ready, we can start.

* MS. PODULKA: Thanks, Glenn. I'm here to talk this morning about physician resource use measurement and I'm going to warn you to begin with that I have five threads. They don't necessary weave together to tell a complete story so I'm giving you a heads up. The five items are the MIPPA physician feedback mandate, which implements our recommendation; CMS's pilot to test it out; guiding policy principles for our final program; options for releasing Medicare claims; and an update on our latest data analysis results.

In the interest of time and lunch, I will talk about all of these briefly. All five are described in greater details in your mailing materials and I'm happy to go into them more on Q&A if you'd like.

So the first item. In our March 2005 report to the Congress, the Commission recommended that Medicare measure physician resource use and share the analysis with results with physicians in a confidential manner. The

Congress enacted this recommendation in the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, and Congress has begun to pilot test how they will implement the final program.

The MIPPA mandate grants the Secretary flexibility on several characteristics of the physician feedback program. The Secretary may chose to use other data in addition to claims, provide feedback to individual physicians or to groups, include feedback on quality of care, and the resources can be measured on either a per episode or a per capita basis or both. And finally, the Secretary may choose to risk adjust the data.

MIPPA also grants the Secretary flexibility to focus the physician feedback program on specialties that account for a significant share of Medicare spending, physicians who treat high-cost or high-volume conditions, physicians who use a high amount of resources compared to other physicians, physicians in certain geographic areas, and physicians who treat at least a minimum number of beneficiaries.

So in response to the MIPPA mandate, Medicare has began to test ways to measure physician resource use and

feed back the results confidentially to physicians. The work is referred to as the Resource Use Report Pilot and it will inform the design of the final permanent physician feedback program.

In phase one of the pilot, which is currently ongoing, Medicare is sending feedback reports to a large sample of physicians in multiple communities and conducting one-on-one interviews with them to get their input. Specifically, the physicians are being asked about the program's measurement methodology and the feedback report format. The pilot uses both per episode and per capita measurement and focuses on four acute and four chronic conditions.

We're going to switch topics. Given that MIPPA grants the Secretary so much flexibility in designing the program and CMS is in the midst of their pilot to test aspects of the final program, we think it is an opportune time to discuss some guiding policy principles. The list you see here is informed by efforts by other organizations and hopefully reflects your comments from our November meeting when we last discussed them. I'm not going to go through all nine now, but I do want to highlight a few of

them.

First, the program should be transparent. Medicare should make publicly available an explanation of its measurement methodology and a description of the data sources used. Currently, CMS's pilot relies upon commercially available episode grouper software packages, but this is only to allow Medicare to evaluate features of the software packages that could be included in a Medicare-specific open source software package. CMS and MedPAC have never expected Medicare to purchase black box off-the-shelf software. CMS doesn't regularly make a habit of pursuing this kind of strategy. It regularly contracts with vendors to develop tailored programs, such as DRGs, and then makes them publicly available. The final episode grouper software that's used for the physician resource use measurement program should also use a Medicare-specific transparent method.

Second, the program should provide actionable feedback. It can't just tell a physician that he's inefficient. It needs to explain why by including detailed breakouts by type of service and condition and other attributes.

Third, the program should have the flexibility to use multiple measures, especially per episode and per capita. As you've indicated, relying on just a single measure, such as per episode, may mask important differences in practice patterns and even allow opportunity for gaming.

Fourth, to be sustainable, the Medicare program needs to provide an opportunity for physician input into the design of the program. The pilot that's currently happening and publishing a proposed rule in the Federal Register are both good steps. Medicare should continue these efforts and perhaps seek additional opportunities for gathering physician input. For example, Medicare may want to consider establishing a formal physician feedback advisory board.

And finally, to be effective, the program must invest in outreach and education to ensure that physicians understand the feedback they receive. Simply mailing a feedback report to physicians is not going to be enough.

Switching topics again, as we move from Medicare's physician resource use measurement and feedback program to a related issue, which is releasing Medicare claims data. You may have heard that there's been a recent court decision that ruled against patient release of physician-specific

claims data. The case began when Consumers Checkbook sent a FOIA request to CMS for patient claims so that it could post information on its website about the number of procedures performed by each physician.

Some stuff happened in between -- I'm not going to go into detail -- but the latest decision from the U.S. Court of Appeals concluded that physicians have a right to privacy, in essence because their Medicare payments can closely approximate their total personal income.

The Court case aside, however, there is interest in releasing Medicare claims data so that entities such as private plans can aggregate Medicare data with their own to measure physician resource use. Data aggregation could address the small "n" problem, where private plans because of their low market share too few positions or too few claims to appropriately measure their resource use.

Note that releasing Medicare claims data could assist private plans in their physician resource use measurement, but without reciprocal data sharing from these plans, Medicare would not benefit from the data release.

Data aggregation is also suggested as a way to address the problem of physicians receiving contradictory

scores from different entities. However, releasing Medicare claims data for aggregation would not result in consistent physician scores without some mechanism for standardizing the measurement methodology. Remember, if these plans use an episode grouper package, there are at least three major packages they can choose from and that management using episode groupers requires numerous methodology decisions on the part of the user, such as grouping claims into episodes, attributing to physicians, selecting peer groups for comparison, setting a minimum number of episodes, and setting thresholds for outliers.

Entities can and will make different but perfectly legitimate methodology decisions that will lead to different results using the exact same claims data. The issue becomes even more complex once other measures besides episodes, such as per capita and quality, are included.

So to help frame what comes next, we have outlined two broad options for your consideration. First, Medicare could release Medicare claims data with appropriate beneficiary privacy protections to entities such as private plans. These entities would then be able to either confidentially or publicly report their physician

measurement results.

Or Medicare could create a claims data clearinghouse to which interested entities could send their claims, where they would be merged with Medicare claims, grouped into episodes, and attributed to physicians using Medicare's methodology. The clearinghouse would return to the entities either the measurement results or the results plus the original Medicare claims data. Like the first option, appropriate beneficiary privacy protections would apply and the entities could then report their results.

Switching topics for the last time. In our ongoing analysis using Medicare claims and episode grouper software to measure physician resource use, we have most recently explored the stability of physician efficiency scores over time and the trade-offs between different attribution methods. We go into much more detail in the mailing materials, but basically we found that physician scores were relatively stable over two points in time, 2002 to 2003. Correlations between physician efficiency scores were quite high for the two years, ranging from 0.84 to 0.91. We further analyzed physicians whose efficiency scores qualify them as outliers in the first year, and 94

percent remained outliers under a slightly broader rule in the second year.

Next, we explored the question of whether to use single or multiple attribution. Single attribution is designed to identify the decision-maker, perhaps a primary care physician, and hold this individual responsible for all care rendered in the episode. Multiple attribution occurs when a single episode is attributed to more than one physician. It acknowledges that the decision-maker, if there is one, has incomplete control over treatment from other providers, even when the decision-maker referred the patient. There are significant trade-offs between these methods, so we wanted to see if a quantitative analysis yielded a clearly better method. The punchline is that it doesn't.

Physicians' efficiency scores are pretty similar regardless of which attribution method we used. Of course, multiple attribution resulted in more physicians being held accountable. We found that multiple attribution based on total dollars resulted in about 70 percent of physicians attributed responsibility for a minimum 20 episodes, where single attribution methods resulted in about half of

physicians being attributed responsibility.

So finding no clear winner among attribution methods based on our statistical analysis means that the choice between attribution methods probably comes down to a qualitative decision based on the policy goals of the program. For example, if Medicare would like physicians to focus more on the effects of the referrals, they might select a single attribution method. Alternatively, if they would like to trigger conversations amongst physicians, they might select a multiple attribution method. In fact, there might be reason for and room for more than one attribution method in the final program.

So we've gotten through five items and I wanted to remind you for the Q and A session. First, MedPAC has recommended that Medicare develop a physician resource use measurement program, and this was enacted in MIPPA. CMS is currently piloting physician resource use measurement and feedback to explore issues, so now is an opportune time to discuss policy principles. Sharing Medicare claims data raises various issues. We find that physicians' efficiency scores are stable from year to year. And finally, there are policy trade-offs between single and multiple attribution,

but both yield similar results.

And if it's of assistance, we've outlined a few discussion questions. First, what policy principles should guide the physician feedback program? Second, is there a policy direction for Medicare claims data sharing? And third, are there any technical questions you'd like to revisit on the data analysis results?

Thanks, and I look forward to your discussion.

MR. HACKBARTH: Nice job, Jennifer. Thank you.

What I propose we do is have our round one clarifying questions, and then when we go to round two, I would like to use the discussion questions to help focus the feedback that we give Jennifer. In particular, I would like to see some focused discussion on the second bullet, well, on both the first two bullets. I think those are good topics for us to focus on.

So round one, just quick strictly clarifying questions. Let me see hands. We'll start over on this side.

DR. CROSSON: Maybe this is a clarifying question with respect to the presentation, but also with respect to the discussion. Are we considering the two first bullet

points as separate issues? Or are we considering the interrelationship between the two?

DR. MARK MILLER: I guess I'll take this one. I think we had started off the notion of treating them as separate question, that right now, the Congress has said go forward, put this information out, engage the physician community. It's starting to happen, and you could take the first set of issues as what do we as a Commission think how that process should go. And then we envisioned the second question as, if we're going to be sharing this data with the private sector to make their own efforts, how should that occur? Is it just letting the data go, or do you have more this clearinghouse function? So I think we conceived of them, and Jennifer, as two different questions, but maybe you see a relationship here that we didn't see.

DR. CROSSON: I do, but I'll do that in the second round.

DR. REISCHAUER: This is just an extension really of your discussion of the pilot. They are doing a pilot and a subsample of the pilot is being subjected to interviews, mostly about the method that they're using. I was wondering if anybody is thinking about a control group for this, for a

different topic, which is does this kind of information in talking to physicians affect behavior? We have a lot of evidence on profiling and its effect or lack thereof. But it strikes me the environment has changed very much in the last few years, and so unless that evidence is worthwhile, I mean, it's just something worth thinking about for the future.

MS. PODULKA: What's going on right now is phase one of the pilot, and that does not include questions about, and what have you done to change your practice.

DR. REISCHAUER: I wouldn't expect it to, but you can then go in later and look at the practice behavior for unaffected people, people who are part of the pilot, people who were part of the pilot and were interviewed, and see if there are changes.

MS. PODULKA: Right, so I was going to add is phase one is going on right now. The agency already anticipates a phase two that would begin later. So it's not necessarily included right now, but they're considering the design for phase two, and one option would be to include a look-back with the original group.

DR. KANE: I share Bob's question. First of all,

is there any design in here for evaluation of the impact on behavior? It sounds like not yet.

And then the other question is, is there anything in the design that helps -- that creates a vehicle for physicians to share best practices and how they improve their efficiency in reaction to this data?

MS. PODULKA: There is an official evaluation of the program, which could include a function about physician behavior. GAO is mandated to report by March 2011, I believe. Right now, there isn't necessarily a mechanism that I'm aware of for physicians to share best practices, but one thing I mentioned which I think is kind of a nifty idea about the Physician Feedback Advisory Board, it could definitely be a format for having that shared.

DR. CASTELLANOS: Good job. The question I have is the question that you brought up on the feedback concerning a large sample of physicians and the one-on-one interviews. I kind of looked into that. Do you really think it is a large sample of physicians?

MS. PODULKA: Well, they are sending it to -- now I don't have total "n" --

DR. CASTELLANOS: They are sending it to 125

physicians in each of the six communities. There are eight focal conditions and there are 13 specialties involved.

MS. PODULKA: They have six communities so far, but in the end, they are going to have 13 total communities. It is in the hundreds, or over 100 in each community. Again, CMS is somewhat constrained by resources. I know this is a perennial topic and --

DR. CASTELLANOS: I'm not arguing with that. What I'm suggesting is maybe we could suggest really getting a robust or a larger population feedback.

MS. PODULKA: That's definitely something they could consider for the phase two.

MR. GEORGE MILLER: Very quickly, in the report you mentioned about the geographic variation of Medicare spending suggests there's more variation in physician practice patterns. I want to tease that a little bit with other issues that I brought up before, and that is the disparity in treating minority populations, and if that was at all reflected here about resource use. I'm not sure I can tie that together, but we've had discussions where minority populations didn't get the same care as the majority populations, and again, I don't know if that has an

impact, but just raising the question if there could be -- quite frankly, it may be the reverse, that not enough resources are being used for minority populations, if that was taken into consideration.

MS. PODULKA: Absolutely. I think in many ways this could be a very effective tool, because a lot of attention is paid to the high-cost outliers.

MR. GEORGE MILLER: Right.

MS. PODULKA: But you can also use physician resource use measurement to look at all sorts of efficiency, and when we use efficiency here, we refer both to the cost of the care and the quality. And so you can look at sort of best practices for efficiency, and when you include some robust risk adjustment that includes characteristics of those beneficiaries being treated, I think you can really zero in on who is doing good things and who is doing bad things.

MR. HACKBARTH: So this is really about developing a fairly robust analytic tool that can then be applied to a lot of different purposes, including looking at disparities.

MR. BUTLER: In order for me to answer number two, I would just like a little bit more information. You say

that in the examples, that the private health plans would be the most likely user of the aggregated data and you -- at least that's the theme. And it talks about pediatric cardiac surgeons, you have a greater "n". I'm not sure exactly what health plan decisions would be made differently with this data, so if you can think about what that would be.

And then, also, who are the other likely people that are chomping at the bit to get their hands on this data?

MS. PODULKA: I'm not -- I do think private plans would be very interested in using this to aggregate with their own data to address problems where they have small "n" for physicians. But the court case involved Consumers Checkbook, which is known for making the comparison of the Federal employee health plans. So there could be all sorts of numerous entities out there who might be interested, both for-profit and not-for-profit. They could use it for their own services, like a private plan might use it for their networks. But they could also use it for very public information. Consumers Checkbook wanted to post this on the website.

DR. MARK MILLER: Peter, was that what you were --

MR. BUTLER: The answer, I didn't -- so if there was a small "n," what would they do if they had a bigger "n" with respect to -- what problem are they trying to solve?

MR. BERTKO: Peter, let me try to address that. Small "n" that means that if there are 150 cardiologists in the greater Chicago area, one plan in particular might only be able to have enough "n" to look at the 20 of them. With Medicare in particular and cardiology in particular, you might be to combine the data and look at 100 of the 125.

MR. BUTLER: What do you want to look at, is the question. You contract based on rates and other --

MR. BERTKO: Well, I want to have the -- in my particular case, it was the relative efficiency and quality compared to the people -- their peer group in Chicago in the same practice.

MR. HACKBARTH: So to develop a network, for example.

MR. BERTKO: Network development, in particular.

DR. CHERNEW: It helps John tier doctors.

DR. MARK MILLER: It could be that. It could also be we notice among our physicians an uptick in the use of

this service and we think that there is a clinical argument for that or a clinical argument not for that, so now we are going to educate physicians on the use of this particular service. And I think there's not simply building the net, where there's also watching patterns of care and saying, why did this service begin to spike or why is the service falling, that type of thing.

MR. BERTKO: No, it's not, but there are practices out there, I mean, and Jennifer said this. It works. It's reasonably stable.

MR. HACKBARTH: Okay. Let's turn to round two, and as I said earlier, I'd like to get to these questions, so put your hands down for just a second because Arnie is first and so I'm going to put on my best Arnie imitation here. Obviously, these comments aren't specifically focused on the questions, but still important, and I hope I do this adequately.

Arnie's first point was that we're spending a lot of time, as in the ACO discussion, trying to figure out new payment system structures that will alter the behavior of physicians and other providers, and he's not against that by any stretch, but he said it also is important, even if you

do those other things, to shape physicians' understanding of their own practice. And so this is an important and necessary step no matter what else you do in terms of other payment policies. This is education, in Arnie's view, for physicians, helping them understand their practice as it compares to their peers in their community.

A second point is that although this is sometimes seen as a set of tools developed by, for example, insurers, to be imposed on physicians in sort of an adversarial way, Arnie thought it important to emphasize that, in fact, the origin of these tools is with physicians. You have physicians with a research bent, but physicians who care about good practice have been involved in developing these tools in that spirit, as a way of helping physicians do a better job.

A third point was the tools are imperfect, as are all the tools we ever talk about at MedPAC. They need continuing refinement, and arguably they are not yet sufficiently refined to link to payment. But in Arnie's view, they are certainly good enough to provide meaningful information to physicians in terms of how they compare. They're pretty good at distinguishing between, as Arnie put

it, the top, the middle, and the bottom. They may be less good at distinguishing degrees of performance in the middle range, but at a high level they are pretty good discriminators.

A fourth point is that he believes it's very important for Medicare to enter this field, which has to this point included mostly private payers and researchers, and it's particularly important because of the size of the Medicare population and what that data can do to enhance the power of the tools. It follows from that that he would like to see Medicare data made available for pooling so that all payers can better assess the performance of physicians. The physicians have a stake in that, that they are going to be evaluated one way or the other and it is in physicians' interest that they be evaluated on the most robust data available as opposed to small slivers of their practices, as often now the case.

So he would like to see sharing of data, and his notion about the best first step to do, that is option 2(a) in the paper.

Jennifer, why don't I have you describe that for the benefit of the audience. Did you go through that in

your slides? Well, I guess at the bottom there, yes.

MS. PODULKA: Right. So 2(a) refers to the option to create a claims data clearinghouse and send the results alone back to the entities.

MR. HACKBARTH: So the raw data would not be sent out to Humana or another, but Humana could say, here are our data, combine it with Medicare and analyze it using your tool and give the reports back to us. And so Arnie advocates that option as the first step.

Next, he said that, again, these are imperfect tools, but nothing improves tools so much as use. As we use these, they will get better. We will get input from a lot of people, including physicians, that will help us make the tools better over time.

So I think those were Arnie's major points. The bottom line is he thinks this is a very important thing to do.

Now let me see other hands for round two. Again, I'd like you to focus on those two questions in particular. Let me start with Karen and we'll go down this row and around.

DR. BORMAN: My bias and my comments will be that

I think that this and bundling, in my view, probably represent potentially the most useful tools we have going forward, because I think they are things that potentially build on some things that we have and therefore are an easier transition to make, in addition to the places that they potentially impact. They could then build into some of the other things we've talked about.

In terms of the policy principles, I think the first one you brought up, transparency, I cannot over emphasize the import of that. It just will have no credibility without that. That will be an absolute deal breaker, cut you off at the knees, whatever, so transparency is absolutely necessary.

I think maybe the second piece is that the transparency will in part enable is what I might term collegiality or collaboration. That is the tone in which this is brought forward and the mechanisms to actually make it be, as Arnie's comments were just related to, a growth experience. One of the things that sometimes happens in residency when we tell you to go do something that seems unpleasant is we tell you it's a character building experience. There's going to be some element of this on the

recipient no matter how you slice it. So I think that this collegiality piece is important.

And I would say that in addition to the transparency part, that the Physician Advisory Board or some entity, some process other than, yes, you can send us your to the Federal Register or whatever, is important beyond the value of any comments that might come out of it as a commitment to a mechanism for dialogue.

I would suggest, and I will relate to comments later, that that group, in addition to establishing this collegiality, should also be a vehicle that will enlighten potential strategic planning to later phases of this and, in fact, should include individuals who represent various specialty boards, and I'll flesh that out in a moment.

Another principle that I think is fairly important is the "keep it simple" principle here. And while I think we are all excited about the potential power here, all of the ways we can think of to permute the data and use this process, the first thing we've got to do is make this work in some way, make it viable in some way, accept it in some way. If we try and craft a grand scheme the first time around, I'm afraid that we will not enable success of what

could be something very important. This is one of those times where we need a base hit and build on that, and not necessarily to blow it out of the park.

So I would suggest that some of the things in keeping it simple relate to how we define the participants, we define the conditions, the validity of the measures that we use. And also very much so the nature of the explanations provided with the data and then all the ways that the outreach happens. The driving principle for that interaction, I think, needs to be some element of simplicity and focus. I think focus is as much of a piece as simplicity. So that would be another principle in my mind.

Another one would be looking at this as a multi-pronged or staged phenomenon. For example, I could hypothesize that in a first phase of gains that the gains will be merely from actually seeing what you do in a measured way that will have some validity put to it. As much as practicing physicians we may whine about various systems or things -- one of the things that I certainly teach in practice management courses and so forth is that you may not like Medicare rules, but they are in black and white and you can go read them and you know more so than any

other payer what you're getting and why you're getting it. And so I think that does transfer to some inherent credibility to data that comes from the government, if you will.

And so in that respect, I think there will be just some, wow, for the outlier particularly, I'm way out here. There will be that shock value piece, whatever, that will be the first round of gains with this. And just the notion that, you know, I'm a little off, particularly if you're in a group practice where your partners get materially different scores. That may have an impact.

I think the next phase and probably the one that will last longer is the potential use of this for practice-based learning and performance improvements and change by the individual, and that, in my view, should be linked to the maintenance of certification process for those who are board certified. For those who are not, perhaps to the maintenance of licensure process, which I'm not as conversant with. But being a board member, unless John tells me otherwise from an actuarial standpoint, in a few years, I will come up on my third recertification examination. The American Board of Surgery has

recertification since 1976. It was one of the very early boards to have the process. So we have lots of people who have done their third recertification.

Obviously, the process now is much more multi-pronged. There's things that have to be done every one to two years as opposed to just study up for a big exam, a single high-stakes exam at the end. I think that the boards are charged -- one of the ABMS principles relates to performance assessment and practice. This could be a huge step toward facilitating that and it incents the physician because they get a two-fer, at least. They get something that they've got to do relative to MOC. They get something that enables them to, just on a personal motivation to get better, and potentially allows them to figure out practices that will allow them to get into some of the bonus or at least no withhold program. So it becomes an enabling tool for multiple things.

So I think thinking of this in a phased strategic way, not losing sight of that, and making sure that this physician communication board doesn't just get hung up in the details of answering questions or whining that it thinks about that strategy would be important things.

MR. HACKBARTH: On that point about how this links to the activities at the various specialty boards, I'm involved with the Board of Internal Medicine and can't speak anywhere near as authoritatively as Karen has, but what she just said really resonates with conversations I've heard members of the Internal Medicine Board have. If you can link this to their own internal activities assuring quality, assuring that physicians are improving their performance, it becomes a two-fer and its power is enhanced and the burden on physicians is reduced. The ABMS is in the process of trying to beef up that process for all of the various specialties, the recertification process.

Arnie, I'm far enough behind schedule that you could have made your own comments, but I did want to begin this discussion with the points that you have made. I'll allow you to leap in at your well. We are now in the process of going around with our round two comments and Peter is next.

MR. BUTLER: A lot of people to speak, so I will be brief. This is at the heart of comparative effectiveness. We can't make advancements if everything is sitting in a black box that people can get at, so I'm

supportive of the principles pretty much as written with obviously some added good comments around the table.

With respect to the second question, I don't think we're at option one of releasing at all and just letting people go after whatever they'd like. I'd kind of defer to Arnie's suggestion of option 2(a), although my only hesitation is we've got to make this easy to get at. So if it becomes a bureaucratic thing, that you send in your data and eight months later you get it back maybe the way you wanted it or not. We just have to think through how that would work because it should be pretty darn easy to get in and out of the data if we're going to make it accessible.

MR. HACKBARTH: Arnie, did you want to make a comment? Let me see the other hands on this side. Nancy?

DR. KANE: I think the policy principles look good. I would add that there should be efforts to evaluate behavior after these reports are out in practice after a while.

On the claims data sharing, we haven't mentioned this yet, but the way it is phrased now, the only people who get data back are those who produce claims and I'm wondering if we need to think about a broader audience for the data,

particularly the providers themselves or the health systems that may want to use this to inform themselves about how to develop what clinical protocols or performance measurement systems that target a certain diseases and the way they through the system.

And then the other group who might want access to this claims data would be health service researchers, and I'm thinking about George's question about how can we use this data to identify disparities and other types of things that would inform policymakers.

So I just think the claims data sharing piece needs to be expanded, perhaps, not right away, but not just to those who provide claims but to others who may want to use that data for appropriate purposes.

MS. PODULKA: To start, and maybe you can jump in if I -- there is a mechanism for health services researchers and other entities to have access to Medicare data. The problem that surfaced in the Consumer Checkbook case -- and you're right that they don't have their own claims -- is the way they wanted to report them at the physician individual level. So right now to have access to Medicare claims, you have to comply with the way Medicare sees its responsibility

to steward those claims. What we are recommending would be beyond or outside of their current authority or interpretation of their authority.

DR. KANE: I didn't mean just the Medicare claims. I mean the combined -- if there is a clearinghouse where both private and public sector claims are placed, I think it would be helpful to think about how do you make that available for more than just people who put claims in.

MS. PODULKA: So you mean if Humana and United send their claims, they don't just get back the Humana and Medicare claims. They get the Human and United Medicare claims.

DR. KANE: Not just them, but others who are trying to do research.

DR. CASTELLANOS: First of all, I agree with Karen and all her very good points that she made. When this data becomes available, it needs to be actionable. In other words, a physician or the provider really needs to be able to act on that data, so it really needs to be pretty well identified, also.

MR. HACKBARTH: Say what you mean by identify it, Ron.

DR. CASTELLANOS: Well, a lot of times you'll get a report from especially the private companies telling you to do something and they said, out of this percentage of patients you did this. Unless I know who the patients are and I can look at the data and go back to my records, it doesn't make any sense to me. So the data needs to be actionable, where I can look back and say, you know, you're right. I should have done this.

MR. HACKBARTH: Jennifer, any reaction to that?

MS. PODULKA: We've actually gone through with some of the companies their capabilities for drill down. Now, these aren't necessarily utilized by the private plans when they're doing analysis, but we were amazed. Mark, I think you sat in one of these. They can start at your overall level. They can break it down by conditions or type of service. And then they can further break it down to the individual visits and show you the patient who came in and the services you provided that day.

Now, that level of detail doesn't fit very well in a printed report. And so one of the things I noted, just mailing a five-page feedback report is not going to be the final step. It can't be. The program should ideally have

the capability to allow physicians to see this level of detail.

MR. HACKBARTH: Is that something that CMS is planning to do, that drill down capability?

MS. PODULKA: I can't say. I don't know if they are.

DR. MARK MILLER: I think they're very much at stage one, and some of the things that I think Jennifer is talking about is you would have the ability to perhaps go online and say, okay, now I want to dissect this report and dive for your own experience.

MR. HACKBARTH: Okay. Anybody else on this side? Let me just see the hands here so I know how much we have got to do. John?

MR. BERTKO: A couple of quick comments. I'm also very supportive of this. It is, as Arnie said through Glenn's lips, good enough for now. On the question --

MR. HACKBARTH: I was more eloquent than that, Arnie.

[Laughter.]

MR. BERTKO: A question here about having a clearinghouse. I'm for 2(a), which is the clearinghouse

with results, with a note that it takes a while to combine other people's databases. You have to be repricing everything. So I'd want the caveat hopefully to read something like, start with Medicare data and then and the other payers' claims data in there. And you'd have to say, I think, that you get combined data, that is other payers plus Medicare, if you contribute, because otherwise there would be little incentive to do the work of contributing. So just if you can consider those nuances.

DR. DEAN: Thank you very much. This is very interesting stuff and, I think, important. I would certainly, first of all, second what Karen said. We need to keep it simple and understandable because if it's not, we're going to drive away a lot of participation or may get a lot of pushback.

Secondly, I would really argue that for the multiple attribution part of it, at least depending on the structure of the practice or the structure of the system you're in, I mean, I think people should only be held accountable for things they can control. For instance, there's an awful lot of things happen with my patients that I have no control over once they get into the system. So

they get referred from one specialist to the next and I don't find out about it until three or four levels down the line.

And so, now probably, for instance, in the Kaiser system that doesn't happen, my guess is. And so it depends on the structure of the system. But in my setting, I have no control over a lot of the things that happen.

I was struck by something Nancy said, and I don't know if she was referring to this, but a question of who has access to the data. For instance, it would be extremely helpful for me as a referring physician to have access to the performance data of some of the consultants I use, because quite honestly, I don't know them. Many of them are a long ways away. I don't see them on a day-to-day basis. I don't exactly know what's happening. And I don't really know whether that's possible or not, but --

MR. HACKBARTH: Let me link Tom and Ron here. We're not using this for payment. We're using this for information. Ideally, Tom would be able to look at his data, in fact, see that when I refer to Dr. so-and-so, it produces lots of imaging and lots of additional specialty consults, whatever. When he gets his data, is he going to

be able to see, oh, it's my referrals to Dr. so-and-so that are producing this stream of stuff, or is it going to be so aggregated that he can't figure out which of his consults is producing all this stuff?

MS. PODULKA: You raise a very good question, Glenn. Anytime you start to disaggregate and you drill down by condition, and as I described, even individual episodes and patients, you're going to start to be able to figure that out. And I could see that it would be of tremendous benefit even just to list which other specialists and providers are involved. You might not even be aware, I mean, other than the initial referral, if there's things down the line. If you just had a list of the names of who else are involved in that episode, it could be helpful. But then we're raising the policy question of the confidentiality. So then this sort of goes back into your lap.

MR. HACKBARTH: The confidentiality of the other physician, you're talking about, not patient confidentiality. Again, this is, to me, reminiscent of some of our discussions around medical home, also, where we say, well, we want these physicians who are designated as homes

to influence these patterns of care, but they don't know about them or they may only know little pieces that they hear from patients. They don't get systematic information. This is the sort of tool that we need to be developing, including the drill down capability that allows them to learn what happens when I refer to Dr. Jones.

DR. DEAN: And Arnie wrote a very interesting paper about practices that were successful in controlling costs and upholding quality, and somehow they had much better data about the consultants they used than I do. I don't they did it. I admire what they did. But this would be a very valuable tool if we could make it available.

DR. MARK MILLER: One step down that road, which is not every consultant that you used, but the point that Jennifer was making earlier about multiple attribution. If you go to a process of saying, okay, I'm going to make the attribution for this episode to the heavy hitters in the episode, then at least there may be two or three physicians that you're aware of and say, okay, this is the report of what happened to the episode, even if it's not each and every consultant.

DR. DEAN: [off microphone] There certainly are a

couple of specialties that consume most of the resources.

MS. BEHROOZI: This is really fun, and actually I see a lot more integration between your five separate parts, I think, than you gave it credit for. Partly the way you wrote it helped with that.

But also Jay's comment earlier about the relationship between the policy principles and the data release point. I think they really come together, particularly around the options for data release that include results, because that's where you get to reinforce or build on the policy principles of transparency and buy-in and things like that.

It does seem to me that we're not talking about a confidential feedback system anymore, right, if we're talking about releasing results to other entities that may be using it right, private payers or whatever might be using it differently. So that's a big step and so all of those policy principles then, it seems to me, we need to be really clear that we are doing this the right way so that because it will now be used in a different way than just confidential feedback, there can be a high degree of confidence and reliability and consistency. So I think

that's one way they relate.

I think also just the whole notion of -- you talked about Medicare not wanting to buy things off the shelf. But in general -- and Medicare is special. But in general, the idea of customization runs counter to efficiency, sort of generally when you're implementing change and implementing systems and things like that. That doesn't mean customization is a bad thing, but it's a trade-off.

So in our overall system where we spend whatever it is, $700 billion too much because of administrative burdens and things like that, a lot of that is because individual entities are reinventing wheels that shouldn't have to be reinvented. And it does seem like accountability measures, as Arnie called it earlier, is not necessarily one of those places that benefits by the free market competitive branded version of, ooh, my physician resource measurement tool is better than yours, but rather building the best one together brings down costs overall somewhat in our system and produces these other positive results of having it be reliable and having buy-in and things like that.

I just wanted to make one more point unless you

wanted to talk on that point.

I think that just releasing raw data as opposed to releasing the results are like two opposite things. You put them as sort of alternatives on a continuum, but I think that they really run kind of in counter directions when it comes to that issue of not customizing and having things be that much more reliable. So I think that's it.

MR. HACKBARTH: I was just going to pick up on your point about customization, which is I think is a very good one, and in fact, as I have tried to learn about these things from a physician perspective, one of the things that I hear often now from physicians is I get all of these conflicting reports. One says I'm a good physician. The other says I'm a bad physician. What am I supposed to do with this stuff? Their reaction is to just ignore it. I can't reconcile it. It doesn't make sense. So having all of these different flavors is, in the real world, a real problem.

The customization issue here for Medicare is a little bit unique in the sense that it's closely linked to transparency. Medicare can't take an off-the-shelf product which is a black box, the details not knowable, and say,

we're going to use that. That just won't hold water for a public program.

So to some extent, Medicare is forced by that to have its own. But then that makes 2(a) sort of appealing. At least let's give people the option to say, private payers, we're going to use the Medicare product in the name of standardization, consistent signals to physicians, and pool the data.

MS. BEHROOZI: Right, exactly. Not that anybody should be prohibited from inventing their own wheel, but Medicare having customized it in the best way possible according to all those policy principles, with buy-in and input, that should be the new thing.

But the other point I wanted to make was in terms of the data that you're talking about, it's just fee-for-service data right? The claims data.

MS. PODULKA: Correct.

MS. BEHROOZI: So I just wondered about -- and you say that Medicare has a big enough "n," but we look at it on a national basis. I'm sure there are pockets, whether it's specialties that you identified or areas where there isn't enough "n." So how about requiring those MA plans that pay

claims, like private fee-for-service, requiring them to dump their data into here, and now I know I'm going far afield, but CMS does administer Medicaid and Medicare. HHS administers them both. Let's maybe suggest to Congress that States be required to report their data and then they get it back, and boy, wouldn't they love to be able to look at the quality of Medicaid providers, and probably a lot of them don't have the resources to do this themselves, so anyway.

DR. STUART: Recall that CMS has a regulation -- I'm not sure that they've actually put this into place yet -- that will get MA event-level data and claims from those who actually have claims, and because that is supposed to be used for risk adjustment and because you're talking about risk adjustment here, it sounds to me that a way could be made to include that in here, as well.

DR. CROSSON: I am an enthusiastic supporter of reporting physician use information. I have been from the beginning for all of the reasons that Karen delineated. And I think the principles that were laid out in the paper and some of the other ones that Karen added, also I would support. So that's fine.

The concern I have with respect to the second

question and the options, or in fact how we think about the public release of the information, relates to what I thought was the thinking process we went through when we originally supported the idea of the reporting of the physician use information. And that was, and maybe I remember imperfectly, but it was essentially to be a step-wise process. In other words, we would first report confidentially. The idea there was several-fold. It was to try to make sure that the reported information got a chance to be improved around things like risk adjustment, the clinical relevance of some of the stuff, to give the physicians the chance to recover from the fact that this is a new thing in their life, to have some input into the process, and also to begin to change behavior. There was a sense that the physicians respond really quite well, and it has certainly been my experience, at least initially to confidential information and to have a chance to change behavior before something else transpires, including up to changing reimbursement based on performance. All of which I support by the way.

But it seems to me here now we have sort of two parallel things going on. One would be now based on the

law, CMS going ahead with the confidential reporting process based on an analysis of the Medicare claims data.

But then a separate process, even under option 2(a), where basically the same information is now provided to private entities, clearinghouse or not. And then as it says in each one of these three options, the entities would then be able to either confidentially or publicly report the physician measurement results.

So my concern is whether or not -- whichever one we pick of these -- we have essentially sort of two things in conflict. One is we're trying to bring forward a confidential reporting process to gain the trust of physicians, to incent behavior change, and then simultaneously we're going ahead and supporting another process which has a very different reporting process and could completely supervene the one that we started out with.

So one potential solution to that would be if we end up choosing option 2(a), which is the one of those that I would pick, is to put some proviso in there that this issue of publicly or confidentially reporting be managed somehow in parallel to the CMS initiative. In other words, when the CMS initiative is confidentially reporting, then

these would have to be reported confidentially also. But then when CMS moves on to more public reporting or to other levels of accountability, then the other process would be released for that purpose.

MR. HACKBARTH: I think you're right, and Mitra touched on the same thing. There is a disconnect here if we go to 2(a) immediately with our prior emphasis on confidential and we need to figure out how to reconcile that.

I have Mike and Bill and Jack and then we're done. Mike?

DR. CHERNEW: I believe strongly that the principle of transparency is important, although I'm afraid that that's going to be a bit of a barrier to moving quickly for a number of reasons. So I have a question about that. The first one is how transparent are the HCCs and the risk adjustment methodology and other sort of technical things that are done with in the Medicare program? I'm afraid that if we wait for Medicare to develop its own, or maybe purchase one, that it will just take a long time until you get this to work and you'll end up with a product that conflicts with existing ones. So anyway, I think

transparency is really crucially important, but it gives me pause.

I also think that the idea of risk adjustment is really important, but I'm very worried that it's going to be imperfect in however you do it. One of the ways that no matter how you risk adjust it, people will look at it and say, well, but you didn't realize I had blah, blah, blah. And that's just the way it is.

As long as we're just releasing information to people, I'm fine with all of those flaws. So despite my concern, I would rather release the information, try and do the best job we can before having Medicare develop their own process with public comment and make sure everyone's done whatever they've done and gotten everything right. So anyway, that's my view on that, but I do think those are incredibly important principles.

With regards to 1(a), 1 and 2(a) and that question that was raised, so as a philosophical point, I'm generally supportive of as much data release as is politically feasible, subject to various confidentiality rules, but I think that should be released. I'm very skeptical of the 2(a) method, and I would be supportive of it if you could

convince me that CMS could do it well in a timely manner.

I remember a discussion we had about an hour ago about an under-resourced, not always given the most ability -- and this is a relatively complicated thing, and I've been working with some people that have been working with groupers and it is a -- the idea that even claims data, coming from different organizations in different ways -- this is a non-trivial information technology exercise. And the idea that we're going to put the resources into an organization that is going to do it well and have output that is then confidential is wonderful in a world that has the appropriate resources and I would be all for giving them the resources to do that. But I think that in the process we go through, that might be underestimated and we might not end up as well.

I actually prefer releasing the data in an option one kind of strategy. I'm not subject to the political reasons. I can see a lot of reasons why that's not a good thing to do. I'm afraid when you do that, no matter what we say about how the data is going to be used, you'll see it for tiering. You know, Medicare might not use it in certain ways, but believe me, public payers -- private payers,

they're going to see the power in this data and it's going to go well beyond having a physician understand how they stacked up.

So I think we really have to have a discussion about how far we want to go down this road between something that's sort of quick and easy and confidential and giving feedback, which is sort of where we started, to this system would be a whole heck of a lot better if Tom could figure out how the specialists that he's referring to actually behaved in a somewhat timely manner without six DUAs and a bunch of other things that in North Dakota everyone's going to hit the asterisks.

The other thing I'll say in response to Karen's comment about simple and understandable, again, I agree wholeheartedly about simple and understandable. I just want to add a third adjective, that it needs to be right. And the problem sometimes with simple and understandable is you've made compromises to make it understandable and simple as to what you're doing, which then later people will explain to you why it's not credible.

And so there is -- I know this in the work that I do -- there is always a tension between getting it in a way

that people think is credible -- risk adjustment is the perfect example. This simplest way to do it, ignore a lot of the risk adjustments. It's just this is your average claim per person. You understand exactly what it is. It's very simple, you know what it is, but it's not going to have any credibility. And as soon as you start worrying about other aspects of how you've done these things it becomes -- if you do it without multiple attribution, for example, people say, well, that's just not credible because I refer to one person and now it's all going wherever it is. I don't find that credible. If you do it with multiple attribution, it's much more complicated and people are going to argue about the aspects of the attribution.

I think Jennifer did a great job of saying, you know what? It doesn't make that big of a difference, and I believe that completely. Someone is going to say, that's on average, but for me, it's different. It's not true in Cleveland or wherever it is and I have a different type of practice because all my patients are over six-foot tall, or whatever it is.

So I guess, again, my view is I'm glad that this is after all of our payment update meetings and this is the

beginning of a process to figure out how to do this, because I think it does require a lot of philosophical and technical discussions to make sure we come up with something that's sufficiently sophisticated to achieve the goals that I think we all would like it to achieve.

DR. SCANLON: Like Mike, I see the real power of these data, but I reach the exact opposite conclusion, which is why I wouldn't allow it to be released sort of in the claims form, because it would totally destroy the issue of transparency because we'd have all kinds of people using it in different ways and we wouldn't know sort of how they're using it.

MR. HACKBARTH: Just so I understand, Bill, you're saying you wouldn't allow the Medicare data to be used by private --

DR. SCANLON: In the aggregate, yes, but not as claims. Not releasing of claims. So I'm in favor of 2(a), as well.

I think a part of this is that it's important -- I'm on the National Committee on Vital Health Statistics, the HIPAA advisory body, and basically there's a sense that de-identified data today is a becoming an oxymoron. De-

identified data of the type we're talking about here today, which is data that were going to be useful for something, where you know the physician, you know the diagnosis, you know the date, you know the service, that's not de-identified. That's going to be -- and you take away the patient ID, people are going to tell you about their ability to mine that data and identify sort of the person that was involved.

The assurance from a privacy perspective that can come here is the entity that receives the data and the requirements that are imposed upon that entity, the penalties that would be imposed upon that entity if they disclose the information, it's not going to come from the data itself. So we need to think about it in those terms, not this idea of just stripping off the name, because that's not going to work.

MR. HACKBARTH: Just so I'm sure I understand, Bill, what I hear you saying is that if we give these sorts of data to private insurers, it's not just physician identification that is known, it's ultimately patient identification.

DR. SCANLON: They will be able to infer who the

patient is through a variety of mechanisms. And it even applies to certain levels of aggregation. We can say that we've put together five people, but if we put them together in a particular way and there's enough information there and their characteristics are unique enough, the combination of those characteristics are going to identify some of those people.

It's again to this issue of data mining. You have other data sources that you can bring into play and that you then sort of can identify an individual in a data set that has supposedly been anonymized, but it isn't in reality. It's the --

MR. HACKBARTH: If you do 2(a), does that avoid --

DR. SCANLON: If you do 2(a) at a high enough level of aggregation, there is no issue. But this is -- I mean, it started with, I think, with Tom's comments. What level of detail do we want to give different parties sort of that are going to be part of this process? And in thinking that through, we have to think about sort of what are going to be the risks in terms of identification. And we're not going to always be able to say that we've totally eliminated the risk of identification, so therefore we have to turn to

sort of plan B in some respects, which is to say we have got to impose a responsibility on the person receiving this that they are not going to disclose this information. That's the critical piece here in terms of protection of privacy.

DR. CHERNEW: Glenn, could I just say I agree 100 percent with that comment about that's how you have to deal with the confidentiality issue, and I think the only challenge is how good you think 2(a) could be. It has the advantage, if you could get data from all the different plans. If you just release it, you get just the Medicare and United or Medicare and Humana. So I agree completely with Bill's assessment.

DR. SCANLON: The second comment would be to the issue of, again, sort of Mike suggesting that our risk adjustment process today has its problems. We could do a better job in terms of episode definitions, etc. Think about this, not for the short term but for the longer term, in terms of the linkage between this and the $20 million for health information technology and the idea of meaningful use.

What is it that we want in exchange for the $20 million in terms of the kind of data that are going to flow

to sort of both Medicare and private payers that would allow much more robust analysis to be done here? I think that's sort of a key. And it also could be combined with a notion of actually trying to achieve one of the original goals of HIPAA, which was administrative simplification. Instead of having sort of the information come in, or be requested by every payer in somewhat different form when it comes to adding on additional items to a claim, okay, that we end up standardizing the information in a way that it simplifies it for the provider perspective, but increases the power for the payers and the Medicare program in terms of being able to analyze the information and understand much better what they purchased.

MR. HACKBARTH: Okay. Mark, you gave me a big budget and lots of time and I managed to over-spend it by a fair amount.

We will now have a brief public comment period before lunch.

MS. McILRATH: Hi, I'm Sharon McIlrath with the AMA. There may be somebody in the room from CMS that could clarify this, but on the subject of the reports that are going out, in a meeting with the physician person it was, I

think, the understanding of everyone in the room that there were going to be 250 reports total to the 12 cities and in eight conditions, 13 specialty groups.

So when you do the math, it's not very many reports.

And there was a fear in the physician community that it's going to be going to one specialist in a community and if that person doesn't choose to fill it out, they're not going to get a lot of information.

And I think it does have to do, they've been very good about trying to reach out to the physician community. I think it has a lot to do with the resources, which is sort of the perpetual problem here.

So just in terms of thinking about what you can do, and perhaps we all had the misunderstanding, but I think that needs to be clarified.

Also, I just wanted to thank you for doing the principles and to sort of weigh in on the side of the transparency.

There's an issue that's going on now with the review, the medical review software that CMS has sent out and that the MACs and the RACs are using. And I won't go

into it here but it's causing some real problems and it's also going to mess up a lot of the data because it's turning out that some things that are really inpatient admissions are now being coded as observation care so that the hospital will at least get paid something, rather than having the claim denied.

And then I just wanted to also weigh in on the side of giving the physician the identification of the patient. Although it seems like that should be a simple thing and it would also help Dr. Dean figure out who the consultants were if you knew who the patient was, there is at least one demo where it's my understanding that CMS has not been willing to release that information to the physicians because of the fear that maybe they've got somebody else's patient in with your data and so the physician might not be looking at only their own patients' data. So it's sort of a Catch-22.

MR. HACKBARTH: Okay, we will adjourn for lunch and reconvene at 1:30.

[Whereupon, at 12:30 p.m. the meeting was recessed, to reconvene at 1:30 p.m. this same day.]

AFTERNOON SESSION [1:30 p.m.]

MR. HACKBARTH: Okay, first up for this afternoon is Medicare Advantage.

MR. GLASS: Good afternoon. Today, we will present some additional analysis for the Medicare Advantage payment report that was mandated in MIPPA. As you may remember, our mandate has three tasks.

Next month, Dan's going to address the first task, measurement of county-level spending. We discussed the second task in January and found a very high correlation between planned cost and fee-for-service spending. And today Scott will address the third alternate payment approaches, and all of these tasks are discussed in full in the mailing material.

To begin, I will provide some information you asked for last meeting and review the Commission's position on the Medicare Advantage Program and how it informs our work on this report.

You asked about the distribution of beneficiaries and MA enrollees across payment areas. So, here on this slide, we're looking at how beneficiaries are distributed by fee-for-service spending in their county residence.

Looking at this you will see that most beneficiaries, that first tall yellow bar, live in counties where the Medicare fee-for-service spending is less than $741 per person per month. At the other end of it just 3 percent live in areas where fee-for-service spending is above $900 a month. Now, the unusual breakpoints on this chart are related to the MA benchmark floors of $741 and $819 as we show on the next slide.

In this graph we have the green bars, which are the ones to the right, which show the distribution of the enrollees in MA plans by the MA benchmark of the county where they live. There are no benchmarks below the lower floor of $741 which is that first blue line. About 15 percent of MA enrollees are in counties with benchmarks of $741 to $818, and that is above the lower floor but below the large urban floor which is the second blue line. Most enrollees, 60 percent, are in areas where the benchmark is between the large urban floor and up to $899 a month.

Finally, almost 25 percent of enrollees are in areas with benchmarks over $900 a month. The difference in the distributions gives you a clue as to why spending on your average enrollee in a MA is much higher than for the

average beneficiary in fee-for-service.

One other distribution of interest is that of high-quality plans. We show here the distribution of plans by their CMS quality railings. The green bars are the local Coordinated Care Plans, that's either local HMOs or local PPOs. The Yellow bar is regional PPOs or private fee-for-service plans. CMS ranked MA plans on a 5-point quality scale, with the average being 3, and note that there are many plans that rank 3.5 stars or above, the last three bars on the chart there; we refer to these as above-average or high-quality plans. Almost all of these high-quality plans are local Coordinated Care Plans. Only one private fee-for-service plan ranks at 3.5 stars or above.

Now, there are a lot of caveats behind this chart, not all plans are ranked and that sort of thing, but our point here is to note that there are some high-quality plans available, and almost all of them are CCPs. And by the way, these 96 high-quality plans include a 41 percent of the CCP enrollment.

Returning to the report, let's remember where the Commission is coming from as we think about the third task. MedPAC has a long history of supporting private plans in the

Medicare program. The Commission maintains that beneficiaries should be given the choice of delivery systems that private plans can provide. Private plans have the potential to improve the efficiency and quality of health care services delivered to Medicare beneficiaries. That is because they can use financial incentives, care coordination, and other management techniques that fee-for-service cannot.

If the plans are paid appropriately plans would also have the incentive to be more efficient than Medicare fee-for-service and offer better value for the taxpayers. To provide MA plans has the incentive to be more efficient than fee-for-service Medicare, the Commission has recommended that the program be financially neutral between fee-for-service and Medicare Advantage Plans. That is, pay the same for similar beneficiaries. The commission is concerned the current MA system is not financially neutral.

Specifically, the Commission is concerned that the payments under the current MA payment system are too high, 14 percent above the costs of caring for similar beneficiaries in Medicare fee-for-service.

Second, Medicare is subsidizing the participation

of inefficient plans and these are plans not designed to coordinate care and improve quality.

Finally, even though some beneficiaries get extra benefits from MA plans, Medicare is heavily subsidizing those extra benefits, as much as $3.26 for each dollar of extra benefits in private fee-for-service plans. This is not a wise use of Medicare funds, particularly given the concerns for Medicare's sustainability and the federal deficit.

This brings us to today's discussion on future MA payment systems. The Commission maintains that all the options considered should set benchmarks at 100 percent of fee-for-service costs, consistent with the prior Commission recommendations. Doing so will restore incentives for plans to be efficient. CBO estimates that returning MA to payment neutrality will reduce spending by $150 billion over 10 years.

The second consideration is that the availability of efficient, high-quality plans is an important goal for the MA program. If we are going to pay for private plans in Medicare, we expect them to be an efficient alternative and we should require them to provide high-quality care to

beneficiaries. This leads us to the following points:

During the transition to financially neutral payment levels, payments will likely remain above fee-for-service is Medicare phases in lower benchmarks to lessen disruption for enrollees. Those higher payments should be contingent on higher quality. That is, higher quality plan should be paid more than low-quality plans. This would encourage high-quality plans to stay in the program.

One possible outcome is that, after the transition, MA payments could be higher for plans with demonstrated quality higher than the traditional fee-for-service program. In other words, payment could be financially neutral on a quality adjusted basis. We have a forthcoming report and how quality in MA plans could be compared to quality in fee-for-service plans.

Scott will now address the third task, other approaches to MA payment.

DR. HARRISON: Congress has asked the Commission to examine alternate approaches to MA payment. We have previously recommenced larger payment areas than the county level, but we're not going to talk about that today.

In this section we examined the alternatives for setting payment benchmarks for the MA program. We look at four options for setting benchmarks administratively and we look at some of the challenges involved in simulating competitive bidding options.

We modeled each of the alternative benchmark formulations with data from 2009 plan bids. We included all plan types, but we have excluded special needs plans and employer group plans because they are only available to subgroups of Medicare beneficiaries. We also eliminated counties in Puerto Rico because we are missing some important variables for those counties. The results I will present assume that plan bids and service areas do not change. We compare plans, 2009 actual bids, with the new benchmarks that would result under each alternative. We assumed that plans that bid below the simulated benchmarks would continue to do so and therefore be available, although the extra benefits they offer would probably be reduced. This is a conservative assumption in that plans might bid lower than they currently do in order to attract or retain market share.

All of the options we simulate are financially

neutral, meaning they would reduce the average benchmark from 118 percent of fee-for-service to an average of 100 percent of fee-for-service spending in the first year. Our simulations are static and look at what would happen if the new benchmarks applied in 2009. However, some of the options could encourage shifts in enrollment patterns over time, which could affect the savings generated by the option.

I'm going to show you a series of simplified graphical representations of each of the four options. Imagine the counties arrayed along the bottom in order of fee-for-service Medicare spending in the county. The corresponding benchmarks run up the side. So, a point on the graph would represent the fee-for-service spending in a county in the benchmark for that county under whatever option we are discussing.

Let us first consider the current benchmarks. The yellow lines show the simplified relationship between fee-for-service spending and the current benchmarks. Basically, benchmarks cannot go below the floor, which David mentioned is $741, and above the floor, benchmarks generally are slightly above fee-for-service spending, which here is

represented by the light blue line. For visual simplicity, we are ignoring the fact that there were actually two floors and that benchmarks can sometimes be significantly above fee-for-service.

Now, one option would be to set benchmarks to local fee-for-service, which would mean setting the benchmarks along the blue line. Note that all counties would see a reduction from their current benchmarks but some counties might seem rather small reductions.

One criticism of the local fee-for-service approach is that there are some very high fee-for-service spending counties with very high use of services. Some policymakers may find it inequitable that those counties should receive high MA benchmarks based on high fee-for-service utilization. These high benchmarks enable plans to offer significantly more generous benefits which are not available to the rest of the country. Also, there are some very low fee-for-service spending counties where the providers and beneficiaries have been very frugal and plans cannot survive at those low rates and provide any extra benefits. So, one option that would address this criticism would be to set a floor at the low end, use

fee-for-service spending rates in the middle, and set a ceiling at the high end. This so-called hybrid option was actually suggested by some of the Commissioners.

The floor and ceilings could be set in different ways. For these simulations we picked a $600 and a $960 ceiling so that the average benchmark approximated 100 percent of fee-for-service.

One option indicated in the mandate that we have discussed before is setting the benchmarks that take into account expected plan costs. That is, benchmarks would be higher in areas where plan costs would be expected to be higher and lower in areas where they were expected to be lower. More specifically, we interpret MIPPA as asking us to examine an option where the benchmarks would be set using a blend of local fee-for-service spending and national fee-for-service spending.

Low spending areas on the left of this graph are the places where plan costs might be expected to be higher than fee-for-service spending. Those areas would have a higher benchmark than fee-for-service. Those high spending areas on the right where MA costs are expected to be lower than fee-for-service would have a lower benchmark than

fee-for-service.

The blend line pivots off the 100 percent of fee-for-service line and those lines intersect at the national average for fee-for-service, which, for our simulations here, are $734 per person per month. Because the national average is below the current floor, it is clear that all counties would see a reduction from current benchmarks under a local/national blend.

Here we see another option for setting benchmarks that take expected plan costs into account. Local fee-for-service rates account for both local service use and local input prices. In theory, managed-care plans can manage utilization so there would be less variation across the country.

So, we take the national average fee-for-service spending and adjust by local input prices to set the benchmarks. The formulation would set benchmarks higher in areas where plan might be expected to have to pay providers more, but would not set higher benchmarks based on higher service utilization. Another way to put it is that we've created a normative standard for utilization. We would be saying that plans should be able to provide the Medicare

benefit using no more than average utilization.

Now, this option cannot be illustrated with a line, so we have that cloud there. The cloud around the national average line illustrates that there is almost no relationship between local fee-for-service spending and local price levels. Areas with similar prices can have very different fee-for-service spending patterns. We've added points representing Minneapolis and Miami. Despite the fact that fee-for-service spending in Miami is about $400 per month higher than in Minneapolis, average prices are about the same and actually Minneapolis would have a slightly higher benchmark than Miami under this option. Under this option, also, some benchmarks would rise from current levels.

Now, I want to point out to the Commissioners that there are two versions of this option in your meeting materials, but to simplify it, we're only presenting the one labeled input price adjusted blend.

This is a summary of some of the characteristics of the four options. You see that the 100 percent of local fee-for-service option would produce the largest benchmark differences between high- and low-spending counties, but

each county would have its benchmark equal to local fee-for-service. The input price adjusted blend would produce the narrowest range of benchmarks but would have benchmarks in some counties either well above or well below local fee-for-service spending.

All of these options are financially neutral to fee-for-service Medicare, meaning, in the first year, they are equivalent to the option that CBO has scored as saving more than $150 billion over 10 years for the MA program, but CBO only scored the 100 percent local fee-for-service option. And although all of these options start out financially neutral, plan bidding behavior and beneficiary enrollment choices could result in differences between these options over the long run. Unfortunately, we can only simulate results based on current behavior.

So, now, with a look at the simulation results. Policymakers want to know whether plans will be available if the benchmarks are changed to produce the estimated savings. The simulations measure plan availability by whether the plan bids are above or below the simulated new benchmarks. As I said earlier, we assume that plans that bid below the simulated benchmarks would continue to do so and therefore

be available, although the extra benefits they offer would probably be reduced.

Currently, 100 percent of beneficiaries live in counties with plans bidding below the benchmark. Of all the alternatives, option four, the input price adjusted blend, maintains the highest levels of availability. 94 percent of all beneficiaries and 88 percent of rural beneficiaries would have a plan available.

The 100 percent local fee-for-service benchmarks, option one, results in the lowest availability: 80 percent overall and 67 percent in rural areas. The main reason that the input price adjusted blend results of the highest availability is that it turns out that these benchmarks were actually good predictors of plan costs and really even better than the blend.

Here we present a second set of availability results for local Coordinated Care Plans, which include HMOs and local PPOs only. We report separately on the local Coordinated Care Plans because the Commission has raised concerns about growing plans committed to coordinating care.

The plans with the most potential to coordinate care are the local CCPs, so we look to see how widely

available they might be under different payment alternatives.

Local CCPs are currently available to 87 percent of Medicare beneficiaries, but even with current benchmarks as high as they are, they did not result in high availability in rural areas. Only 60 percent of rural Medicare beneficiaries have a local Coordinated Care Plan available.

All alternatives that reduce the benchmarks reduce availability significantly in both urban and rural areas. As before, the input price adjusted blend preserves the most availability; 75 percent of beneficiaries overall, and 46 percent of rural beneficiaries would have local CCPs available. Meanwhile, the local fee-for-service option would result in 66 percent overall availability and 31 percent in rural areas.

Now, the Commission is especially interested in assuring beneficiary access to high-quality plans. We have simulated how these benchmark options might affect the availability of players that have demonstrated higher quality. Currently, 55 percent of beneficiaries and 34 percent of rural beneficiaries live in counties where they

could enroll in high-quality plan. Measurement issues suggest that there may be additional high-quality plans available in Medicare Advantage, but we are limiting the category to those plans that have successfully submitted the data that allow CMS to award 3.5 or more stars.

The table shows that all of the options that reduce benchmarks reduce the availability of high-quality plans. The lowest availability occurs under the local fee-for-service option. However, the input price adjusted blend does not produce a steep drop in availability. Overall availability drops from 55 percent to 49 percent overall, and availability in rural areas drops only 3 percentage points. Further, if Medicare provides quality bonus payments for high-quality plans, availability might not drop much from current law while the program could save some money.

Now, let's consider something other than availability. Policymakers have also been concerned about the level of extra benefits plans may offer. We simulate the level of extra benefits offered by simulating the rebates resulting from plan bids and the new benchmarks under each alternative. I need to note that this table is

different than the one in your meeting materials because I have removed the plans with zero rebates to characterize only the plans that bid below the benchmarks.

In the group of plans that we are using to simulate the alternative benchmarks, the average rebate paid by Medicare is $96 per member per month. The average rebate for urban plan enrollees is $101 and it is $59 for rural enrollees. Under any of the options, the average rebate is also reduced.

The option two shows the highest level of rebates is setting the benchmark at 100 percent of local fee-for-service spending. The reason this option provides the largest rebates is because it changes the benchmarks in the highest spending areas the least. Miami in particular is known for its high fee-for-service spending and the very high level of extra benefits offered. The input price adjusted blend provides the lowest level rebates. And across all options, rural beneficiaries have rebates about half as large as urban beneficiaries.

These numbers show that the benchmarks could be reduced to fee-for-service levels and plans could still provide a high enough level of extra benefits to attract

enrollees. Further, if the benchmark were reduced to fee-for-service spending, it is conceivable that policymakers might allow the plans to keep the full difference between the bid and the benchmark for extra benefits rather than the current 75 percent share that they get. In that case, each of these rebate figures would be multiplied by 1.33.

Now we're going to move from administratively-set benchmarks to setting benchmarks based on the plans' bids, as there has been a lot of interest in that lately. This slide is just meant to give you a flavor of what the bids look like. Plan bids vary widely, and as we move to the right, the average fee-for-service spending in a plan's service area increases, the ratio of the bids to fee-for-service spending declines, and the variation in bids increases.

If we use bids to set the benchmarks, we would likely have benchmarks well above fee-for-service in low spending areas and benchmarks well below fee-for-service in high spending areas; however, there are many problems to overcome in order to simulate the effects of using bids to set benchmarks.

To simulate how such bidding might work requires making any assumptions on both the nature of the bidding itself and the response of the MA plans to the incentives caused by bidding rules. For simulations, specific controls would have to be finalized. At a minimum, decisions would have to be made on features such as: what point in the bid distribution would determine the new benchmark, lowest bid, immediate bid, the mean? How would the bids be weighted? Do all bids count? Are there limits? Answers to these and many other questions are needed to simulate a competitive bidding design.

Further assumptions on plan behavior would then have to be made. For example, we don't have plan bid data by county. A plan submits one bid for its entire service area, which normally covers more than one county. If the bids were to determine the benchmarks for each county, presumably plans would need and want to submit separate bids for each county. The assumptions we make with regard to how plans would bid at the county level would strongly influence the results.

Finally, our simulations assumed the new benchmarks are fully phased for 2009 to compare with the

plans' 2009 bids. When the bids are used to set benchmarks, we believe there would be a dynamic process that would play out over several years as plans try to outmaneuver one another to secure market share. Again, the gaming assumptions and assumptions about plan entry and exit would greatly influence the results.

Because the results of the simulations would be very sensitive to all these assumptions, we did not run simulations for this option. However, we would expect that the benchmarks would be lower than current benchmarks but we don't know how high they would eventually be relative to fee-for-service spending. We also would expect that bidding would result in benchmarks higher than fee-for-service in some areas and lower than fee-for-service in others, and we would expect that bidding would result in lower levels of extra benefits than today.

As in the past, whenever we have recommended setting benchmarks at 100 percent of fee-for-service, we have acknowledged that there should be a transition to the new benchmarks to limit disruption to beneficiaries. Under a transition, the new benchmarks can be phased in over several years.

Because the Commission is especially concerned with retaining high-quality plans, a key point of the transition should be to limit the loss of any high-quality plans. During the transition, extra payments could be made to plans that have demonstrated good performance on quality indicators. As benchmarks are lowered to attain financial neutrality, high-quality plan payments would not decrease as fast and low-quality plans would either improve or their payments would decrease more rapidly and they would likely exit the program.

Of course, a transition would lower savings for a few years. CBO's estimated 10-year savings are predicated on full implementation of the 100 percent benchmarks in 2011. If full implementation were delayed, savings during the transition would be lower.

So what's next? We are on schedule to report to Congress in June. At our meeting next month, we will finalize our discussion of the measurement issues surrounding CMS's estimates of county-level fee-for-service spending.

But now, I want to invite your comment and I'm sure a lot of discussion. Are there other benchmarks you

would like us to simulate for the report? And we would especially like some feedback on the transition. Thank you.

MR. HACKBARTH: Good work. Very good work.

Let me start out with a couple comments to frame the discussion. This is a mandated report originally due in 2010 but we have accelerated to try to complete for our June report this year. We did that because there was a lot of interest in getting our analysis and thoughts earlier.

What I envision for this report is that we would go through a series of options, much as the materials in the notebook do and Scott's presentation did, and say here are different ways that you could restructure the payment system and here is some information about the impact as presented just now and here's some commentary about that, without making any boldfaced recommendations that you choose number one or number four or whatever. This is an analytic report on options that they have asked us to consider and some we've generated on our own. So that's the product that we're looking to produce.

Now, another word about the context, clearly, based on the President's budget and other discussions, some people are looking at Medicare Advantage savings to finance

other things that they want to do, whether it's health care reform or offset SGR. They're looking at this as a way to reduce Medicare outlays and produce savings for other things. And so, that's the context in which we are doing this work, which is a source of some anxiety for me -- and David and Scott and Mark are aware of this -- because I think that estimating the long-term budget impact of these different options is very tricky. So, even though there -- work out to be 100 percent of fee-for-service in year one, where they would end up over the 10-year budgetary time horizon, I think, is a very different question. I would think that you would get pretty different results depending on the option chosen.

So, would you go back to 15 for a second?

If you look at the two right-hand columns, the benchmark under the different alternatives compared to fee-for-service, and you see as you go down through the one, two, three, four options, you've got an increasing -- it doesn't necessarily increase in a straight-line fashion. You've got some options where there is wide variation; there's going to be big changes. The bigger the change, the greater the likelihood of a strong behavioral response. So

if you all of a sudden have some benchmarks that the relationship to local fee-for-service costs varies widely, either at the high end or the low end, you're going to get a behavioral reaction to that which may mean that even if it's 100 percent of fee-for-service in year one, the year ten result could be very, very different. So, I'm anxious about that, people look through this and look through our analysis and say, well, here's the impact analysis on plan availability and say, with this option we've got lots of available plans, we've got lots of high-quality plans, it's neutral to 100 percent of fee-for-service. Oh, this is a great option -- neglecting the fact that, in year ten, it may be way more costly than 100 percent of fee-for-service. So, I just feel better now. I've shared my anxiety with you all about how all of this stuff is interpreted.

DR. MARK MILLER: Actually just a different way to put that. I think some of -- or a different way to help people understand: As we showed at the beginning of the presentation, you have a lot of people in some of the higher cost areas. If you drive the benchmarks down there, then plans may not people to attract people, which means the savings that people are getting might be smaller than you

would be guessing over time.

MR. HACKBARTH: And conversely, if you have large gaps at the other end where were paying private plans still substantially more than fee-for-service, and that process continues to run its course, you can get more and more people opting for that option which means that it's going to be expensive.

If all of your growth is in the areas under the newly structured system where you have very high MA payments relative to fee-for-service and you choke off the growth in Miamis and the Las, you're going to have all our private plan enrollment where it adds to costs and none of it where it reduces costs. That's the dynamic effect that I'm worried about.

So, with that as preface, let me see hands for the first round of clarifying comments.

DR. CHERNEW: All of these numbers are risk-adjusted and assume the risk adjustment; is that right?

DR. HARRISON: Yes.

DR. CHERNEW: And you're comfortable that the risk adjustment behind this is reasonable relative to the old era of that was just age/gender stuff, that this is -- that the

risk adjustment does a pretty good job?

DR. HARRISON: Yes, to a rough approximation. It's what's working now. We don't have any reason to suspect that it's not, particularly for these kind of purposes.

MR. BERTKO: Scott, current law includes the removal of the deeming tool for private fee-for-service and that is likely to perhaps -- I say this carefully -- eliminate lots of those plans. Have you eliminated them in this?

DR. HARRISON: No, these options are for 2009. What would happen if the bids came in this year and the benchmarks had been set this year.

MR. BERTKO: Okay. I would suggest that because I think we would want to compare current law to some future law as opposed to the status quo.

MR. EBELER: We have a phenomenon of a lot of plans and products but relatively few competitors because of the concentration in this industry in ways you've shown in previous charts. Do we have data that we'll be able to put in here that shows how many different companies are bidding in these different market areas? I just think it will be

particularly relevant when we assess the competitive bidding model.

DR. HARRISON: We certainly could do that. We have not, now. A lot of times you have one contractor offering many plans, also. So, sometimes we're not always sure who owns who.

MR. EBELER: My sense is, if we look at concentration, and it's an empirical question, in some of these communities there's not as many competitors as it sounds like, and we should just know that what we think about competitive bidding.

DR. REISCHAUER: If you could put up slide 19.

These are the rebate dollars and I just wanted to make sure I understood what you said right, which was that if we were to say to plans under one of these alternative systems that we'll give you the total difference up to 100 percent of fee-for-service rather than just 75 percent for your extra benefits, and it was 33 percent more, which means that the average amount that the average plan would have would be bigger than what it has now for extra benefits?

DR. HARRISON: Bigger, and actually -- right.

DR. REISCHAUER: There would be $100 for the 100

percent of the fee-for-service, so you'd have a sense -- a bigger pot of money for extra benefits.

DR. HARRISON: But they're not available everywhere.

DR. REISCHAUER: Yes.

DR. HARRISON: Right.

DR. STUART: Yes, that's interesting.

You talked about the number of plans that would be high-quality plans that would come in under the benchmark and then also, overall, the bid level relative to the benchmark. What's the correlation between bid level and these quality stars? Do you know?

DR. HARRISON: We have not run that.

DR. KANE: On slide 18, this does that mean that only 33 percent of -- if you could switch to 100 percent local fee-for-service -- this just means that their bid would now be only 33 percent instead of 55 percent would have their bid -- but it doesn't adjust for the fact that they may change their extra benefits or -

DR. HARRISON: Correct.

DR. KANE: So, this doesn't -- so, okay, I think it's pretty hard to figure out what it means.

DR. HARRISON: That's why we also did the rebate one.

DR. KANE: But you didn't do it by quality. You only did by plans -- you didn't buy the high-quality plans.

DR. HARRISON: You'd like to see rebates for the high-quality plans?

DR. KANE: Yes. We're talking about the plans that we want to preserve and I guess it would be helpful to get a bigger sense of what that means in terms of rebate dollars and what their flexibility might be. So, if they got -- yes -- It's hard to put it all together when they're different populations for the slide.

DR. HARRISON: We're trying to keep the number of slides down.

DR. KANE: Yes, I know.

MR. GEORGE MILLER: One question I have is, by definition of the counties, I believe you said that if a plan offered an MA brand in the county, it is covered, but because they’re offered doesn’t mean that -- I mean, because the plan is available doesn’t mean it’s offered to all of the residents in that county but it seems you’re giving credit for that.

DR. HARRISON: No, it does mean it's available to all people in the county. Now, they may not sign up for it, but it's available to them.

MR. GEORGE MILLER: Or they may not market or have local brokers selling that plan.

DR. HARRISON: They're supposed to.

MR. GEORGE MILLER: Okay. All right. That's my concern in rural areas, because that -- my anecdotal information says that is not correct, but I'm not sure what you do about that.

The second part of my question, though, is the assumption in this whole analogy is that fee-for-service is an efficient provider of services even at the low end or the high end and that may not necessarily be true. A low rural provider may be more efficient than high spending urban area but everything is calibrated specifically to fee-for-service, correct?

DR. HARRISON: Except for the option of -- could you put up the cloud option?

MR. GEORGE MILLER: This is interesting.

DR. HARRISON: What we found just by doing this is utilization varies widely and it has nothing to do with the

price levels.

MR. GEORGE MILLER: And therefore the efficiency issue is taken care of here with the cloud but on the high-end that 100 percent of fee-for-service can be totally inefficient.

DR. HARRISON: But there the option would be to actually pay based on the average utilization so you'd be giving more advantage to counties where it was efficient.

MR. GEORGE MILLER: Okay. I think I got that.

MR. HACKBARTH: Just to be clear, George, I don't think anybody is saying that 100 percent of local fee-for-service represents efficiency. That is not the argument for using that as a potential peg for Medicare Advantage rates. In fact, I would say that nobody that I know of who has thought more than 15 seconds about Medicare thinks that 100 percent of fee-for-service represents a level of efficiency uniformly across the country. That's what all of the variation analysis is about when we have these huge differences in Medicare spending per beneficiary. We all know that isn’t efficient.

DR. MILSTEIN: Looking at these models -- looking at these options that we've modeled reminds me of how

fundamentally clunky this approach to incentivizing, at this point, in this example, plans to improve Medicare portability and quality is. Have we given any thought to a greater deviation from the existing model?

I'm sort of struck by the contrast between this and the transparency and relative appeal of what we saw in the accountable care options where you basically say, okay, everybody starts out in a given place in efficiency. We've got to figure out how we get everybody in the country to migrate down. In some ways, our accountable care organization proposal was a way of doing that in which the unit of intervention was an accountable care organization. Have you given any thought to essentially modeling a more profound shift in how Medicare pays for Medicare Advantage Plans with something more analogous to what we've hypothesized for accountable care organizations in which the plans, to extend the analogy, rather than the accountable -- just like the accountable care organizations, begin to have an opportunity to be incentivized to more strongly improve quality and reduce Medicare spending?

Right now I have other bases for rewarding plans than whether or not they are reducing Medicare spending

growth and quality. Did we consider a more radical --

DR. HARRISON: You mean like quality bonuses?

DR. MILSTEIN: No, just a more -- right now we have this benchmark process and these examples take as a given that the current bidding approach should continue and now where trying to think about how we change -- within the context of the current bidding approach, we might make alterations. Have we considered modeling something that is a further departure from the current bidding process in which we begin to simply, at the margin, incentivize the Medicare Advantage Plans to do the same thing that we were attempting to do with the accountable care organizations?

MR. HACKBARTH: Let me take a crack at this and then Mark and Scott and David can rescue me. In a one sense they're similar. The model we discussed at accountable care organizations started where they are and said, this is what you've been spending. That's how Medicare Advantage works, too: It says this is the spending level in Miami or Minneapolis, wherever. And your rewards are going to come from changing where you started; that, they have in common.

Now, where they're different, the model of accountable care organization that was presented towards the

end of the paper said, in terms of how we calculate future increases, let's use a flat dollar sum, and this was the $500 example, which translates into a higher percentage increase for those ACOs that have low cost to start with, and a smaller increase for those that have a higher starting point. So that is different than Medicare Advantage, and that's why you're focused in on it.

Now, here's the rub. Whether you're talking ACOs or Medicare Advantage Plans, if it's voluntary and you allow people not to participate and you start to ratchet down tighter and on the high cost ones and you've been historically too high costs -- we can get you down and it's voluntary, they say, okay, I won't participate. I will go back to unconstrained fee-for-service.

If you really want to address geographic variation in a way that people can't escape it, you've got to do it in traditional Medicare and on a non-voluntary basis. If you make it voluntary either by, you can do it with Medicare Advantage Plan or not or ACO, you can do it or not, your tool just doesn't grab, would you try to ratchet down and deal with the geographic variation issue?

So, in some ways, you keep coming back to the same

policy choices. If you really want to deal with geographic variation, which I think is imperative for the Medicare program, you start to go to, it's got to be across the board for everybody; there's no escaping it.

DR. MARK MILLER: I'm not sure that I have a lot to add. When you mentioned it, I started, in my mind, immediately started going to the $500 thing. Is that what you meant as a different way to set the benchmark? So I don't think I have anything to add.

DR. MILSTEIN: In some ways, thinking back on my clinical career, we've got somebody that's addicted, and we're trying to figure out how to bring them down in a way that doesn't create a lot of social waves. It's a very analogous problem.

DR. KANE: If you're successful on your fee-for-service, wouldn't that make the plans have to keep up? I don't know if you built that into your model at all, but if fee-for-service itself was being pushed into a more cost-constrained mode, then the benchmark should go down with that, shouldn't it?

MR. GLASS: If you correct the current problems in the benchmark setting, the ratchet problem, yes.

MR. HACKBARTH: Let me try sort of another angle on this. I am really sympathetic with the people, including members of Congress and Senators from the low-cost states, of which Oregon is one, who feel like this system is unfair.

Under traditional Medicare, in the high-cost areas, plow in all this extra money. We're talking about twofold more differences on a per beneficiary basis. The quality, as shown by Elliott Fisher and others, is often worse. So, that's in traditional Medicare.

And now, in Medicare Advantage, we say, well, if you're a beneficiary that lives in one of those high-cost areas that you're fortunate enough to have Kaiser Permanente and CLA, they can come in under the high traditional -- umbrella of the high traditional Medicare fee-for-service costs and offer a very rich benefit package that people in Iowa and Minnesota and Oregon and other places don't have if you go to a 100 percent of fee-for-service on Medicare Advantage. This isn't right. This is perpetuating a regional inequity.

So, whatever the logic of my 100 percent of fee-for-service might be, it doesn't meet with their perception of inequity. So, I've been wrestling with other

ways that you might deal with that without creating what to me is an equally bad incentive of rewarding people for going into private health plans that do no more than mimic traditional Medicare except it costs more. Is that really the signal we want to be sending to either the plans are the beneficiaries? That's what I fear we're doing right now.

The alternative that I've been playing with is to say in, well, those low-cost parts of the country where traditional Medicare is an efficient plane, as George was mentioning, maybe what we ought to be doing is, within traditional Medicare, rewarding the beneficiaries in those areas. If all of Medicare looks like Minneapolis, we have a very different set of issues to deal with on health reform and long-term Medicare sustainability. The problems wouldn’t go away completely but they would be greatly relieved.

So why don’t we give some reward to the people in those places where Medicare is doing pretty well and maybe squeeze a little bit more? John estimates and proposals or you could squeeze some more in the very high-cost areas, probably not wipe out plan participation and beneficiary enrollment, and do some reallocation of dollars there. But

don’t flow the benefits for Iowa and Oregon and Minneapolis through Medicare Advantage, do it through traditional Medicare, through premium discounts for Medicare enrollees in those areas.

Now, there's lots of complicated math to work through to figure what the budget impact of different ways of doing that might be, but that seems to me a better way to deal with some of the strongly felt feelings about regional inequity without corrupting Medicare Advantage as a tool for encouraging innovation and importing innovation into the Medicare program.

MR. BUTLER: I was feeling great about this chapter. I feel I actually understood it until you called it clunky. The methodologies, because I think that they really are laid out well.

DR. MILSTEIN: Not the chapter.

MR. BUTLER: I know, but the methodologies, because I think that they really are laid out well.

My question relates to availability in that you make a very black and white decision. Above benchmark, you’re not going to participate, below, then you will. Obviously this will be one that Congress will be very

sensitive to. And just as I think the floor was largely put in to create, in a clunky way, accessibility, I think they'd want to know a little bit more about the predictability of departure.

Now, there have been departures in the past for a variety of reasons. Do you think if you had more time or more analysis you could be a little bit more predictive of who might actually leave the market if you put in some of these methodologies?

DR. HARRISON: Back in the late 90s when there were a lot of plans left, a couple of factors. One, plans that were new to the area and didn't have deep roots tended to pull out, and those that didn't have a lot of enrollees there tended to pull out. Other than that, and rural areas, also.

MR. GLASS: There are plans that pay that actually charge premiums and are in now. In other words, they are plans that bid above the benchmark and are there now and we could describe them somewhat.

DR. MARK MILLER: I had two thoughts when he mentioned that. One was the one that you went right to, which is to remind people of what has happened in some of

the past experience, and that's stuff that we could summarize pretty quickly and easily and have as part of the report.

But the other thing I thought of what he said that was we can express -- this would be maddeningly complex -- I see it as probably more as an appendix type of thing - but express the variation around the benchmark: What proportion of plans and availability fall within a couple of points of the benchmark versus quite far away from the benchmark that get some sense of that? But I don't know that we can be much more sophisticated than that, Scott.

DR. HARRISON: You may also get a little bit of flavor from where the bids are. Basically, and I can't remember what the cut point was -- I think it was in the paper. Something like, if your fee-for-service is under -- I don't know if it was 550 or 600 -- nobody bids within 10 percent of fee-for-service; they just can't do it.

Whereas, you see what the bids look like at the high end, they're all well below fee-for-service. So it really will depend on what kind of area you're in as to what the bids look like. You can also see that the variation is a lot tighter at the low end.

MR. BUTLER: I would just think that where the costs of entry or departure are small, then you would have it more likely to be responsive to the changes in rates. So, a private fee-for-service plan might come and go a lot more quickly, for example, than some of the others that have a whole managed-care infrastructure associated with them. I think that would be the kind of thing that we'd want to know, or at least comment on if we thought that was a likelihood.

DR. HARRISON: We can do that. Yes.

MS. HANSEN: Just a clarification, especially with the private fee-for-service plans in discreet counties, can it be filtered out -- especially, I think one of the concerns oftentimes legislatively is with rural areas. So, the ability to discern the difference of population of Medicare beneficiaries who are under now private fee-for-service and still under regular Medicare -- a regular fee-for-service, I mean?

MR. GLASS: You mean penetration rates by County?

MS. HANSEN: Yes, proportion.

MR. GLASS: Yes.

DR. HARRISON: We know that but how would you like

that summarized?

MS. HANSEN: I guess the concern was just looking at some of the arguments of -- I think they made that earlier in the morning, the argument sometimes that we would deprive people of plans. And if the plan, from my understanding, is not fundamentally different from regular fee-for-service, there is just a begged question of who is subsidizing that 118 percent extra on the private fee-for-service side.

DR. HARRISON: One of the ways we tried to look at that, and I don't know if this is quite getting at this, is really looking at the Coordinated Care Plans and getting rid of the private fee-for-service. So, these figures would show what it would be like without the private fee-for-service.

You'll see right now, for instance, only 60 percent of rural beneficiaries have a local Coordinated Care Plan available.

DR. KANE: Isn't that the population we're worried about disrupting are the ones who are actually in at already, not the ones that have access to it?

DR. HARRISON: Well, that's one way of putting it.

MR. GEORGE MILLER: There is an equity issue, though, because all taxpayers are subsidizing the MA plans, and yet the rural population, which has a smaller percentage in the MA plans -- 100 percent of them are subsidizing it. And you even go down with the alternatives. So is that an equitable issue?

DR. KANE: Isn't the population --

DR. REISCHAUER: Those are just the managed-care plans, the CCPs.

DR. KANE: Yes, but are we worried about beneficiaries having access to them or that -- or what happens to beneficiaries who are actually in them, because they are the ones who are enjoying these benefits of excess of fee-for-service that everybody is subsidizing? How many people are we dealing with who are actually in the -- I'm not so sure that we have to worry as much about the ones who have access to them.

MR. GLASS: You want to look at enrollees.

DR. KANE: Yes, the people who are vulnerable to this change are the ones who are actually enrolled.

MS. HANSEN: There are two points: one is the vulnerability of the changes that may come down when if

they're going to be reductions. What's the transition question for that?

My first one was still just, when people don't want to change, understandably, the normal resistance of taking away, say, the subsidy and the growth of the private fee-for-service plans as a subset that has been so rapid, and if my information is right, that the difference between really the private fee-for-service plans operating under the MA mantle as compared to regular fee-for-service is fundamentally not different. So, is that assumption reasonably correct? I need to be corrected on that otherwise.

MR. GLASS: Think that's what Glenn means when he says that these plans essentially mimic fee-for-service Medicare, just at a higher price.

MS. HANSEN: So my point I guess is really relative to just having an argument of, even if we were to start to differentiate where some of the transitions would occur first, it seems like it would hurt beneficiaries least in those environments where the fee-for-service plan and the private fee-for-service plans really become the first discussion point.

DR. HARRISON: I think you're right. Yes.

DR. CHERNEW: The payment is indifferent. So, if you lower payments in an area right now, you're not targeting just the private fee-for-service. I mean, I guess we could have that discussion.

You're targeting all the MA plans in that area.

DR. HARRISON: But the fee-for-service plans tend to bid higher so they are going to be hit quicker by reductions in the benchmark.

MR. EBELER: I want to make sure we don't lose the purpose of this chart.

Your question is right. One of the criteria that politically has to be looked at is how many people are currently in plans, because we have dramatically overpaid, that we need to worry about. The theory of this chart is slightly different. There is another policy criteria that says, are we trying, are we encouraging, the plans that we think are the ones that will be the agents that will help us with delivering reform?

So, I'm not disagreeing that we need to chart you need, and this may not be the right way to state it, but it's a different objective than what we're talking about

here.

MR. HACKBARTH: Let me jump in on this. I feel deeply ambivalent about this transition issue. On the one hand, just by my nature, I don't like abrupt changes and I worry about abruptly changing rates and the effect on people. I generally believe you want to move in new directions in a gradual basis, particularly when we're talking about potentially hurting Medicare beneficiaries.

On the other hand, the longer that you keep overpayments in place the more people are going to roll, and your transition problems in some ways get bigger. Not only more beneficiaries are affected but also more political resistance. And so, how do you strike that balance is tricky.

I want to remind people of one thing that was suggested in a presentation in the paper. One way that you can potentially divide plans for the transition is based on quality scores. There are reasons to have reservations about the quality scores, in some ways that they are crude, but in a way, I find them more compelling than planned type categories. We, many of us -- I know we’re not fans of private fee-for-service, but, boy, there’s huge variation as

to what constitutes a Coordinated Care Plan. Some of them I think would be wonderful and I really am worried about protecting them against an unduly fast transition; others, frankly, I'm not so worried about, because although they fall under the legal category of Coordinated Care Plan, they're really not doing much good for Medicare beneficiaries.

If you focus your transition protection more on high-quality plans, one of the ideas offered in the presentation, that might be a reasonable surrogate for plans that actually can do something to improve care. So, just food for thought on the transition issue.

I want to get to round two. You have round two written all over your face.

[Laughter.]

MR. HACKBARTH: We've got a little less than a half-hour to go. If I could, let me establish a framework for round two that would be helpful to me at least.

This is going to be a two-part report. Part one will cover all of the analytic stuff, not just what we reviewed today but things that we talked about in the paper having to do with the questions that were asked about

administrative costs and are they properly accounted for, the rate geographic unit and the VA issue. So all of that is the analytic stuff that will be in part one.

Part two, as I said at the outset, won't have any boldfaced recommendations, but it our opportunity to help Congress think about the analytic work that we've presented.

I think the lead section in part two is, what are your goals for the program, because the goals for the program drive what the right payment mechanism is. If your goal for the program is maximizing plan availability, you do one thing. If your goal is to maximizing opportunity for quality improvement and cost reduction, you do something very different. And so, to me, that's sort of the first step in our commentary, if you will.

A second piece as I mentioned earlier might be a subsection of part two that says, we understand the geographic equity issues that are at stake here, and the frustration that they cause. Here are some other ways that you might think about addressing geographic equity. I mentioned one, and it's not the only one by any stretch. And so, if people have some thoughts on that geographic equity issue I would welcome those in round two.

A third category and we've just been touching on it is transition issues. So that's another thing I think we probably ought to address in our commentary in part two. So, those are the three boxes I see. I urge you to help me help the staff fill them, but if you think there are other boxes that ought to be in part two, please say so.

So, let me see hands for round two comments.

DR. CHERNEW: I find this fascinating although difficult to get my head around for a reason I'll mention in a second but I just wanted to sort of go on record, and I think this is consistent with what has been said by others here, that I for one believe that one of the benefits from the MA program, at least a subset of the plans in the MA program, is that they create systemwide spillovers to other aspects of the program.

And in thinking about the analysis, instead of thinking about it conceptually as separate -- this is what fee-for-service is -- here's what we're going to pay to MA plans. The MA plans, particularly, sort of, types of MA plans, need to be given some credit for helping the system evolve in a certain way. I think that's important, although I think it's hard to quantify and hard to figure out how to

deal with that in a policy way.

But it does suggest, for example, that in high-cost fee-for-service places, we might want to most encourage the MA plans because they might have the most did they can do their relatively speaking, although the geographic equity issues that would come up with a policy of that nature are a little complex, admittedly.

That brings me to my last point, which is I think in thinking through all of these types of options a paradigm of policy analysis -- if we did this, how would behavior change -- is really important. So, I understand why you've done which is done because it's very difficult to think of, but I guess I'm still struggling with as much as we know about how the plans would change behavior in response to X, Y, or Z, how the bidding would change or not. And there's a lot of complicating things in here that I think just need a little more fleshing out from all of us, anybody. Most important to me is the ramifications of things like putting the fee-for-service costs into the bid calculation for benchmark versus not and how you think about the pros and cons of issues like that.

I think this is a great start in thinking about

how to do this and I wish the issues were a little simpler, but I enjoyed it a lot.

DR. CROSSON: Thank you. I have one question and then one comment. The question is that I realize we're not heading towards a point recommendation, but what I wonder for the next discussion, will we be able to see or is there anything, really, that we can look at at the next meeting to sort of compare the competitive bidding approach to the administrative benchmark approach and kind of look at the pros and cons to those two things, without necessarily saying, and therefore we support this one or the other? I think that would be at least helpful to me.

MR. HACKBARTH: I think that's a question for you guys.

To me, the overall theme of part two, the commentary section, is, here's our analysis of these options, the pros and cons of doing it each way. So I think I would focus the question, do we plan on come to including competitive bidding as one of the options here given what was in the President's budget?

DR. MARK MILLER: Our discussion of the competitive bidding wasn't motivated by the President's

budget. We actually were getting questions well in advance of that from the Hill saying, as long as you're thinking about this, think about this too.

I think the best that we could do to deal with your question, and obviously you guys need to pay attention here -- I don't know that we could quantify and compare in that way, like, have a hard simulation and say, here are the results of one versus another. What we could do is qualitatively compare and contrast an administrative approach with a competitive bidding approach. I think that is within reach, but I think what Scott was trying to say in his part of the conversation is there are too many moving parts for us to, in any reasonable way, simulate the effect and have any confidence. You even hear some trepidation in our confidence in the static administrative proposals and how they play out over time. So, it would have to be almost a side-by-side, here's some issues with administrative, here's some issues with the competition, and kind of go at it that way.

DR. CROSSON: That's what I thought.

DR. MARK MILLER: Have I over-committed you? Yes, but can we do it anyway, I think is the question.

DR. CROSSON: Then, the comment has to do with the transition piece and I appreciate the focus on that. I do think that there is a value to phasing this in over time. I understand the other side of the equation also.

But there will be potentially, I think, disruption of beneficiaries as well as, quite frankly, disruption to some of the plans, particularly those that have the infrastructure, and probably as you stated, Glenn, a compelling interest in trying to support the continuation of the high-quality plans during that transition.

I like the proposal to do that, to link performance of various kinds to the rate of change of payment. I think that's consistent with our thinking on other issues of payment.

And I would just ask one other thing, and that is as we do that transition analysis and think about what to look at and what to bring forward that we also take into account the actual 2010, if you will, payment baseline that we will be working off of as a function of both the current payment mechanism but also as a function of some of the recommended changes in the 45-day notice it will likely impact on the actual payment, the baseline from which that

transition would likely take off.

DR. DEAN: I appreciate Mike's comment about struggling to get you your arms around it; it's a struggle. I would also say that one of the things that has confused me for some time is really what, just to follow up on your comment -- what are the goals of this program? Because I think we started out, as I understood it, it was to be innovation and cost-saving and new models. And then it seemed to me that a lot of the policymakers -- it sort of evolved into a way to expand benefits, and then there was the whole equity issue which got very -- it's really a serious issue.

I just wonder, and I haven't thought through the implications of all of this -- but I wonder if it wouldn't make sense just to take away the requirement that any plan that bids below the benchmark has to give away part of that potential profit in new benefits. In other words, maybe we haven't provided enough incentive for people really to innovate, and we've added in this requirement that they have to have these additional benefits which has created lots of tension and frustration and aggravation.

I don't know. It seems to me that it may have

confused the issue more than -- in an attempt to make it -- I don't know whether it is an attempt to make it more fair or whatever, but it certainly has confused the issue.

The second quick point is that I think some point we have to realize that not every model is going to work across the country. We have sort of taken this model and said, it really doesn't work in rural areas, and yet we're trying to make it work in rural areas and it's costing us a lot of money; that's where, largely, the private fee-for-service model came from. I think everybody said it doesn't work very good. It cost us a lot of money and I think we really just have to face up the issue. We've got to use models based on what the realities of the environment are. I don't know, it's very confusing.

MR. BERTKO: A couple of questions and then I'm going to make Scott and David's life both harder and easier. So, the questions are, I'm much in favor, as Mark knows and Scott, of the competitive model. The first reason is that I think there is substantial savings opportunity in the high-cost areas.

And Scott, if I remember, your chart there is 30 percent of beneficiaries who live in high-payment areas.

So, there are bucks to be had.

The flip side, I think the mirror image is also true, that there are also probably, I think, good CCPs in areas where they can't deliver at 100 percent of fee-for-service. I, at least, for one, would be quite open to saying, okay, you need 110 percent but you're delivering excellent care, go ahead.

And then, this is where the details of the competitive bidding mechanism comes into play. I want them to begin elbowing each other towards the bottom of the competitive bid. Whether the payment rate is chosen by the middle or at the lower end of that I think could make some difference in moving downward, at least on that pressure.

Secondly, I'm going to just emphasize what Jay said on transition. No matter what we do it's likely that beneficiaries are going to have changes in benefits. I think a three- to four-year transition process in my mind is appropriate for bringing them downward to the new level that they end up with. It's the same thing for plans, too. Believe me, it's really hard to have an abrupt transition.

So, thirdly, here's the pluses and minuses, Scott. I'm going to look back on the pictures that you have there.

I'll start with the easiest one to first. These are your graphs of alternatives.

Option four, where you have input price adjustments. I think we all know that input prices are -- and you've shown it here -- are a very small part of the difference and it seems illogical to ignore the demand, fraud and abuse, other kinds of things. So if I were you -- and I'll ask Mark and you, Glen, to think about it -- throw that one away because it's not likely to have -- well, I think any benchmarks you come out of that payment rate are going to be just arbitrary, but that's an opinion only.

There's a similar answer about, I think, option three -- no, option three is okay because it attempts to at least include some parts of the local cost delivery elements. I mean, it's a blend, and that didn't work particularly well following the BBA but at least this one doesn't have the very firm caps on it.

Slide 12, I think, has some similar arbitrary elements. You said it yourself that -- wrote down the 960 and 600s are completely arbitrary. It might be more than 600 or less than 600. It might be difficult to get down to 960, although I think in some places it would be fine, in

other places that might be difficult. So I think two is also very arbitrary. So, I would leave you with one and three for modeling purposes, and that's the simplification.

Making it more complex, I think I'll follow the comments made earlier about actually trying to do some dynamic modeling with a very parsimonious set of assumptions. That is, you might say a couple of things change and we then use the simplified assumptions to say what happens to the margins and then use your same rule to pop in or out, whether you still have plans left in those particular counties.

That would include a maybe a substantial P4P. So, I'd go up to a 4 percent plus and a symmetrical minus 4 percent for good and bad plans, particularly in this transition period.

MR. HACKBARTH: Let me pick up on that for a second. We talked about potentially linking payment to quality as a transitional device as a way of, in particular, limiting the impact on the really high-quality plans. People will remember that we have recommended for a long time P4P overall in the Medicare Advantage program, and I could imagine a system that might say, we're going to,

without endorsing a particular model -- we're going to tighten the relationship between plan payments and fee-for-service costs. We recognize that in, say, Minneapolis, that might mean Group Health is now in a situation where its Medicare Advantage Plans or payments are really going to be squeezed.

If Group Health of Minnesota is demonstrably producing higher-quality than is available in the rest of the Minneapolis community, that might be a reasonable basis for, pay more to them, not just as a transitional matter, but in the long run. My concern right now is that we're paying more to all plans without regard to their quality and their ability to improve relative to the ambient level of quality in the community.

So, that is another angle that we may want to address in part two of this report, is a better way to deal with the Group Health of Minnesota problem is quality of payment enduring in the long term as opposed to trying to jigger the basic MA payment structure. Another thought for people to consider.

DR. REISCHAUER: I didn't until you spoke, and John to.

I was wondering if you have a correlation between quality and the size of rebates or the value of added benefits? Because John says, well, there are some areas that this high-quality plan maybe just can't survive at 100 percent, but the high-quality plan might be one also that's providing extra benefits and it's the extra benefits that, in effect, are making the quality high. And so, we have a problem of disentangling A/B from the CCP package. I think we've got to work on that before we get too far down this line.

In theory, I agree with this idea that high-quality plans, we should cut them some slack, but in any kind of transition and more permanently -- because I think where we would like to be is pay-for-performance that includes traditional fee-for-service Medicare as well as Medicare Advantage Plans and transferring resources from one pot to the other if there are qualitative differences.

MR. BERTKO: So let me give you an example. This is in the under 65 area. One of the big health plans is offering a diabetes into its under 65 members in which case they pay much more for diabetic supplies thus improving the health but costing more because they're paying more money

out the door.

DR. STUART: Much of what I had has already been said, so I will be very brief.

I like the idea, actually, of including some discussion of equity because I think equity is a really important issue here and it cleaves kind of on the political side, too. I'm not saying that you ought to get into that. But the last thing that we want to do is to come up with a recommendation that we know is going to be dead in the water as soon as it gets to Congress. I think paying attention to that is something that makes sense.

What I have heard around here is that, at least on efficiency grounds, there's not a very strong argument for trying to push these health plans in rural areas. We want the opportunity to get the extra benefits, and some of that extra benefit that you get in the high-cost areas is something that should be examined in the context of where you want to be. So I think it's one of the fundamental principles of you're not just trying to improve efficiency but you also want to pay real attention to equity.

And that, I think, is also at issue you can raise with respect to these models. You say the likelihood is

that the benefits will drop, the extra benefits will drop. Well, that's obvious: It is going to drop. Where is it going to drop? How much is it going to drop? Are some of these -- I'd pick up the point that Glenn did, that the easiest way to do equity in the rural area would simply be to have a premium rebate or a lower-cost premium. So, some of that flavor, I think, is important to have in this chapter.

MR. HACKBARTH: And sometimes traditional Medicare is the high-quality efficient plan.

DR. KANE: I am wondering how much agonizing over the transition we really need to make, given that, in the policy debates I've heard out there the Medicare Advantage Plan has already been cut about six times and has funded most of the health insurance coverage reforms as well as the SGR fix. So, I just don't know how much political will there really is hear about a rational transition, but that's just one observation. I've heard several people spending that away already in the last months.

DR. KANE: They haven't done it yet. Talk is cheap.

One of the things I was wondering is I remember

reading about the bigger geographic area helping to smooth some of the variability in the high fee-for-service -- some of the variability around the fee-for-service benchmarks. Would it be helpful to include -- assuming they went ahead with smoothing the geographic -- making larger geographic areas as the starting point? First of all, what would that do? And then, how would you make the transition smoother, less onerous, and particularly for the high-quality plans?

We're kind of treating some of these separately, but it seems to me that these bigger geographic area reforms might take care of some of the inequities right off the bat. I'm not sure that's true but it just struck me that that was -- separating them didn't always make sense to me.

MR. HACKBARTH: Do you have any sense of that, Scott?

DR. HARRISON: For the simulations that doesn't really help because we take the bids by service area as opposed to bid for each county, which is one reason we can't do the competitive bidding very easily.

And so, even rejiggering into the larger service areas, it all depends on what rules we pick for, would they go into the larger service areas or not?

So, I've done a version, and it comes out pretty much the same as what you've seen now.

MR. HACKBARTH: There is variability at every level that you look at. You carve it up in different sized units and you're always going to find variability.

And one of the reasons, as you point out, for going to the larger geographic units was that we wanted to avoid sharp cliffs as you move across these boundaries. And so, you're smoothing some of the local variation, and that's one of the strengths of this. But that variation is small compared to the national issues that we're talking about.

DR. KANE: It just struck me that we have other tools going on at the same time and it got a little confusing.

I guess the last thing is that the -- it seems to me the transition -- the goal -- I would put forth a possible goal is protecting the plans with a lot of enroll -- the high-quality plans with a lot of enrollees, not a lot of beneficiaries with access in the transition because that's where the political pain is, is really the people that are already in there and receiving these, not weighing them by how many people have access but really weighing them

by how many people are actually in them.

And then, in the long term, you want to balance the geographic equity and the access. But in the short term I think it is just the enrollees -- and focus on the enrollees more than the number of people in the market area.

MR. GEORGE MILLER: First, I want to thank the Chairman for focusing us on goals because I said earlier that we need to decide as we go through all of these chapters what the ultimate goal is. I like to think that you start with the patient in mind, what we're dealing with.

But the question comes to mind, are we trying to save money or are we trying to improve quality or doing both? As we design this, we should keep that in mind.

Nancy brought up a point on transition -- I'll get to that in a second -- but I think either John or Bruce mentioned about the equity issue, particularly in the rural areas. Again, I will recant that all of us as taxpayers, we're paying for the additional benefits for the MA programs and the rural areas just have a disproportionate lower share of that. That's inequity part.

Then, going to transition, if I don't have a benefit and someone else has it and you tell me I've got to

wait longer and pay more to help that other person keep it, then that's the other side of the transition issue. So, no, I guess I've said enough, other than the point about competition.

I somewhat support the competition, although I understand you can't model it. I'm just wondering if getting the wider areas, you couldn't use the Medicare Part D area for the simulation for a larger area.

DR. HARRISON: I don't think that's our problem necessarily. It's really that -- in other words, you would have -- all plans would have to serve these multistate areas?

MR. GEORGE MILLER: Correct. It would be larger, but a county is an artificial geographical boundary and that's not where the market goes.

DR. HARRISON: We had gone to someplace between those two, between the county and the region.

MR. HACKBARTH: This happened, George, before you came on the Commission.

MR. GEORGE MILLER: So, I'm a new guy again.

MR. HACKBARTH: I think it was three years ago we did a lot of analysis to try to identify new geographic

units. And basically, what we would be doing in this report is referring to that work.

MR. GEORGE MILLER: It's the new guy issue, again.

[Laughter.]

MR. BUTLER: One question and then I'll make my comment.

My understanding from what you said, it sounds as if the competitive bidding will be in the chapter, but looked at from a qualitative standpoint in terms of the pros and cons. Is that where we're headed? We're going to try to accommodate that?

MR. HACKBARTH: And just to reiterate my opening point, all of -- I think the 10-year conversation on all of this is qualitative, because of the dynamic effects.

So, for some of these options, we'll have first-year estimates of their impact. For competitive bidding, we wouldn't even have first-year; for all of them, the 10-year horizon is qualitative as opposed to quantitative.

MR. BUTLER: Then my comment would be, as drafted, this looks like competitive bidding doesn't jump out at you as something that he we would be anxious to do necessarily. You site some experience from competitive bidding under Part

C to date which really hasn't gone very far.

Now, there are different circumstances. I'm actually not one in favor of competitive bidding. I have great reservations about it working, for some of the reasons it hasn't worked here. Or you can turn even to our experience with DME for god sakes, right? A different program, but putting together competitive bids and doing it is not something that government does all that well. You can go back to Medicaid selective contracting and a number of other things. Now, I know there are obviously differences of opinion at the table around that, so that's why I'm bringing it to our attention, that we ought to do as well as we can on that pros and cons, and I think the draft as it is, we'll have to put some more on the table to kind of clarify some of those, and I think it is important issue.

MR. BERTKO: Can I just point, Scott and Peter, maybe you, to Choice Care in Massachusetts which I just got a blip on one of my sets that said that they actually are going to come in flat or maybe even some cost decreases in their third year, which is a competitive bid for a single benefit program. Nancy, you probably know about that a little bit.

DR. KANE: They were sort of forced to.

MR. BERTKO: [off microphone] Commonwealth Care, not Commonwealth Choice.

MR. EBELER: I have an open mind.

MR. HACKBARTH: We're down to our last few minutes here.

MR. EBELER: Just quickly, I think we have to help frame what is being described as the equity issue and particularly the efficiency of running the equity money through a health plan -- I think it's something Glenn raised -- but you've done the previous analysis where we showed the three-for-one cost of the extra benefits.

We may want to do that analysis on the A/B bid itself, how much of that money actually flows to the community that George is worried about in the form of benefits versus how much is in fact absorbed in administrative and non-benefit payment costs. I just think we need to help them think through that issue.

Just another minor point, this crosscutting issue of paying for quality. My guess is, in the short term, we're not going to be able to compare plan to its community just because we don't have enough data in its community.

We're going to have to rank order the plans in the short term. In the long-term, we obviously want to aim there.

MR. HACKBARTH: Correct and, of course, everybody remembers another one of our mandated reports is to try to help Congress develop a system whereby plan quality can be compared to fee-for-service quality in the community. But that's a complicated thing that's down the road a ways.

MR. GLASS: Right. So, through the transition, plans would be compared to other plans, and then eventually to the fee-for-service.

DR. SCANLON: Just a quick point. If we are going to get into the equity area, I think that's it important that we do look at the geographic distribution of where the Medicare money comes from, because the Part B premium which is flat per capita across the country is probably less than 20 percent of total revenues. The Medicare Part A payroll tax, there's an unlimited base there, and then the rest of it, about 45 percent, is coming from general revenues, which is based primarily on income. So, that distribution, from looking at inequity -- that distribution matters a lot and is going to potentially mirror some of the costs differences we see in terms of spending because it's tied to price

levels in these different areas.

DR. CHERNEW: One thing that I'm worried about a bit in the bidding stuff, which I don't think came out, is the stability of this over time. because you could have plans not knowing that much about what the benchmarks are going to be until they get it and then it can change from one year to the next and the benefits could rise or fall. So, on an ongoing basis, even if it was working well once, debating on the structure of it, we would have to at least worry about what the stability for what the beneficiaries are. Because they can't switch -- they don't want to switch from one plan to the next on an ongoing basis based on what happens to them has ramifications for how a bidding system would work.

DR. REISCHAUER: I might have heard him wrong, but I think John recommended that we drop options two and four and I would disagree with that. I like them all -- I mean, I like some better than others, but to go through the range of possible ways you can handle this, I think it's important to lay out all four plus the competitive one.

A lot of talk about equity. George mentioned the taxpayer and the taxpayer is represented in this as the $150

billion that we're going to "save."

Bill mentioned that maybe we should look at where the money that supports Medicare comes from geographically. I would stay a million miles away from that if that were possible. We're getting into a very different kind of issue which strikes me -- I'll let you come back.

My two cents on the equity is, let's not forget the equity issue that these overpayments cause Part B premiums to be higher and so fee-for-service folks have a little -- and that's not counted in this $150 billion; it's a saving to individuals.

And finally, a question for Scott and David, urban/rural, remind me, is this metropolitan, non-metropolitan, or is it a different designation? Is it Department of Agriculture rural/urban?

DR. HARRISON: It's just urban/rural, but it's based on the Metro areas, right Dan? Yes metro/non-metro.

DR. REISCHAUER: It's metro/non-metro, which is really very different from urban/rural. George is real rural, non-metropolitan isn't.

DR. SCANLON: My statement was, if we're going to consider equity, I would stay a million miles away, too, but

it's this issue that is raised which is that everybody pays the Part B premium and therefore we've got to somehow equalize Medicare payers across areas. I think that's totally wrong. We should be thinking about efficient purchasing across areas. I'm happy to be with you as long as we keep it off the revenue sources -- off the table completely.

MR. HACKBARTH: Arnie, last word, real quick.

DR. MILSTEIN: Go back to Jack's comment about reconceptualizing this program as what we'd like it to be, which is a vehicle for a delivery system reengineering and better value.

I was reflecting on this discussion, and respecting Michael and Peter's comment about one of the critical variables here is stability for the beneficiaries, I just want to raise for staff consideration whether or not we are standing far enough back from this program to consider all of the variables that could be manipulated to better achieve that vision for the program.

One of the variables that I guess I'd appreciate some staff feedback, not immediately but as you get a chance to process it, is this notion that the length of the

beneficiary commitment can only be one year. Can we convert that into a policy variable? Obviously, all of this assumes it's a policy constant, it's the same as it always has been. But there are many benefits, not the least of which is preserving of stability of plan option if we were to model the implications of letting the plans bid for more than one year, and obviously giving the beneficiaries an opportunity to lock in a plan of benefits for more than one year.

MR. HACKBARTH: Okay, have we given you enough to think about for next few weeks? Thank you. Good work.

Next is another mandated report that I don't think we've talked about at all to this point. So this one pertains to chronic care demonstration programs.

MR. RICHARDSON: Thank you. Before I start, I would like to acknowledge the work that Hannah Miller did on this paper and presentation.

Good afternoon. In this session, I am going to present the results of the work that we have done in response to a mandate from the Congress to the Commission in the Medicare Improvements for Patients and Providers Act to report on how Medicare could improve the way it tests, evaluates, and disseminates innovations in the care for

Medicare beneficiaries diagnosed with chronic conditions.

First, I am going to give some brief background, very brief, on the impact that chronic disease has on beneficiaries and in the Medicare program to illustrate why it is important to focus on payment and delivery system reforms for chronic disease care and beneficiaries. I will then touch on the mandate in MIPPA for the Commission to review the results of the most important experiments that Medicare has tried for the past 12 years to improve care for beneficiaries with chronic conditions in fee-for-service Medicare, most of which, but not all, have failed to produce the hoped-for results.

I will summarize the results of four of these initiatives and the preliminary lessons learned that researchers are starting to draw from these activities.

I will then go over a proposal for one specific approach to changing how Medicare could improve the research and development of chronic care improvements, namely, the Medicare Chronic Care Practice Research Network. In the interest of time, I will go over the results of the demonstrations and the network proposal fairly quickly. There is a lot more detail in your mailing materials that I

won't go into here, but we could talk about in question-and-answer during the discussion period.

Last, I would like to introduce some broader issues of Medicare research and development that are raised by the mandate in MIPPA and that are a natural extension of work the Commission has been doing for a number of years.

First, as background, it is important to acknowledge the combination of chronic disease and care coordination gaps and the problems that it causes for the Medicare program.

Medicare spending is concentrated among a small percentage of beneficiaries. That is shown on this slide, Slide 4. A MedPAC analysis in 2004 looked at Medicare claims for the Medicare fee-for-service population and found that the top 25 percent of beneficiaries accounted for almost 90 percent of Medicare spending. This distribution of spending was also looked at by the Congressional Budget Office in a similar report which found that 75 percent of the beneficiaries in those high-cost categories had one or more chronic conditions.

MedPAC, the Institute of Medicine, the National Priorities Partnership, and others have looked at the care

coordination gaps that contribute to these high-cost and low-quality outcomes. Lack of care coordination among multiple physicians results in duplicative testing, including laboratory and diagnostic imaging, poorly coordinated care transitions from one setting to another and poly-pharmacy issues.

To illustrate the number of physicians that are involved for beneficiaries with multiple chronic conditions, I would introduce this figure from my Pham and colleagues at the Center for Studying Health System Change, which clearly show that as the number of chronic conditions among Medicare beneficiaries in fee-for-service increases, the number of physicians involved in their care also increases rather dramatically. The purple bar is the median number of total physicians involved in their care, and the yellow bar on the right-hand side of each of those tranches is the number of practices. So not only is there a greater number of physicians involved in the care, but those physicians are spread across a greater number of physician practices.

Finally, previous work by the Commission has established that Medicare fee-for-service payment structures and payment policies create distinct disincentives for care

coordination. As was mentioned earlier, in Medicare fee-for-service doing the right thing often costs providers money. It can lead to lower utilization and, therefore, less revenue for hospitals, physicians, and others in the payment system. And as we discussed last year in our work on the medical home, there often is no payment under Medicare fee-for-service payment rules currently for conducting care coordination activities that improve the quality of care and potentially lower costs.

The Congress and CMS have initiated several demonstrations and pilot programs over the past decade that have taken a variety of approaches to try and find out what does and does not work in improving care coordination for beneficiaries with one or more chronic illnesses. As part of the MIPPA provision that directed the Commission to undertake this study, the Congress specifically required us to examine two of these initiatives: the Medicare Coordinated Care Demonstration and the Medicare Health Support Pilot Program.

We also believe it is informative to look at the results to date of two other ongoing demonstrations that are using different types of care coordination interventions to

improve the quality of care and reduce costs: the Care Management for High-Cost Beneficiaries Demonstration and the Physician Group Practice Demonstration.

The MIPPA provisions specifically instructed the Commission to use the results of our analysis to assess the feasibility and advisability of establishing a Medicare Chronic Care Practice Research Network, and we are to report to the Congress on this work by June 15th of this year.

Next, I am going to go over the three demonstrations and one pilot program, and then we will get to the Chronic Care Practice Research Network proposal.

First up is the Medicare Coordinated Care Demonstration, or MCCD. This was authorized by the Balanced Budget Act of 1997, and it actually launched in 2002. There were 15 sites in this demonstration, and most of the sites targeted beneficiaries with multiple chronic conditions, although a couple of them focused on beneficiaries with only one.

Each site was paid a monthly fee which ranged from $80 to $444 per member per month, with an average of $235 at the start. The fees that were paid to the sites were not at risk, but the programs were expected to be budget neutral.

There was voluntary enrollment in all of the sites, and the beneficiaries who volunteered to participate in the demonstration were then randomized into a treatment or control group at each site. At its peak, the demonstration had slightly over 18,000 enrollees spread across the 15 sites. The sites varied in size from 90 enrollees in the treatment group to over 1,500. But most of the sites, about 9 out of the 15, had between 400 and 750 beneficiaries in the treatment group.

The results of the MCCD as far as cost and quality are displayed on this slide. None of the programs reduced net Medicare costs. The only statistically significant results that were established by the independent evaluation, done by Mathematica Policy Research, were that the costs to Medicare were actually increased in the sites that had statistically significant results by between 8 and about 40 percent. There were no positive effects on patient adherence measures that were evaluated by Mathematic. There were a few positive outcomes on the process of care measures; there were, however, high levels of beneficiary and provider satisfaction with the programs.

Two of the sites, however, were approximately

budget neutral or close enough to be budget neutral for CMS to negotiate with them to extend for another two years, and they will be extending their activities through 2010. The final evaluation for the program will be available later that year or probably more likely in 2011.

The Medicare Health Support Pilot Program took a slightly different approach. It was authorized by the MMA of 2003, and it had eight sites which launched in 2005, also after a competitive Request for Proposals process. Each of the sites here were also paid a per member per month fee, and they were at risk for cost and quality, unlike in the MCCD.

The research design here was different. It was an intent-to-treat model where about 290,000 Medicare beneficiaries across all the sites were randomized into an intervention or comparison group in the eight geographic areas served by the sites. The Medicare Health Support organization were then given contact information for the beneficiaries assigned to the treatment group, and they were allowed to begin outreach to those beneficiaries and their providers. The cost performance, however, was based on the Medicare cost for the entire treatment group, whether they

enrolled with the Medicare Health Support organization or not. So obviously the organizations had an incentive to enroll as many of the beneficiaries as they could, intervene with them, and try and alter the trajectory of their medical costs.

Here the fees were between $74 and $159 per member per month, and there was initially a requirement under this pilot that the sites save 5 percent in medical costs plus the fees that they were being paid. Later this was changed to simply budget neutrality; the sites, though, still had to recover at least the fees that they were being paid.

The results of this pilot program were that the cumulative fees paid to the sites far exceeded the savings produced. Before taking into account the fees paid, four of the sites actually did reduce medical costs by about 1 to 2 percent on a PMPM basis. But once those fees were factored in, all of the sites increased costs to Medicare by between about 3.5 and 9.4 percent, or roughly $50 to $130 per member per month.

The independent evaluation of this pilot, which was done by RTI International, found limited impacts on beneficiaries' satisfaction with their care; some positive

but, again, limited impacts on self-management measures -- that is, the beneficiaries' ability to maintain their medication regimens, perform exercise, check blood glucose levels, and things like that; and also some limited impacts on the physical and mental health functioning measures that were evaluated by RTI.

They did find some positive effects in some sites on process-of-care measures, but as far as outcome measures go, there were no statistically significant effects on hospital admission/readmission rates or the use of the emergency department.

The third demonstration we looked at was the Care Management for High-Cost Beneficiaries demonstration. Unlike the other two, this was actually a CMS-initiated demonstration. CMS solicited proposals under a competitive process from six sites. They required each of the applicants to be a physician group, a hospital, or integrated delivery system. Unlike the other programs, CMS did not define targeted chronic diseases in this demonstration. Each site was allowed to propose its own enrollment eligibility criteria.

Most of the sites participating have

beneficiaries, since they are focusing on people of high cost with multiple chronic conditions, with congestive heart failure, diabetes, and one of the sites is actually focusing on beneficiaries with chronic kidney disease, which is unlike most of the other demonstrations.

Like the Medicare Health Support, this also uses an intent-to-treat model where CMS identifies the beneficiaries in the service area, tells the sites who these beneficiaries are, and then allows them to go enroll as many as possible to intervene with them.

These sites started in the fall of 2005 and the summer of 2006. It is smaller than the other demonstrations. It only has about 5,600 beneficiaries enrolled in four sites at the time that number was generated. These sites, each of the sites has between about 540 and 2,200 enrollees. This is a bit of a ray of sunshine, I guess you could say, in the demonstrations so far in that CMS recently announced that -- in January of this year, they announced that three of the sites had achieved close to budget neutrality and met the financial terms and the quality performance terms of the demonstration, and were going to be extended for one

additional year with an option for up to two more years if they continue to succeed.

Unfortunately, CMS hasn't released a lot of information, not nearly as much as they have about the Coordinated Care demo and Medicare Health Support. So we will be looking for more information from them as that comes out.

Lastly, we looked at the Physician Group Practice demonstration. This wasn't specifically designed to be a program for care coordination interventions; however, we think it is relevant because what a lot of the physician group practices and other participants in this demonstration are doing is working on improving care coordination to reduce the medical costs and improve the quality of care for the beneficiaries that they treat.

We have talked a lot about the PGP demo before, including this morning in our ACO discussion, so I won't belabor the details here. I will just take a quick snapshot here of the results.

First, on costs, I describe them here as possible reductions in total costs. I just want to make sure that I am clear about what that bullet means in case there is any

confusion given what Dr. Stensland said this morning about the results from the perspective of looking at it through the ACO lens. The MedPAC staff have some significant questions about whether these savings being reported by CMS are actually being achieved once you have controlled for some of the coding and other issues that are going on potentially at the sites. However, it still remains a fact that CMS in August of last year announced that this demonstration had saved $17.4 million over what would have been spent in the absence of the program and awarded about $13 million to those four sites. So we are in a somewhat different place than CMS, but from the agency's perspective, they are seeing savings there.

It is unequivocal, however, that they have improved the quality measures that have been tracked in the course of this demonstration. These relate to diabetes and congestive heart failure, and all of the sites have had noticeable and statistically significant improvements in those quality measures.

CMS has extended what was originally a three-year demonstration for one more year, and that performance year will end in March, at the end of this month.

So, to summarize all of the foregoing analysis, in terms of costs, we have seen little evidence to date of cost neutrality let alone savings. Having said that, there does seem to be some apparent success in some of the demonstration sites with some elements of the population and certain elements of the interventions, and I can talk a little bit more about that in the Q&A.

In quality, there seems to be some evidence that, again, some of the programs and some of the interventions with some of the beneficiaries can improve quality.

A lot of the experience with these three demonstrations and one pilot program, though, have raised some significant questions about what CMS' capabilities are in operating and administering this type of activity, both in terms of the resources that they have to devote to it and the process of putting together a demonstration, running a demonstration, and evaluating its results.

There seems to be too many observers' eyes, limited flexibility in CMS to generate, test, and evaluate potential policy improvements. This includes flexibility to adapt the demonstrations once they have started, and there also seems to be no clear process for translating the

results of these demonstrations into policy improvements.

In light of that, there has been a proposal put forth by a coalition of provider and research organizations called the Medicare Chronic Care Practice Research Network. This is a proposal from these organizations that are listed in your mailing materials -- and also shown illegibly on the slide up there -- which are a group of academic medical centers, care management service providers, and long-term care providers to form what is essentially a practice-based research network. The graphic that you see there shows the individual entities that would form the sites on the bottom of that figure, and up above that is an administrative structure and a research structure that would be used to come up with ideas, evaluate the ideas, and rigorously test and evaluate the data that is being generated by the practice-based research network itself, which is the area surrounding the circle.

In the paper, I call attention to the fact that there are many similarities between the design of this proposal and practice-based research networks run by the Agency for Healthcare Research and Quality, or AHRQ, and we can talk some more about that in our discussion, if you'd

like.

The key points of the MCCPRN proposal is a network to test specific care coordination interventions, and this is very much in the spirit of practice-based research where there are specific policies, procedures, and protocols that would be tested through the network, that would be evaluated as part of the network's mandate, and to the extent that they were found to have positive effects, either on cost or quality -- ideally, both -- the network would produce guidelines about best practices which could include in their proposal -- as described in their proposal, I should say, toolkits, how-to guides, and operations manuals, which then could be disseminated across a number of different settings and used to improve the quality of care for beneficiaries with multiple chronic conditions.

The network itself, though, would also be an experiment to develop faster evaluation methods and measures for how these interventions can be tested, evaluated, and disseminated out into the clinical practice.

Now, financially, the network would be funded out of the Medicare trust funds. There was a legislative proposal introduced in the 110th Congress, in 2007, that

would have authorized $60 million over five years for the operation of the network. It is important to remember that, similar to all of the other demonstrations and pilots I have talked about, the underlying Medicare fee-for-service payment policies and structures would remain in place. So essentially out of this funding amount, let's say for the sake of discussion that it is $60 million, that would be used to fund the administration of the network and to pay care coordination fees to the sites participating. But the proposal, as put forth anyway, does not envision doing any significant reforms to the payment policies under Medicare fee-for-service. The proposal also points out that the fees paid to the network sites would not be at risk in terms of cost outcomes or quality.

The staff have some concerns about the proposal for you to consider, the first one of which is that the network sites in this proposal would not be competitively selected. There is an issue here of a precedent being set for having an established network come forth basically as is and having CMS adopt it as is. And I think one way to think about this is the question of whether this particular constellation of providers and the administrative structure

that would go on top of it is the right network to test the interventions in a way that generates generalizable and scalable results.

Alternatively, should CMS, as AHRQ has done with its practice-based research networks, define criteria ahead of time that would be used to solicit a proposal for a network and build it and then under that structure use task orders to more quickly disseminate ideas and test them, do the analysis, and investigate whether those results are applicable to a broader set of settings? That is, is the structure of this network representative enough of the bulk of Medicare providers in the community to be a good laboratory for testing these innovations and having them be embraceable by the bulk of Medicare providers?

Second, we have some concerns over whether the fees that are paid to the sites should be at risk. In our analysis of care coordination activity in 2006, the Commission looked at two different ways that sites in any care coordination program could be at risk, which is that the fees themselves could be at risk, as in the Medicare Health Support program, or we could have a shared savings approach like they use in the Physician Group Practice

demonstration. One question for you to think about is whether that is something -- whether either of those approaches is something you would like to use in a network like this.

Third, we have some questions about the role that CMS would play in the administration of the network. If you'll recall from the paper, the governance structure as proposed would include CMS among all of the network sites that would also participate in the network, and we have some questions about whether -- and part of this is the nature of how a practice research network would work. Some of the ideas for what should be tested should come up from the network, but CMS, working together with 13 organizations in the administration of the network, could raise some questions about how much control and influence CMS could have over the types of innovations that are being investigated.

And, finally, as I noted, AHRQ has several practice-based research networks already in place. One of them is organized around thousands of primary care practices. The other is organized around several integrated delivery systems. And we have a question of whether there

might be some duplication of a practice research network like this that would be operated by CMS and not AHRQ.

But, more broadly, this proposal and the results of these demonstrations and pilots raise some larger questions that we think the Commission -- we would be very interested in hearing the Commission's views about, really about the whole enterprise of Medicare research and development. And these are very fundamental questions that the Commission has grappled with over the last several years, and we think that this presents a good opportunity -- not necessarily for the specific report that is due in June, but over the next report cycle perhaps -- to think about these broader issues. Where should these ideas for research and development originate? How much should they come up from the grassroots versus coming from the top down? How can these policy ideas be tested and evaluated more rapidly and create replicable and scalable interventions?

If the current system is not working and there are some other ideas out there, like the practice-based research network concept, that might improve them, is that something that the Commission could look at?

What changes do we need to have in the R&D process

to accelerate the dissemination of evidence-based practices out into the community? If one of the problems with the current research and development activity at CMS is that a lot of good ideas come up but they do not go anywhere, how can that dissemination process be sped up?

And, finally, looking at CMS itself, what capabilities does CMS need to have to be able to do research and development on a $460 billion program? The current ORDI budget within CMS is about $30 million. That may be somewhat out of scale to $460 billion.

MR. HACKBARTH: Very efficient.

MR. RICHARDSON: Extraordinarily efficient at doing what it does, which there are those who question what that is.

So, with that, I will be quiet and look forward to your questions and discussion.

MR. HACKBARTH: Good job, John. I have been wrestling with this one a little bit myself and just thinking about this process and how long it takes to try to do, if you will, a new idea in Medicare. And sort of my rough timeline is, you know, for a large-scale project, given how small ORDI's budget is, if you want to do

something large scale, it has to be specially authorized by Congress along with the funds, and, you know, that takes a year, at best, to go through the legislative process.

Then once that happens, you know, you have got a year or a year-plus in planning, implementation, and signing people up. And then you've got two or three years for the demo itself, another year or two for evaluation, and then it goes back through the legislative process for another year or two. You know, you are talking about a process that runs anywhere from six years to 12 years to do something.

That scale doesn't quite fit well with the pace of innovation that we need, so I think this is a very important topic.

Let me see hands for the first round of clarifying questions. We'll start with Karen.

DR. BORMAN: You've nicely, here and in the chapter, you've all reprised the efforts thus far and sort of the striking lack of demonstrable effect, and I have to -- I guess this is more a comment than a question, but a little bit of a question is the things you've pulled out from the last one, you know, three did this in some things, whatever, is that not potentially when just chance that at

least some positive results would be found? It just seems to me that we are grasping at some serious straws in that particular piece, and we need to be honest about that.

I guess the other thing is what, if any, of these studies, as you've looked at them in great detail, have any kind of attempt to measure out a placebo effect here. I think we all know, certainly those of us that have seen patients and those of you that have been patients can appreciate sometimes the therapeutic effect of, you know, a good conversation with a physician and/or the fact that you've got somebody to call, or whatever.

I just kind of wonder here about can we separate out the background noise of sort of this analogy to the placebo and chance alone here based on any of these study designs.

MR. RICHARDSON: I think on the statistical issue -- I'll do that one first -- that goes to the question of how big do these need to be. I mean, the larger the cohort that you are studying, the more statistically you can be reasonably sure -- there is always going to be -- even if you have a 95-percent confidence interval, you are always going to have that possibility of the result you are seeing

due to chance. But the more people you have involved and the more sensitive your measures are to an effect -- and I will get to your second point in a second -- you know, the better statistical validity you will have in those results.

So one of the potential problems of having a demonstration or a study that is too small is that you need some very large effects in, say, reduced hospital admissions with a small group of people to be reasonably sure that the effect that the -- I am sorry, that the intervention that happened with those people are the reason for the effect that you are seeing.

DR. BORMAN: If I could touch on that, I guess maybe what we are getting to is a question of interpretation, and just to pick on the last one that you went through where you had a fairly extensive study and the only thing positive that could be said out of it was that in these three things on some measures, something was better, if I understood things correctly. Okay.

One could look at that, that that is just -- you know, if we said that the alpha here is going to be 0.95, that this is sort of -- out there in the 5 percent, that if we tested enough, did it often enough, that we are going to

find some positive effect that may or may not be related to the intervention. That is one potential.

Another one which I think you have just described is that you are imputing that this is potentially a type two error, that there were not enough subjects in the appropriate groups to detect the difference if a difference exists.

Based on what you know from an extensive review of this, can you make a judgment about which it is more likely to be? Is this more likely that these positives were just because we have tried to break this out into enough sub-group analysis, about enough sub-topics that we finally found something to be positive about? Or is this more likely to be that we've missed an effect based on what you can judge about the studies, recognizing that it is an imperfect world?

MR. RICHARDSON: Given the breadth of the effects that they were looking for in terms of quality improvement, process-of-care changes, you know, some of which are subjective -- not process of care necessarily, but beneficiary satisfaction and things like that -- I would tend to think that they are detecting real effects, and I am

more confident about that when the effects are larger, I guess is all I'll say. But it is interesting. One of the sites in the MCCD had a very large negative reduction in hospitalizations. I am going to hazard a guess that that was a result of the intervention, given its size and its direction, which was the intended effect. However, that was one of the sites that was not budget neutral because the care coordination fee that was paid was so large, it obliterated all of the savings achieved from that reduction in hospital admissions.

So if you pull them apart like that, you can see something. Put them back together and suddenly that disappears.

MR. HACKBARTH: Let me ask this, and maybe, Karen, you can help me. My understanding of the design of a lot of these things is that we break them up into sites where the intervention, broadly defined, is tried and the sites often have, you know, 500 or 750 people involved. The intervention actually varies across these sites, and so we are testing the intervention uniquely in groups of 500 and 750. But when we were talking about ACO, we were bandying about the number of 5,000 as a minimum to be able to detect

reliably differences in total cost of care. Yet here we're looking at cells with 50. Aren't we biased towards finding no effect?

MR. RICHARDSON: With the exception of the Medicare Health Support pilot, which was much larger.

MR. HACKBARTH: Yes, right. But isn't that sort of -- aren't there scale issues with --

MR. RICHARDSON: Yes, and I think that goes to the question, some of these larger questions: How do we design a research and development process that can give us some results that we have some confidence the intervention --

DR. BORMAN: Motivated by our thought about comparative effectiveness, I am also motivated by how I as a physician have to use, albeit imperfect, medical literature to make a decision about how to treat a class of patients. And at the end of the day or in the middle of the night in the operating room, I've got to make a decision. Do X or do Y and make a judgment.

If I were studying a twist on an operation this many times and this many ways and this is all I could come up with positively, I'd probably stop doing that twist on the operation. So just, you know, trying to bring this into

a world that has some face validity relationship to clinical care. That was the purpose of the question.

DR. MILSTEIN: John, two questions. First, what is the scope of the question that we're trying to answer? Are we trying to make a recommendation with respect to an R&D process that would uncover methods of producing more health with less money? Or are we trying to make recommendations on an R&D process with respect to Medicare policies that might have a better chance of eliciting methods of delivering care, you know, that would produce more health for less money? That is my first question. Why don't you answer that first.

MR. RICHARDSON: For the purposes of the report to Congress that is due in June, there are two things we need to do. One is evaluate the Medicare Chronic Care Practice Research Network proposal and in doing that evaluate the structure and implementation and results of two of the demonstrations I went over -- the Coordinated Care demonstration and the Medicare Health Support pilot. I'm sorry. I keep calling them demonstrations and pilots. The same thing. In addition to that, we thought it was useful to look at two other demonstrations that we think bear on

that question. That is what we need to do for the report to Congress in June.

These larger issues of what kind of research and development enterprise, if you want to call it that, Medicare should engage in is not necessarily part of the report to Congress. We think that it is hard to pull them apart because how we approach the question of whether there should be a Chronic Care Practice Research Network implicates a lot of these larger issues, but for the immediate task before us in June, we don't necessarily need to do that. However, we are taking this up as something that you might want to look at down the road.

DR. MILSTEIN: The second question is, as you think about this, are you looking more broadly with respect to alternative methods of making this happen? You know, in September there was -- I think it was September, or maybe it was February. February. There was a terrific Health Affairs paper on the tremendous success they've had in Germany on moving chronic care performance measures up quickly. And so if we're going to look at this or any other proposal -- you know, I guess it is more of a suggestion than a question, but maybe we should look more broadly as to

what is working and then think about how that might be translated on to Medicare.

MR. HACKBARTH: That is, in fact, I think, for the longer term. We need to do the short-term response to the specific request, but for our longer-term thinking about this, I agree with that approach.

MS. BEHROOZI: This might be a variation on what Karen asked, and I feel like it's a dumb question, so maybe it was answered, what you were talking about, Karen. But it was kind of like the last thing you said, you know, you would change what you were doing if you saw that it wasn't working. I am kind of trying to figure out what the "it" is that has been studied here. Is it things, is it processes, or is it entities that have done them?

So when you said, Glenn, you know, 500 people at each place, well, that's different places. Are they doing different things? Are they doing the same things? Are the things that they're doing the same?

We participated in a study that focused very narrowly on telephonic follow-up post-physician visit for men with PSAs over X level, or whatever, and that was the thing that was being studied. It wasn't how we did the

thing. So I'm missing something here.

MR. RICHARDSON: I talk a little about it in the mailing materials. Let me just for the sake of this discussion give you some examples of the types of interventions that have been tried in the different settings.

For example, in the Medicare Health Support pilot, which was focused on a more telephonic case management approach, there was also, in addition to telephonic care management, some intensive case management for beneficiaries identified by the entity as particularly high cost or high risk of hospital admission. There was patient education on self-care. If you have diabetes, this is what you should be looking for; this is how you should be taking care of yourself. Medication management support --

MR. HACKBARTH: These aren't things, though, I think is what Mitra said. These are categories of things that can be executed very differently.

MS. BEHROOZI: Exactly. Did they all do that same list of things? Was there any control on that?

MR. RICHARDSON: No.

MS. BEHROOZI: I didn't think so. You know, it's

a combination of sites and types of interventions that we don't know exactly how they cross-hatch, so you don't know which things to cross off the list that did not work. Maybe it is the places you have to cross off the list. And, you know, it kind of goes to what Arnie was saying. Let's look at something that has worked and what is it that they have done, as opposed to, well, you know, this place wasn't good enough at it and that place didn't use the right combination and these things didn't work, but we are not sure that they were all done in all of these places. You know, it is the discipline of designing the study, I guess, that I'm kind of feeling like I don't have a handle on it here, and I don't know that we should do more of it that way.

DR. SCANLON: On this point, though, there is this question of designing something for the real world, and the real world is going to have variation in it. And so the question is if you shorten your list, can you develop a policy that you are only going to get the things on your short list? Or if you put out this short list, do you end up sort of getting some of the things that you wanted to exclude?

This kind of goes to your point, Glenn, about

being able to only analyze at the site level, if the demonstration was done well enough, there was enough control over the variation that we're talking about a policy intervention, and in the real world it is going to vary. And we need to know sort of when that variation occurs, does it result in the intervention being ineffective? Because we are not necessarily going to be able to go in and say do exactly this.

MR. HACKBARTH: I'm out of my league here in terms of study design and how businesses do this. But one of the things that strikes me about this is it's a very academic model that says you do this at this site, and let's assume it's well specified. And then you keep doing it for the next three years, even if you are on the ground there and think, well, geez, this isn't working. And a business would say, oh, wait a second, I need to change; this isn't right, so I've got to tweak the model. But in this academic model of research, no, you don't change it.

DR. CHERNEW: The intervention that they're testing isn't the clinical intervention. It's the payment intervention. And then they're allowing the underlying organizations to do whatever they do because the hypothesis

is, if we were to pay -- an example would be capitation versus not. You would evaluate capitation versus not. You wouldn't tell people what to do underneath the capitation. They would do whatever they wanted to do. But the hypothesis wouldn't be a clinical hypothesis. It would be capitation versus not. That is what people would be -- you know, in the RAND health insurance experiment when they randomized people into different insurance categories, they didn't tell people exactly what had to happen within each of those insurance categories. They were testing the hypothesis if you randomized people into a benefit package, this is what the impact is, without being able to say anything about a clinical comparative effect in this thing underneath. This is the equivalent of that. It's just not co-insurance as in the RAND health insurance experiment. You know, the RAND health insurance experiment randomized people into an HMO. The intervention was the HMO, not the clinical thing that the HMO did. And, of course, as people said in that case, that would be generalizable in that case to one HMO, because that was what they randomized into.

No, that wasn't mine. That was just a comment. It's an academic discussion. I can't resist that. I

usually don't interrupt.

MS. HANSEN: Perhaps I could bring it to another applied level. One is to kind of address, Glenn, your point about the size and so forth. I'll just speak to something that was done. The next one is the question of using other examples where things do work as well as in studies that have worked already, and I am curious then, to bring it back to this proposed project, why representatives of projects that seem to have worked before in chronic disease management don't show up in this group, so this whole selection process of this whole effort, also.

I'm just so glad I was born a generation ago, and that is, you know, I think I lived through this whole demo project, and I can give you some absolute years of how long it took to do the PACE project. It was four years of demo and 14 years of replication and movement beyond that, for a total of 18 years in order to move it from test to legislation. So that just gives you anchored, real stuff that happened with the PACE project. So we got legislation passed on capitated financing.

But the size aspect was interesting because it relates to these numbers, and when we speak about ACOs

having relevance perhaps at the 5,000 level, and then there are these numbers of anywhere from 300 to 700, with the one outlier of a larger group, you know, the populations may be very, very different. Assuming the chronic disease side, it's multiple chronic diseases going on with many medications and a lot of care management.

So the size ends up small, and if we parallel it to what nursing home size, if we are going to talk about that level of frailty, you know, average nursing homes are no longer than 100. And so it's just we're talking about apples and oranges when we talk about money flowing to a population.

So I just wanted to perhaps give a reference point that we may be talking about different populations so that their size is going to be perhaps looked at differently.

Then the other thing is even in the United States, a couple of other projects that have been trying to do this on scale are the people we know of, Dr. Eric Coleman from the University of Colorado and Dr. Mary Naylor from the University of Pennsylvania, and I think Dr. Chad Boult is doing some stuff in Hopkins, and there are other people doing it on the commercial side with Evercare and so forth.

So there seem to be existing models that are dealing with this issue, and that leads me to wonder how this construct of this proposed network -- I don't see actually any of these other types of groups that are involved here. So this whole question of why these seven -- is it 13? -- seven of whom, of course, were in the previous demo. So it does give me pause to question what this brings together that's different and moves on further when people have been at risk financially for other kinds of things when the payment levers were there.

So I do have some pause with the idea of just a construct of offering 13 systems to come together this way and not to be at risk also.

MR. RICHARDSON: We recently got some information that was from the group, which we've met with a few times now -- that came after the mailing materials went out -- that gave a little bit more detail than we had seen before about what they would be doing. And, specifically -- I should back up a second. They've actually gotten some planning grant money from Congress to put the coalition together and do some research using the data from the Coordinated Care demonstration, which a number of them were

also participants in. And they are looking at those data to see if they can identify some common specific interventions that were used in a number of the sites, in addition to some things that weren't tried but that other research has shown may be useful, like Eric Coleman's Care Transitions project and Dr. Naylor's project, and applying -- so the idea would be if what worked in the different sites or appeared to work from the data analysis that they're doing, plus these additional interventions were tried and experimented with through a network, as they proposed, that that would yield some result or we would have more information about whether that particular combination of interventions was successful or not.

MS. HANSEN: This is strictly an editorial comment. I think that given the fine work that has been done, and I think some of the findings from the demonstrations -- and this is so vernacular. You know, a lot of this is not rocket science, and it's our ability to follow people during critical transitions. Again, the work that has been done by -- papers that have been, you know, juried and so forth, and now being tested in the marketplace.

I guess I just need to feel, you know, what is the value add with all of this versus the diffusion of available knowledge and getting it into practice, more like what IOM will say. From the time you have a finding, you know, does it take -- I forget how many years -- 13 years, 17 years in order to diffuse it to really a practice point? Is that not where the funding, the effort, and the execution really should be going so that we get more people served rather than studying the angles again?

Again, and I say that I think earnestly only because having lived this model, lived this stuff for 25 years, I just think that it's time to get on. Like Karen was saying, get it out there and let's do it.

MR. HACKBARTH: Through my bad example, we've sort of mixed rounds one and two, and maybe even three. This is a round one? Okay, go ahead.

DR. CHERNEW: Did they do a power analysis?

MR. RICHARDSON: I don't know.

DR. CHERNEW: What's the status of the MCCPRN proposal? In other words, is it funded? Is it --

MR. RICHARDSON: No. The proposal would be for -- it would have to be authorized by Congress, and the proposal

would be to create a network like this and authorize funding for it within CMS.

DR. CHERNEW: In thinking through that -- so here is the last clarifying -- I see two things. The first one is funding and authorization for an intervention of some type, of some sort. And then the second one is a separate funding to evaluate whatever is done. So one activity is you can't evaluate -- if you're just hanging around the table here, you can't go out and decide I want to evaluate the following type of Medicare payment intervention, because CMS isn't doing that Medicare payment intervention. Right? That's hard to do. But if CMS was doing any type of Medicare intervention, like Mathematica and RTI got those evaluations in a competitive bid, once the actually intervention was designed in the -- so I'm unsure if the MCCPRN proposal is both a proposal to change something Medicare's doing, the payment, and to then give the people who are running that also the authorization to evaluate it -- so they're evaluating their own intervention that they've designed -- or if it's a proposal just to evaluate something else that's ongoing.

MR. RICHARDSON: It's a proposal to come up with

ideas about interventions, not payment. I think that that is -- I'm glad you mentioned that. There would be no change in the underlying fee-for-service payment system here. The funding would go to the sites that are carrying out the intervention. And the funding would also be used to create this infrastructure to evaluate it.

DR. CHERNEW: But what is the intervention? No, but I'm not even sure what --

MR. EBELER: It's an ACO.

MR. RICHARDSON: No. The interventions would be the types of activities that I was describing earlier, which, again, could vary from site to site. But the proposal is to as closely approximate it from one site to the next to reduce the variability so that you had some confidence.

MS. BEHROOZI: This is actually a follow-up. Mike said that the test here is a test of a payment policy. So if that's all it is, then line up how you paid, you know, in each of these programs how you did the payment for the care coordination work and see which was most effective. I don't know if that actually correlates. Maybe the PGP is the most effective, but maybe that's because it's the primary care

providers who are involved instead of some third-party organization based on Boston or Minnesota, or wherever Health Dialogue is based.

The thing is, though, if it's about payment policy, then payment policy should be set to encourage efficiency and quality and all of those things, and the studying of which interventions work seems to be better housed in this already existing entity, the AHRQ effort. And one of the reasons for this particular type of thing, care coordination, or what's been demonstrated, it seems like to me, through, you know, the evidence that you have given us and based on the limited evidence that CMS has released -- I mean, one of the frustrating things in the paper I think is when you say, well, they haven't really told us a lot about why it didn't work. But even just, you know, in our own experience in our organization where we actually are using Health Dialogue -- full disclosure -- for care coordination -- and their fees are supposedly at risk -- is that we've got some members who respond wonderfully, and their lives are changed and they're grateful to have somebody to talk to on the phone. And there are some people who don't want to be bothered, and I see evidence of that

here with the self-selection. Educators know that people learn in different ways, and so, you know, in the health world it's not much different. People respond to things differently. So a one-size-fits-all, a mega program, you know, paying a gazillion dollars and then finding out later it didn't work because -- you're not quite sure why it didn't work -- just doesn't seem like the right way to go. So I would actually not support the whole new bureaucracy thing.

MR. HACKBARTH: We'll count that as the first comment in round two. Bruce will have the second.

DR. STUART: First of all, I thought this was an excellent although rather depressing chapter to read, and I think the end is really important in the sense of trying to pull together what you see and evaluate the evaluations of the demonstrations. So I think there are some lessons here that should be learned.

As far as this proposal is concerned, obviously I have not read the proposal, but did they mention PBRN in the proposal? So they want to do it like PBRN?

MR. RICHARDSON: They mentioned them, I think, to help us understand what they would do.

DR. STUART: All right. Well, I've sat in on several study sections for PBRN, and the way that process works is the networks are out there. There is money that comes to the table. AHRQ says, all right, well, we're going to bid, we have an RFA for ideas, and sometimes they're rather narrowly defined; other times they're widely defined. Each of the networks or parts of the network can bid on a piece of this. They put together a proposal. It's a research proposal. It's not a demonstration and then a separate evaluation. It's a research proposal. It's a thing, a something that is going to be evaluated. And then that goes through a scientific review process, and the proposals are scored. And, you know, the good ones generally are funded, and the ones that aren't so good generally are not. Nobody's guaranteed any money under this thing.

I will say, however, that the general quality of the research design -- now, I am not going to push this too strong, but the general quality of the research design in that type of a framework -- and this is true in the action framework as well -- is not as high as it is for other types of either investigator-initiated proposals or for solicited

proposals that go through NIH or AHRQ.

DR. CASTELLANOS: I guess the real question is what did we learn from the demonstration projects to date or what should we have learned. I am going to take a very practical approach.

I was involved with the Green Ribbon Health Partnership, the MHS program in Florida. It was a combination between Humana and Pfizer. And I learned a little bit during that project. I learned what a silo was, but it really wasn't a silo. It was a Fort Knox. There was such a -- this management company stood between the physician, the patient, and the doctor. You know, it was pretty evident when they set it up that this was happening. And we went to them, and we told them that we wanted to get in, we wanted to be involved. But, of course, they had their own mind of doing things, and it fell flat.

What I'm saying, again, what I learned in this is something that I haven't heard during this discussion, that we need to get the physician community involved in this. I think some of the projects that have been successful, the large practice group one and the CMS projects, all are involved with physicians as part of the set-up of the

program. If we're going to make any recommendation, I would hope that we would encourage to have that so there would be a good care coordination between all providers.

DR. KANE: I'm going to go with Arnie's comment and also Jennie's that we should really look at these kinds of activities that have already been evaluated in a bigger scale and longer time and take heart that maybe we can actually do similar things in the Medicare program.

What I learned from this very interesting chapter was that you don't want to rely on CMS for the information you need to manage care. They're way too late, it doesn't do you any good, and it's just way too arbitrary and perhaps not useful. And so that's what we learned, and I'm not surprised, and I don't think we need to spend too much money on it.

But I guess the other thing I'm wondering is if this class of activity could be considered the kind of thing you'd like to see under comparative effectiveness types of research whether, you know, this might be viewed just like any other treatment or protocol, and whether this whole question shouldn't just be put back into the whole comparative effectiveness debate, and just say, you know,

here is one type of care processes that we would really like to have considered in the long term, and just stop treating them as separate. I mean, we didn't hold a lot of policies that we've implemented to this standard of research. It's just a way of stalling it, as far as I can tell, stalling the implementation, and I don't see the point.

I don't know if that's helpful, but that's my opinion.

DR. MILSTEIN: I think, you know, being asked to address this question, as the title of the slide indicates, is a great opportunity for us to lay out what we think would be required for a robust R&D capability within Medicare, an R&D capability that applied not only to Medicare policies, but also the care manufacturing process, the process by which you put in certain resources and certain health emerges. It's that input-output relationship. And I think, you know, Medicare needs an active R&D function with respect to both kinds of tests.

Who knows whether or not the slow cycle times and a failure to home in on current parts of the Medicare program that is working super efficiently and understand -- you know, reverse engineering what that is. But for

whatever reason, it doesn't seem to be happening within the Medicare program and the constraints it faces in congressional funding and authority. So I just think it is -- reflecting on the fact that this has not worked very well, you know, over the last X years, this is a terrific opportunity for us to say as you look across other comparable programs, whether they are within Permanente, within Germany, whatever it is, you know, what do we think is the best bet for an R&D operation that would essentially become for Medicare this vision of a learning organization that is sort of constantly scanning the environment, finding allegedly better ways of doing things, quickly testing, you know, with some rigor as to whether or not it is actually working, and then if it is working, quickly getting the info out and with some concrete recommendations to Medicare as to what policies might begin to drive these, advance these most quickly.

Anyway, I'll stop there.

MR. BUTLER: I have a little different view on this in the sense that we're kind of taking some pretty hard shots at the evaluation model and losing sight of the fact that, first of all, this is not exactly our competency in

this group to comment on this. I think we are all struggling with understanding what the proposal is and how it might be better.

But, also, I think some of our struggles is that, you know, chronic care in the elderly is at the heart of what the whole thing is, and the models are struggling because nobody is owning it, and so these interventions that are being proposed are often a nurse coming in and being the trusted agent to coordinate all this stuff, and no wonder it is so hard to kind of both put the model together and evaluate it, because kind of nobody is owning it. And really, Ron, it is not the -- I mean, doctors care about this, but it is just all falling through the cracks to some extent.

So one of my comments would be that -- and by the way, Rush is one of the 13 participants, and I don't know actually that much about it myself. So that tells you something about it But it's a passionate group that is trying to fill a void, and they're going to go about their research ways in some way, whether it's through this or something else. And this may not be the right model to do it.

In fact, Rush is also a participant in an Action AHRQ Network, and I've also participated myself in another practice research-based, and one thing is true. They take time, they're cumbersome, and they don't create results in an efficient way. What they do do is get an army of passionate people kind of spreading the word, learning from each other, and it does create some momentum. But you're right, it doesn't create real-time, quick results, and that is just the nature of the model. And whether there's a place for that in an overloaded CMS agenda to prioritize it is, I think, something we need to at some point weigh in on, because as we looked at the various chapters and reports that we're kind of all throwing up against the wall and seeing which one sticks, at some point as you do your summary of the overall interventions that we might recommend along the continuum, it would be a nice thing for us to kind of weight these to some extent and say, you know, these ones might -- if we were to prioritize where we might get the most leverage, it might be another way to look at this. A good idea, but in the balance of the rest of the things going on, maybe the energy ought to be a little bit more here or a little bit more there, because we don't do that.

We just give a series of opportunities which end up in some congressional thing that still has to be sorted out. And I think we could help prioritize if we looked at the whole list of things.

MR. EBELER: Two stages. One is commenting on the proposal. I guess I would be on the side it just strikes me this is the wrong way to pick either the entity or the particular design. There's a variety of reasons for that, but I'd start there.

I do think it's a wonderful opportunity to pivot to your last chart. I'd add three things there. One is I think the variable we are trying to focus on in the short term is obviously what is CMS policy levers that we're trying to change.

Second, I think we're talking about two things underneath that, though. I think we're talking about what we're calling R&D, which is an academic model which takes us down one path of design and standards of evidence. I think the other thing we maybe could be talking about is more rapid cycle, organizational, and payment change that has a different standard of evidence but is also something we want CMS to do. And when we blend the tools and the standard of

evidence of those two, we get confused. And I guess I would encourage us to think about both, because it strikes me, again, if we're going to pivot of this to talk about sort of rapid -- really trying to change things, I think we need both tools in our toolkit.

Third, the one thing that is appealing here -- and, you know, maybe we need to say this at some point. We talk about trust fund funding. There is a point in our concern about CMS resources where we may need to speak to financing some of those resources and crossing this bridge between appropriations and trust fund. I think the only place -- Bill, correct me if this is wrong -- where we have crossed that hurdle is in fraud and abuse, and as a result, we've gotten a lot of fraud and abuse activity.

Just at some point we may need to put money behind the words we're saying, so it strikes me as something I would at least think about considering here.

MR. RICHARDSON: Just a quick fact. The quality improvement organizations are also funded directly out of Medicare trust funds.

DR. DEAN: Like several have mentioned, I was troubled by sort of the lack of demonstrated effect. I

also, like Peter, need to -- I have sort of a conflict. One of the organizations in this proposal is the Avera organization, which I work with quite a bit. But, anyway, in their defense -- and it isn't really to really defend the proposal so much, but it speaks to Glenn's concern. They were very frustrated because they got none of their data back in a timely fashion. And as they finally got towards the end of the project and began to get some of the early data back, they found that there were sub-groups that they were dealing with where they could show some effect. And had they had that data on a timely basis, they feel that they could have demonstrated a much more positive effect.

I think that is a fair comment, and it probably speaks to the broader question that if we are going to promote projects like this, it should be built in right from the start that there is an adequate analytic capability on whoever is doing the analysis to get feedback at a time where it can really make a difference.

The other comment that I would make sort of follows up a little bit on what Ron said, and that has to do with the fact that, of the four projects we looked at, the one that came the closest was the one where these activities

were most closely tied with the actual delivery of the care. And it seems to me that those two have to be tied together, and closely tied together, if we are going to expect an effect.

DR. CROSSON: I'll make one point that hasn't been made and then just reiterate quickly some of the others that already have been.

I wanted to just point out that, with respect to the review of the group practice demonstration project, I might want to suggest a little skepticism about the skepticism of the financial impact, because primarily the time frame is still short. So if you look at, for example, the question of whether our belief in the cost savings ought to be obviated by the fact that the coding increased, if you look at the examples on the bottom of page 28, blood pressure screenings, foot exams, cholesterol screening, colorectal cancer screening, and mammography, which are related to the quality measures, you would expect actually, if you're trying to improve all of those things, that several things would happen. Your costs would go up, number one, but also the identification of individuals with hypertension or with diabetic foot disease or with

colorectal cancer or early breast cancer or whatever would also increase; and, therefore, the coding would go up.

However, the purpose of preventive medicine and early detection techniques, in addition to trying to save people's lives and reduce morbidity, is to reduce long-term morbidity and long-term costs. And all of that is not going to occur within a three-year time period. So I just want to make that point.

With respect to this consideration of the MCCPRN, I see nothing in the presentation that would convince me that we should return a positive verdict on this, for all the reasons that the staff has raised as well as the issue -- and I agree with Ron on this, and Tom -- that I think the preponderance of the evidence and also my own experience has been that disease management, case management, care management techniques, the success of them tends to be very closely related to whether they're actually integrated into the care delivery as opposed to applied extrinsically. And I think for that reason alone I would probably view it with some skepticism.

And, finally, on the question of, you know, is there a better way to do this, I wrote down -- after Arnie

talked, I wrote down the term "reverse engineering" also, which I think is exactly the technique. When some nations that were developing after the Second World War tried to figure out how to build an economy, they didn't start from scratch to build a transistor radio or other forms of products. They took ones that were in existence, tried to take them apart, look at them, and make them better, and apply them to perhaps some new uses.

I was also intrigued by the notion that perhaps in doing this and in thinking where, A, the money would come from and, B, where the work would happen, the notion of maybe thinking about comparative effectiveness research -- the definition of that, anyway -- a little bit more broadly might be useful, because there is a question about comparative effectiveness of what? Just clinical interventions, or how the structure of the delivery system and how the delivery system, for example, is paid impacts on the cost and quality of health care seems to me legitimate.

So you can imagine then, given the interest in that, that there might be more money available, and that some of that work could occur in the kind of process that we would call inside of our own organization operations

research. And no offense to academics, but in the operational realm, problem solving tends to take place much more quickly. And I think that model that Jack described, I don't know where that would be done or exactly how it would be funded or how it would relate to CMS and its R&D function, but I think it's a good idea.

MR. HACKBARTH: Just to pick up on that point for a second, Mike, the difference is you're playing with your own money, and when we're talking about potentially paying for new services -- you know, something that Medicare doesn't now pay for, we're adding a new code, so to speak, and a flow of dollars -- then they're playing with somebody else's money. When you're playing with your own money under a fully capitated system, then if you make a misjudgment in your quick movement, you know, you pay the cost. And one of the things that holds us back in fee-for-service is, well, we're going to start paying a new line of revenue to a new set of entities, and if we make a misjudgment, it is going to be more costs on an already bloated system.

I think that's one of the reasons why people seem to be so hesitant about more quick and dirty analysis. Just an observation.

DR. CHERNEW: First, I'll just say something in response to Jay's comment. Most preventive care, which I am extraordinarily supportive of, is cost-effective not cost savings, even if you go for long periods of time. Peter Newman has a New England Journal article on that point. So the idea that doing all these good process things will eventually save you money and it's just a matter of time I think sounds a lot better than the evidence would suggest that it is.

That said, I feel extraordinarily strongly that we should encourage greater use of preventive care in chronic disease management because our goal isn't to make the system cheap. We could do that a lot easier. Our goal is to make the system better in other ways. I think we do have to address costs, but addressing costs by not providing preventive care seems like a crazy thing to do.

So I think that looking at these results and all the multiple comparisons suggest that at least what we've done so far hasn't been a rousing success, and the response to that has to be we have to try better as opposed to we have to throw up our hands.

And so that leads us to the question of, well,

what process should you use? And it's late in the day. I've been up for a long time. I've had a lot of sugar, if you've seen the Lucky Charms I've eaten. And so I'll say this strikes -- this MCCPRN process, which I haven't read or evaluate in any way so I won't speak to that specifically, but the process it followed strikes me as amongst the worst possible processes I could possibly imagine if I wanted to think of a really bad process.

For one -- and I could be completely wrong because I might not know that process. So, again -- are we done?

MR. HACKBARTH: We'll put you down as a maybe.

[Laughter.]

DR. CHERNEW: There are existing review panels for how one might fund and evaluate things like that, where in general you would try to avoid having the people doing the implementation or the evaluation doing the evaluation of it. You would tend to have, you know, a lot of other processes where they might compete broadly against other ideas for interventions.

Now, maybe they've done a great job. Again, I'm not talking about that particular thing. I might see the proposal and compare it to others and say this is one that

should definitely be funded. There are certainly some really high-class organizations involved in that, so I'm not knocking it in any way. But as a process, I think the idea of having money going through -- we might not be able to evaluate this, but the idea that the congressional ways could figure out which ones to do I am more skeptical of. I think it's crucial that there be more money funded to evaluation and more authority to CMS to try innovative ideas. I think other people around the table besides me could figure out the right processes to do that.

I believe strongly that AHRQ should get a lot more money to support the types of evaluations that they do. They're reasonably good at having study sections and figure out what to do. I think a trust fund way to do that evaluation is fine.

One could send that to CMS, through CMS. I am less comfortable how they would execute that. I think broadening the idea of comparative effectiveness research type things to include broad systems interventions is actually absolutely crucial. And I think more funding to do that is very important. And I think any MedPAC statement to that effect would be extremely important.

I think that it's also important to understand the distinction between the evaluation and the design and the implementation, because I know the people who have been interested in this competitive bidding stuff for a long time, and they've become incredibly frustrated because they can't evaluate a competitive bidding demonstration until you have some competitive bidding demonstration. There's all kinds of various road blocks on how to do that. So giving CMS some flexibility as to what they'd do, if they wanted to do episode-based payment and things, that I think is actually crucially important.

You're never going to solve the timeline in how long it takes for the data to be generated and evaluated. That is just how long it's going to take. But to get it through the red tape to be implemented I think is crucial. To have a rigorous, independent evaluation I think is fundamental. And I certainly think more money to support those activities and more authority within CMS to conduct those things is extremely valuable.

DR. SCANLON: I think I agree with the majority that the network idea is something that we should say no to, but I think we should treat it as an opportunity that we've

been asked this question, and we can say, well, there's really a different question that you should be asking, which is that we're starved for innovation in Medicare and how do we get it. And the issue is how do we build the capacity in CMS to do that. And so if you have $60 million that you're willing to spend, we have a place where you could spend it.

But it goes beyond sort of the Office of Research and Development. It's a more fundamental question about CMS capacity, because I think that -- and this is not total familiarity with these demos in terms of how they were operated within CMS. But the idea that there were data lags and that data lags were a real problem is not a shock given the state of CMS health information systems or information systems.

This has been a chronic problem forever, and we can change the timeline in terms of this if we were to change the information systems and kind of bring them into the 21st century, because there are all kinds of organizations that are going to know today what they did today. CMS, in terms of what claims are paid today and to be able to know in detail about them, it is going to be months, if not a year. So that is not something that needs

to be the case. We can change that DNA. We can make them more capable of doing these things.

And so it's the idea of we need to invest in the capacity to administer the program if we're going to get the kind of innovation that we're talking about here in terms of research or what Jack was mentioning in terms of short-term analyses, because you got to have the data closer to real time.

MR. HACKBARTH: Good concluding comment, Bill. Thank you. John, good work, and we'll talk more about this next time.

Let's move to our final session of the day.

We're going to have a presentation by Chris Hogan, an old friend whom we haven't seen for a while -- Chris, good to see you -- on the effect of secondary coverage on Medicare expenditures.

DR. SCHMIDT: Let me introduce him, if you do not know Chris. Last year, you saw a couple of presentations about Medicare's fee-for-service benefit design and some illustrative changes to it. And as part of continuing work on that issue, we're happy to have with us Chris Hogan of Direct Research, LLC.

Chris is an economist with extensive experience analyzing the Medicare program. He is a former staff member of PPRC and MedPAC and is currently a private consultant. And we asked Chris to take a new look for us at the issue of how the presence of secondary coverage to fee-for-service Medicare affects beneficiaries' use and spending.

DR. HOGAN: Thank you. We're running a little late, but I can talk fast so let's get right to it.

The first slide shows you the scope of what we're talking about here. I will take it as a given that most of you understand that out-of-pocket costs reduce health care use. There is a preponderance of evidence to suggest that. The Medicare program was designed with co-insurance and deductibles. But you also know that almost no Medicare beneficiaries actually pay the full Medicare co-insurance and deductible amounts. Your own statistics say eight out of nine in the fee-for-service program have some sort of secondary insurance.

My job today is to remind you of what that does to total payment in the Medicare program, both, I guess, throughout the program on the fee-for-service side and, by reference, to what you pay under Medicare Part C, as

empirically as possible. And then although you hired me as a data analyst, not a policy analyst, I'll just provide you a little jumping-off point if you want to discuss policy.

The proximate reason I'm here is that more than a decade ago, staff of the CBO and the Physician Payment Review Commission independently looked at this issue and came to a pretty solid agreement that secondary insurance increases Medicare's costs a lot, and that the impact was largely on Part B services. But last year -- I guess it was last year -- a paper was published in Health Affairs that said, no, no, you goofed, you forgot to account for Veterans Administration coverage and the free services provided by VA facilities. And if you do that, you get a much, much smaller impact of secondary insurance in terms of how much it raises spending. So Rachel called me up and said, "Would you like to redo the numbers?" And I said, "Fine."

I'm going to take three years' worth of MCBS data. I'm going to compare those who do and don't have secondary insurance. I need three years' worth because there are so few beneficiaries who don't have secondary insurance, it is kind of dodgy to do it any other way. Carefully, I want to say even tediously, address this issue of Veterans

Administration coverage, measure total spending, and anybody could do that, but probably more interestingly, look at the mix of services, not only that spending was higher but where was spending higher when beneficiaries did not have to pay out of pocket.

As a contractor, I can never tell you that it was easy, but I can tell you it was conceptually straightforward. I have to figure out who's got what insurance, throw away the people I don't want to look at, and compare. That's it. And so that's what I'm going to do. And when I compare them, I'll adjust for as many things as I can fit into my regression model in terms of education, health status, and so on and so forth. Once I've gotten the file down to the population I want to look at, figured out what insurance status they have, and done the comparison, after adjusting for all these other factors, whatever else is left in terms of the difference in cost between those who do and don't have secondary insurance, that's what I'm going to call the impact of secondary insurance. It's sort of the standard way this is done.

Unadjusted, before doing any of those adjustments for all those factors, the raw numbers show a very large

difference in spending. Those who have private secondary coverage spend about spend about 54 percent more in total than those who don't. That's a little bit in Part A and a huge difference in Part B.

Now, I can't take that raw number as any estimate of the impact of insurance because the populations who do and don't have secondary coverage are just radically different. So let me quickly go through how different they are.

This is a capsule summary of the differences between the beneficiaries who have Medicare only and those who have any private supplemental insurance, and I've divided it into five sections. I'll briefly describe it as cost and use, demographics, education, health status, and income.

Briefly, the cost and use section, the little boxes at the top, is in a nutshell what you're going to see in the rest of the analysis, that people who don't have secondary coverage pay a lot more and use a lot less.

The demographics, education, and income work out like this: The population that doesn't have secondary insurance is more likely to be single, male, minority, less

well educated, lower income, and still working. And to me that profile very much fits the idea of a population that fits in the notch between being so poor you're on Medicaid and having had such a good career and so much money at the end of your life that you have either employer-sponsored secondary coverage or you can go out and buy Medigap. So I like to think of them as the working poor of the Medicare population, is what we are looking at here.

In terms of health status, they don't report any differences in health status to speak of, but the claims-based health status measure called HCCs, which is on the chart there, shows a big difference in health status. Now, maybe that's real, or maybe that's an artifact of the fact that if 20 percent of these people don't have any claims at all -- in other words, my data are censored in this regard -- I'm going to take it as real and factor them into my analysis.

When I go to a regression-adjusted estimate -- this would be sort of the adjusted analog to those raw numbers -- what I want to show you here and through the rest of the slides is dollar figures for the people who don't have secondary insurance and percentage increases associated

with having secondary insurance. The middle line is just about the average for everybody who has secondary insurance. After I make my regression-based adjustment, total spending for the people who have secondary coverage is 25 percent higher, not much in Part A, a whole lot in Part B. And at this point I could stop. These are just like the results we got 10 years ago. These are consistent in magnitude with the National Health Insurance Experiment. But wait, there's more.

I'm going to show you how the mix of services changes, and all of the succeeding slides are organized the same way. I'll show you a dollar figure for the people who don't have secondary insurance. I'll show you a percentage increase associated with having secondary insurance. And I'll sort them so the big impacts are always at the bottom. So in the next set of slides, you want to look at the bottom and say that's where the additional services show up, is at the bottom of the slide.

Where are the additional services for the people who have secondary coverage who aren't paying the co-insurance? They take place in the office, primarily.

Who's doing those services? Well, it's mostly

medical specialists, to some degree surgical specialists.

What kind of -- oh, I'm sorry.

DR. MARK MILLER: Chris, if you'll go back to your first one, the office has the biggest effect, but it's not zero.

DR. HOGAN: Correct.

DR. MARK MILLER: I appreciate you going fast because it's the end of the day, but perhaps just a little slower.

DR. HOGAN: While secondary insurance is going to increase services across the board to a degree, the biggest impacts are going to be at the bottoms of these slides, and that is really -- so it's not as if -- what am I trying to say? Let me take it the other way.

The effects are now uniform. It's not as if everything goes up 20 percent, 30 percent, 40 percent. What I'm trying to do is get a handle on what has a price elasticity, in the jargon of economics, and what doesn't; what stuff is always going to get provided, and what stuff is going to get provided more often when it is free to the beneficiary. That's what I'm trying to get at.

And so if you look at site of service, is it big-

ticket stuff being done in the hospital or little-ticket items being done in the physician's office? And perhaps reasonably, it's little-ticket stuff being done in the physician's office.

If you ask who's doing it, well, it's not your generalists. It's your medical specialists. Usually the medical specialists end up being the bad guys in all these discussions. What a surprise. That's the way they end up here. I have to be circumspect because I work for people like that now, but that's the conclusion there.

What's being provided, I thought this was interesting. No difference at all. Top of the chart, no difference at all in emergency visits, and if I had put in -- - these are the Berenson-Eggers type of service categories, and there's lots of them, and some of them have too few dollars in them for me to be able to demonstrate what's in them. Sometimes I had to aggregate them up to get a stable enough average. And I've taken sort of representative sample of all these categories. There's close to a hundred of them.

There's no difference in emergency care, and had I shown you ambulance rides, for example, no difference in

ambulance use. So if it's an emergency, co-insurance doesn't matter. At the other end of the scale, minor procedures and endoscopies, well, almost twice as much in terms of minor procedures for the beneficiaries who don't pay Medicare co-insurance.

I'm hoping you'll get the same flavor out of these that I did when I went through them. If I went to look and see what was going on on the inpatient side, it's difficult to get a simple handle on what inpatient care looks like. But this flag is already on the claim, so I decided to go ahead and summarize it. There's no difference in emergency or urgent admits. All of the additional Part A inpatient use is in elective surgery, which is almost twice as much for the patients who don't pay the co-insurance.

Finally, there's nothing more elective than preventive or screening services. They can be delayed, and you do not really see the bad effects immediately. And spending for all preventive services on a per capita basis was just about twice as high for the beneficiaries who had secondary insurance. And I think that is well documented. People have shown over and over again that co-insurance for mammograms suppresses the mammogram rate. Well, there you

go. You are looking at it right there. And understand, please, it's not a huge amount of co-insurance for a mammogram. It's $20 or $30 in the Medicare program, and that is enough to change the mammogram rate substantially.

So at this point, all I've done is show you site-of-service cuts, and I hope you get the same impression from this that I do. It's sort of little-ticket, non-emergency stuff that gets -- and prevention services stuff. I just want to assure you with one cut based on beneficiaries that it's not as if you only see these effects for poor people or you only see these effects for the healthy people or you only see them for the youngest age as opposed to the older. You see these effects throughout, and the way to demonstrate that easily, I think, is to divide the beneficiaries based on presence of some significant chronic condition.

Now, for this slide, I was shooting for the top five causes of death in the Medicare program, and I also added decedents as a classic very sick population, known only ex post. And the bottom is none of the above. The bottom is people who didn't have any of these conditions and didn't die.

The most important thing to get out of this slide

is that the right-hand column is full of asterisks; in other words, no matter who you were, no matter what sort of illnesses showed up in your claim stream, it's always the case that the beneficiaries who basically get their care for free use more Part B care. And the largest difference, the largest percentage difference was among what I would call the "presumed healthy." The people who didn't have any of these top five killers and who didn't die, they had the largest difference in spending.

So at that point, I want to try and sum up, and this is hard. This slide kept morphing right up until yesterday. The first line is always the same. Secondary insurance raises Medicare's cost substantially, and the key word there is "substantial." No different from what was the conventional wisdom 10 years ago.

It's difficult for me to get a nice description of the change in service mix, partly because I don't want to use any loaded words like "unnecessary" or, you know, anything like that; and partly because what you see here is not -- I haven't tested any hypotheses about service mix. I've just taken whatever targets of opportunity I could get to try and characterize it. But to me as an economist, if I

had to put all those observations in one place and try and give a succinct mental model, not tested but just the way I look at it, the people who have to pay their own out-of-pocket costs, they're more tolerant of small medical risks; they're less willing perhaps to pay to fine-tune their health status with modern procedures; but there's no difference when it comes to life-threatening episodes.

Now, having said that, I have failed in my task to have neutral wording here, because you could just -- as I said, more tolerant of small medical risks. You could just as easily have said forced to take more small medical risks, however you want to characterize it. The real bottom line is they take more small medical risks. They use less of these small medical procedures. But when it comes to life-threatening care, there appears to be no difference.

Whatever spin you want to put on the existing data, the one thing I want you to get out of this is "strongly" -- out-of-pocket costs can strongly influence beneficiaries' choices of care. It's not merely 25 percent in total spending, not merely 50 percent for Part B, but 2:1 differences in use of these services that seem to have, I would say, a high price elasticity or high sensitivity to

co-insurance.

With that, let me segue to these two essentially disposable policy slides.

I am not here to give you policy advice, but I will through and queue up some discussions. I'm sure you can do this on your own. You don't need me. You can look at policy either backward-looking for forward-looking, look back at the existing co-insurance or look forward to something new you could do.

Looking backward, if you could limit secondary coverage of the existing co-insurance and deductibles, you would almost certainly save a substantial amount of money. I did a little back-of-the-envelope as I was coming down here, and given the algebra of the situation and given my estimates, 14 percent on average is what I would guess, you would save that on the fee-for-service side, and presumably that would reduce your basis for Part C. So the whole program would come down 14 percent. But if you did that, you'd probably want to rethink the benefit structure. You'd probably rethink the fact there's no stop-loss. You'd probably want to rethink the fact that you charge co-insurance on services that you want beneficiaries to get,

like preventive care. Most preventive care, remember, didn't exist when they -- the mammogram benefit only came in the mid-1990s. So when the people set the structure up early on, they really weren't thinking about preventive care, although Congress didn't exempt it from co-insurance. And the high inpatient deductible, interacting with emergency admissions, it doesn't really seem to do much. It doesn't deter people from getting most of their admissions, because most of their admissions are urgent or emergent.

But with regard to this notion of limiting secondary insurance, I can -- I had a little joke I was going to tell, but I don't dare do it in this audience. Based on my experience with the Physician Payment Review Commission and testifying in front of the National Bipartisan Commission on the Future of Medicare, this is a really hard topic to discuss. And I'll just say name your constituency, I'll tell you why they hate it. And it doesn't go any deeper than that.

Going forward, could you introduce a new and defective co-payment, and here I want to say co-payment as a fixed-dollar amount so people know ahead of time how much they're going to owe for a service. So for purposes of

discussion, let's make it minor. It's a small, fixed-dollar amount -- $10, $20, $30; subject to an annual per beneficiary limit, so we're not going to bankrupt anybody. Of course, the Congress would have to exclude this from secondary coverage by statute, as they did with certain parts of Part D, so the Congress would say nobody can pay this, it's got to come from the beneficiary; and you would exempt the usual suspects.

If you could get that in place, what could you do with it? Well, the easy thing would be an across-the-board fee. It's not very imaginative, but it's fairly safe, and it would almost certainly save you a little money just to make beneficiaries think a little bit before going for that additional service.

The alternative would be to try and target it, to dovetail it with your quality data or to dovetail it with your financial profiling. But I view that as sort of a two-edged sword, that if you're going to use this in that way, you would have to have a fair degree of confidence that the data you use to pick winners and losers has a very high signal-to-noise ratio, so to speak, that your low-quality hospitals, so-called, really are low quality, and your high-

quality hospitals really are high quality, because you are going to move beneficiaries among them.

So my final thought for you is let me characterize these targeted co-payments as a powerful but two-edged sword, and you would have to think pretty hard before you tried to implement that in the program.

With that, I will turn it over for your discussion.

DR. STUART: If I understand your methods, it seems to me that you're actually capturing two effects in your measure of the impact of health insurance. The first is the one that you really want to get, which is the true price elasticity and demand. And the second effect is any unmeasured variance, predilection to use services that is also correlated with having a Medicare supplemental policy. And both of those work in the same direction.

DR. HOGAN: There's a more detailed discussion of this in the paper. And your argument is true for the individually purchased policies, but probably not true for people who have their employer-sponsored coverage.

DR. STUART: Well, I'm thinking about that. That may well be true, but it's also the fact that if you have

somebody that has had good coverage all along, which is the people who have retiree coverage, then they've developed styles of demand that are, arguably, going to be very different from somebody who either does have insurance on the individual market or not.

So, again, I'm not sure that I buy the conclusion that you're likely to get a big saving from imposing what looked like fairly small co-insurance upon people who are currently well insured, in part because of this. So there's a methodologic issue in terms of that missing, unobserved variance that leads to insurance. And then the second piece is people that have insurance and have had it a long time are probably going to be less sensitive than people who just didn't have it at all.

DR. REISCHAUER: I thought this really was fascinating and really a good piece of analysis. Just two little comments.

One is, looking at the use of age as a variable which you control on -- and I was surprised to see that they're close -- this is in a sense a decision one makes at age 65, and then there's a price put on delay. And so if you think of sort of looking at people at age 66, they might

answer some of these questions differently, like they might be considerably more healthy than the ones who choose the other insurance, but then as you go through time, they approach the other group in how they look at respect to health. You know, I think that might have some relevance here.

The second comment is about the looking-forward policy, and I agree with everything you said about the politics of making changes in this area. But one way one could go is, of course, to put a 30-percent excise tax on supplemental insurance policies than went back into the Medicare trust funds to pay for the induced utilization.

DR. KANE: I'm just curious to know if any of that excess utilization -- or that utilization by the supplemental group had any measurable health outcome differences, whether you were able to test that, whether there was a difference in morbidity or mortality between the two groups other than just their utilization differences.

DR. HOGAN: Well, their self-reported health status was about the same. Their health status is as I reported it on one of those charts, and --

DR. KANE: So ones with supplemental, is that the

same? It looks like it's slightly -- is the 109 worse than or better than --

DR. HOGAN: The 109 says you are expected to use more care. You are less healthy is another way to say it. So it's not clear -- I mean, from my standpoint, from adjusting the numbers, it was never clear -- what you would really like me to do is get to the outcomes of care, and that's a hard thing to do, as you know.

I can always say, you know, the health status that you're looking at presumably should be the long-run health status. It should reflect whatever outcomes of care they got over the last five years if their health status hasn't changed.

There was an effect for mortality in here, but I dismissed it. I looked at it and said I don't believe it, because it didn't correlate with anything else, that the population without secondary insurance had a statistically significantly higher mortality rate in one year, not in the other two. So I looked at it and said, ah, I'm not sure I believe that, given the rest of the numbers. I didn't report it out here, but it's reported in the paper. So I don't know that you can make a strong health status

argument.

DR. CASTELLANOS: Really good work and really eye-opening. You know, we've all looked at, all the Medicare providers, how we could save money. This is the first time we've looked at beneficiaries. And we're not going to make any difference unless the beneficiaries change their behavior.

I'm going to just open a box and ask if you had at all thought about cost-sharing and what your issues on that are.

DR. HOGAN: Oh, yes, but I've been told that if I start foaming at the mouth, I am going to have to have my speaker cut off here. I'm an economist, and to an economist, "free" is a four-letter word. That is the bottom line. Joe Newhouse wrote a book -- "Free for All?" -- that discussed the inefficiency of providing health care for free. But it's also inequitable to charge high payments for people who end up being sick. And so it's a real hard issue.

Where I end up personally is that modest co-payments are probably a not unreasonable thing to charge and that absolutely free tends to be inefficient.

DR. CASTELLANOS: Medicare does have cost-sharing now. They have it with the ophthalmologists and cataract lenses, and it's working very well. It's in policy already, so, you know, I don't know why we are kind of not getting close to that, or even talking about it.

DR. MILSTEIN: This potential manifestation of noise that you found with higher mortality in one year, that is the kind of thing that probably is best not left vague, particularly now that, you know, it has been disclosed. And I wonder if it might be possible -- I don't know what our budget is for this analysis, but the software to segregate claims -- segregate hospitalizations into several ambulatory-sensitive admission categories. It seems to me it would be the right place to do this. The software is not expensive. The analysis is not complicated to do. But I don't think we should leave that one factoid to linger. I think we should focus in on what would be a much more specific signal, which is whether ambulatory care-sensitive conditions did go up or not -- that is a much more sensitive signal than mortality -- and then ascertain whether or not that is or is not a problem with higher cost-sharing.

DR. MARK MILLER: I also think that when you start

to get into -- you know, I think the level of analysis that's done here, you can start to delve into these questions, and then they will immediately trigger questions from, you know, certain people about more sophisticated methodologies to start to control for interactive effects. And these things can get very complex and begin to get more judgmental as you get into those methods. So it's a question -- you know, I mean, the first thing we asked Chris to do was deal with this new analysis that had come along and said, oh, by the way, the secondary payer effect isn't that large, which was a shock to a lot of people. And so that was the first thing he dispatched. And then as an added bonus, he kind of took us through some of these effects underneath.

It can get pretty hairy methodologically, and I know we've had -- long ago now -- conversations about how to kind of go methodologically through those issues.

DR. MILSTEIN: It would not require more analysis, but what are your comments on whether or not your estimation of -- what was it? -- a 17-percent reduction, a 14-percent reduction in Medicare spending if this effect were removed? Any comments on the likely applicability of that finding or

relevance of that finding to the Medicare Advantage program, which is where we are struggling to convert that into a vehicle for greater affordability. We're not doing too well. Any comments on the -- since that is a program by which supplementary benefits are provided, it would reduce cost-sharing. Is there any opportunity to -- how far along the study -- it would be interesting to essentially give us some idea as to whether or not there is an equivalent savings opportunity that might be achievable in the Medicare Advantage program via policy changes that might fall along the lines of some of your policy ideas or the idea that Bob mentioned.

DR. HOGAN: I must say I only brought that up to remind you that if you managed to bring down the fee-for-service costs, it would reduce your Part C payments as well, so that your savings as such would be across the board. I really haven't given it one inch of policy thought in terms of the Medicare Advantage side.

DR. BORMAN: I have two sort of definitional questions and one sort of interpretive question. Could you share with me the differentiation of elective admission versus urgent.

DR. HOGAN: It's a flag on the claims.

DR. BORMAN: Yes, I heard you say that.

DR. HOGAN: What I did was test it before I used it, so not shown here -- hospitals don't get paid on the basis of it, and I don't know the difference between emergent and urgent. But MedPAR took hip replacements, found the ones who had fractures and not. Almost all the ones with fractures were urgent. Almost all those without fractures were elective. So hip replacement is indeed intuitively what I expected, and I sort of assumed it worked about right. I'd have to go look up in a manual to tell you what the definition is supposed to be.

DR. BORMAN: Because I would anticipate that for the diagnosis that you just described, that would sort out by diagnostic code. But, for example, the majority of people who under a cholecystectomy, it's going to be on a planned admission basis, but it's not something that they just signed up to do for the fun of it. Probably back there within the preceding, you know, one week to six weeks, or somewhere in there, several months, there have been some episodes of, you know, distress that prompted either physician visits, emergency room visits, et cetera.

Certainly ICD on the diagnosis side is going to be a highly imperfect way to sort out what's truly elective or not. And so I would just urge a little caution about this piece.

I understand the finding that it is all higher, and it makes intuitive sense to me as a practicing physician. But I think as we try and sort of say some things about the magnitude of the effect, I guess I would worry a little bit about endorsing this one at this level of difference, because it is almost a 100-percent increase, without knowing a little bit more about it.

Another one, if you could clarify a little bit, is how did you place people in surgical specialists who do interventions like angioplasty but who are not surgeons, i.e., interventional radiologists, interventional cardiologists. Was it based on self-designated specialty? Or is it one a characterization of the kind of service provided where it sums up in some other system?

DR. HOGAN: It's self-designated specialty. This is a small sample. One more thing, a lot of these measures are targets of opportunity not because I was trying to be vague, but because I've got 1,800 people to work with.

For example, I wanted to look at total knee

replacement as being something that is a clear quality-of-life improvement and people get it when they hurt a lot and presumably it's good for you and costs a bunch. And, you know, there's three in the sample of people. So there was limited opportunity to do anything on a service-specific basis.

DR. BORMAN: Please know I'm not being at all critical. This is a wonderful analysis. It's a good starting point for our thinking. It's wonderful information. A chunk of it fits my biases, so I'm with you, okay?

[Laughter.]

DR. BORMAN: At any rate, if I could ask you about one interpretive question, and it's on page 9 in here. It's the chart with the carrier spending by site of service. In most everything else, at the end as you tried to aggregate this up, in general the conclusion -- and it seemed to match up -- was that relatively minor things are where the money is, if you will, in this. That's why I'm a little surprised that inpatient versus OPD/ASC, why then is that not more different? Because the things that would be in OPD/ASC, generally speaking, will tend toward the minor versus the

major. And I would have thought that might have come out to more of a difference.

Is there something that I might be missing here why those came out so close, basically the same?

DR. HOGAN: I can only guess, if you want me to guess.

DR. BORMAN: Absolutely.

DR. HOGAN: Surgeon's fees is what I thought that was, that the difference in admissions wasn't large, but for the so-called elective admissions, my guess was they were elective surgeries, and you can get a substantial -- this is all Part B, you understand. You could get a substantial Part B payment for a single admission where you wouldn't for a medical admission, say.

DR. BORMAN: I am not following.

DR. HOGAN: So carrier spending is only the surgeon's fees and physician's fees, and so I thought that -- I noticed that, too: Gosh, look at all that inpatient spending. Why shouldn't that be much lower? Because the inpatient dollars were only about -- I'll call it 9- or 10-percent difference. How could there be a 32-percent difference? But I think that the inpatient admissions that

are excess, that are additional in the population with insurance tended to be those admissions that had a lot of Part B services associated with them, such as surgeries, as opposed to medical admissions where you see a few visits and a few test interpretations and that's it.

So I thought that they were probably more physician-payment-rich admissions, but I didn't test that.

DR. MARK MILLER: Can I ask on this one -- because this one slowed me down a little bit, too. And it may just depend on what's in that first row, because, again, you know, I'm looking for small -- you know, consistent with the whole thing, kind of small discretionary stuff, more likely to have a bigger effect.

So in that first row, what kind of population -- because I was thinking labs, but maybe that -- and, therefore, I would have expected a large effect.

DR. HOGAN: Man, that's another -- I'd have to go back and look. I can clarify that.

MR. EBELER: Thank you, Chris. I think your mistake here is you did a little bit of research, and we want a lot more. And I do think if one went forward with a policy proposal in this area, you would need to answer all

the questions we're looking at. This is really a very difficult place to go. I can't tell how you adjusted for MSP, Medicare Saving Program, participants at the low-income scale.

DR. HOGAN: Oh, Medicaid. Yes, Medicaid is definitely out.

MR. EBELER: Right, Medicaid is out. But what about the MSP program?

DR. HOGAN: Medicare secondary payer?

MR. EBELER: Savings Program. The low-income beneficiaries who were above Medicaid, but still get some subsidies.

DR. HOGAN: Oh, I'd have to go back and check the flags to make sure that they're not in there, but I'm pretty sure that they were categorized as having public secondary coverage and would have been omitted. But I have to go check that.

MR. EBELER: Again, I think I'm sort of getting a sense of differential -- I get a sense of how you -- the characteristics of the two populations are different, but I think we would need to know how the impacts differ by those characteristics, again, if we would go forward. I know that

it's easy to list things we want.

I think the MA question is important. On the one hand, you don't worry about this effect in MA because the costs are internalized. But unless we were very confident that MA was really working the way it was intended to work and we were getting a good buy out of it, I think you would worry about driving people from -- if you pursued your policy idea, one, I'd be worried about driving people from fee-for-service and Medigap into MA because it's the place I can avoid cost-sharing. You know, like I say, driving them there now is not exactly driving them to a place we're getting a good buy. So I think we need to think through the MA thing.

I think Bob's idea is interesting, and, in fact, when CBO looked at this issue, that's the option they put on the table in their recent options book, which was interesting.

And, finally, when I think through the policy ideas, your page 2 strikes me as -- if one's going to go down this road, it's going to take a lot of work. It would be more beneficial to be thinking through creatively what and how cost-sharing should work right in the future rather

than trying to kind of backward map and figure out how to change Medigap in the short term. So it just strikes me if we're going to there, it's going to be very intensive. It seems to me this is more beneficial.

Again, I think that part of this is just a resource and time question for the Commission.

DR. SCHMIDT: Just to advertise, next month we hope to bring you something that is notionally getting towards what you were just talking about.

MR. BERTKO: Chris, a couple of things. First, on the VA stuff, to address the question from the last article in 2008, how clean was your removal of them? Because I know that in some cases there could be "ghosts" -- that is the phrase some people use -- in the system. Are you pretty happy with what you've removed?

DR. HOGAN: I was responding to a specific criticism, so whatever they did I did. I left the ghosts in knowing full well that the information is partially correct and partially imputed. And anybody who showed as having any VA service use of any sort, including drugs -- most of it was just outpatient drugs -- I tossed them. So it's a very methodologically ugly thing to do. I would never flag

people based on service use. It's just a dumb thing to do. But it's what I was required to do here.

The ghosts didn't seem to matter much. They seemed to be equally distributed across the categories, as they should be, and so I just left them in.

And there were a lot of things -- when you said MSP, I thought you were saying Medicare secondary payer. I checked those, and they were equally distributed. I put those in. Urban-rural was equally distributed. So there were a lot of things that I looked at and didn't bother with because there was enough to mess with. But I didn't think it made much difference.

The VA beneficiaries were concentrated in the population that has no secondary insurance per Medicare's -- the way they measure it. But they weren't so different in their spending as to make a huge difference, in other words.

MR. BERTKO: Good. I've nagged Rachel probably for two years to see this study, so I'm glad it came out the way that I thought it was.

The second part was I just wanted to double check. The 14 percent that you cited is on $460 billion, so it's $60 billion?

DR. HOGAN: A and B, and eventually it would trickle down to C, I guess, so it would be A, B, and C.

MR. BERTKO: But it's a big number, $50, $60 billion.

DR. HOGAN: Yes. In this day and age, it's tough to say what a big number is, but yes.

[Laughter.]

MR. BERTKO: You got me. I set you up.

Okay. The last one is the co-pay effect that you alluded to. My actuarial experience has been that going from zero co-pays such as Medigap to anything is the biggest effect, and then it's non-linear after that. What comments do you have on that?

DR. HOGAN: That's my impression. I have nothing to judge that by.

MS. BEHROOZI: This is partly because Nancy didn't ask you to slow down soon enough, so I just am going to ask you to just -- when you talk about adjusting for demographics, health status, income, and education, what does that mean in the context of your observation that the group without secondary coverage is more likely to be low income and non-white and, you know, other --

DR. HOGAN: Technically, I'm running a regression, and so I've got both the insurance coverage and flags for all of these other variables in the regression. In the right-hand side of the regression is some sort of spending, and that is it. Anything that I could -- it is a kitchen sink regression. Anything I could scrape off the MCBS that looked like it was relevant got thrown in. Most of those are nuisance parameters, but interestingly enough, if you want to read the full regression results, the numbers all looked -- educated people spend more, rich people spend more. It all sort of worked out right when you see the full regression results. It all matched my preconceived notions, anyway.

So you are limited, so you have got a few flags for the level of education, you've got a few flags for the income. But it's kind of -- I don't want to sound like, you know, they did it, too. But it's what everybody else would do with the MCBS is what I did. And the results seemed to line up well.

MS. BEHROOZI: My question, I guess, is not so much the technical one, but then what the impact of your observation that the people without the coverage tend to be

lower income and non-white in particular, and they're not people with Medicaid. You know, they're not the people whom we always can easily classify as low income. They're the working poor, as you say.]

To what degree can you estimate differences in income having differential impact on what people will spend if they have to pay out of pocket? And let me say it the other way. Your 14 percent assumes that a rich person will be as deterred from spending the $10 to see the doctor as the person who makes $20,000 a year, which makes them ineligible for any public subsidy, but it means a lot more to them than somebody, you know, making half a million dollars.

DR. HOGAN: That's a good -- I'm going to give you two short answers. The one short answer is half. All of that other stuff explained half the difference in spending, and what was left was what I assumed was insurance.

But your point is well taken in a technical sense, that my back-of-the-envelope really is a back-of-the-envelope, and I should have -- I have to think about whether I can do this or not -- stratified it in some way to get a tighter bound on that 14 percent. I don't think it would

make a huge difference, but I should go look. I didn't actually estimate -- I didn't say, for example, except for rich and poor, I didn't estimate different effects by category of beneficiaries. There's nothing really for me to get a handle on with that. But the point is well taken, that if the effects really were substantially different between rich and poor and everybody else is rich, then if I knock the co-insurance off, if they have to pay the co-insurance, it makes such a big difference. In fact, what I found with the rich and poor analysis that's in the paper is that they all seemed to have roughly the same elasticity. A little bit more of an impact on the poor, but not hugely so. But I get the point. I'm not sure I'm going to do the work to fix the point, but I get the point.

MS. BEHROOZI: I really feel like it's accepted as such a truism that behavior is affected equally by payment of dollars. and there's no examination of what that dollar represents in relation to that person's income status. And I think, you know, you made the statement, Chris, that it would be inequitable to charge high co-payments for people who are sick when they really need to access care. Similarly, it's inequitable and probably inefficient in the

broader sense to charge high co-payments for people to whom it means more to have to pay that $10, and then they end up avoiding necessary care, and then it's a very slight impact on emergency admissions, but maybe you see more of that as more low-income people end up not having -- or, you know, working-poor people end up having no way to cover that cost-sharing.

DR. HOGAN: I like to characterize the Medicare secondary insurance market as those who need it don't have it and those who have it don't need it.

DR. CROSSON: I hate to ask this but which round are we in?

MR. HACKBARTH: Round one and a half.

DR. CROSSON: I'll give you a one-and-a-half question or observation then.

MR. HACKBARTH: Consider this the last round.

DR. CROSSON: As I look at this and back away from it a bit, it just sort of, you know, screams at me and says what is needed here is something that people are calling value-based benefit design. So, for example, somehow adding co-payments or exempting or excepting from supplemental coverage the co-payments for imaging procedures and some

other group of things in exchange, for example, for -- on the other hand, exempting from the donut hole in Part D coverage for drugs for diabetes, for asthma, for hypertension, et cetera, et cetera. So that's the rational thing.

I guess to make it sound more like a part one question, I will turn to Rachel and say are we -- when you said we were going to do something next month, is it anything like that?

DR. SCHMIDT: Yes, we will have a discussion along those lines. We've been working on a draft paper -- and we'll see where it goes -- that kind of incorporates some of the material that we've already talked about last year on some of the problems with the current fee-for-service benefit design and some of the inequities that are resulting from it. And we'll include some of the material that Chris has just presented to you, as well as some discussion of given his results, what are the implications for future policies towards, you know, an ideal world of co-pays or restructured cost-sharing.

MR. HACKBARTH: I just want to chime in on this. This has come up in several different ways. I think it

would be very hard, both from a political and a policy sense to sell the idea of what we want to do is get the existing Medicare cost-sharing structure to have effect, because it's so crazy. And what our policy is is to prohibit supplemental coverage or tax it to reduce it so that we could have this cost-sharing structure have its effect. That is not a proposition that I'd want to argue for.

And so still enormously difficult from a policy and political perspective would be to argue for, well, let's redesign it using value-based benefit design, but make sure there's still some -- that's plenty difficult, but to try to reveal the existing cost structure and say this is the way the world ought to work, that's not a sale that I think I want to be part of.

DR. CROSSON: So are you saying that you don't think there's any avenue here from a political perspective we could pursue?

MR. HACKBARTH: No, I'm being definitive about one avenue. Let's not just try to prohibit supplemental coverage so the existing cost-sharing comes into effect. Or sort of a milder version of that is, well, let's tax supplemental coverage so fewer people will buy it, and that

will reveal the existing cost-sharing structure.

MR. EBELER: So you're differentiating between one and two, basically, saying the direction

MR. HACKBARTH: So if you were going to do it, you'd have to do the much more thorough redesign using value-based principles and others to try to come up with something more sensible. I don't think there's a fast track on this.

DR. SCANLON: In one slide, the whole idea of an annual limit -- I mean, and there is this huge gift or benefit that you're giving people when you do put in a catastrophic limit into Medicare which is missing now. And the question is can you politically say there should be a trade-off for that, because that's -- Medicare is bad insurance, and so the question would be: Are we making Medicare better? But, you know, we've got to restructure the entire sort of cost-sharing side to do that.

MR. HACKBARTH: Right. And as a basic principle in insurance design, I certainly believe that that would be a good trade. But, again, the trade I wouldn't make is, well, let's do catastrophic coverage and then keep the existing structure of cost-sharing in place. I'd say let's

do a real trade and say, you know, this is the amount of money we have to spend, let's design it so that it's more likely to have, A, the quality effects that we want and, B, equitable effects in terms of low-income people and other things.

DR. CHERNEW: First of all, I think it was two years ago when Mark and I testified about value-based insurance design when we came here, something like that, so I can't tell you how -- first of all, I'm thrilled to talk about the demand side stuff. I'm even more thrilled that someone before me mentioned value-based insurance design. I want to say two things about that.

The first thing is it's not clear that all of the low-value care is this sort of very cheap thing. There could be a lot of people with very expensive care where there's a lot of waste. I won't name any clinical areas here. But I do think it requires more thorough thought as to how to design this, and I do think that no matter what -- either we go to some broad payment-oriented approach or we try and capitate or do something else and let people ration one way, or -- say either/or, or we incorporate demand mechanisms more, and I think in either case one of the

1 themes of today is some more clinical nuance throughout the
2 system, be it in payment or co-pay cost-sharing, is really
3 valuable. And having a system move that way and having
4 MedPAC say that we need more sophisticated clinical nuance
5 to get the value we want I think is a wonderful statement.
6 The question I had was really mundane compared to
7 that wonderful thought, which is, Did you control for
8 geographic region? I'm a little worried that you have
9 people without coverage, say, in the South -- there's a lot
10 of variation geographically in use, and my guess is there's
11 a lot of variation in supplemental coverage, geographic
12 variation in supplemental coverage. So in all of these
13 cross-sectional design things, I know you've controlled for
14 a ton of individual beneficiary stuff, and I think you
15 controlled for urban-rural. But sometimes if you had people
16 in the -- the stereotypical critique would be people in the
17 South don't have supplemental coverage and the South is just
18 cheaper, and so you find people without supplemental
19 coverage spent a lot less. I don't know if that is
20 controlled for that.
21 DR. HOGAN: It's not controlled for it, but I
22 looked and there really weren't even urban-rural

differences. So as far as I could tell, they were pretty homogeneously placed across the country, but I can certainly put in dummies for some level --

DR. CHERNEW: Historically, that was the case. It might not be the case now.

DR. HOGAN: The MCBS is a poor design for trying to look at regional variation in secondary insurance coverage because it's so clustered. There's only about a hundred cities. I think that's right. So it's real hit or miss as to who you've got in there. So it's not clear that anything will show up -- it's not clear that any expected geographic pattern will show up, but it's certainly not hard to reconfigure that to put in dummies for regional.

DR. KANE: I'm assuming there was no Part D in here to -- I'm just wondering if this same population had differential behavior with Part D only because Part D does have one place where they all have to experience the same donut hole and --

DR. HOGAN: It didn't exist.

DR. KANE: I'm sure it didn't exist, but is there any way that there could be --

DR. HOGAN: It literally didn't exist.

DR. KANE: I mean, it didn't exist in that era.

DR. HOGAN: Right, right, so I couldn't --

DR. KANE: So the other way to think about it might be, well, what are we finding now about Part D? Is there a way to take the lessons of how behavior differentiates by income, education, and even whether or not -- I don't know if we can link that to whether they have supplemental coverage or not, but what can we learn from Part D about how people might behave if they're more at risk for their drug coverage? Is there any way we can take those, what we've learned about Part D, even though it's different years, different people, and apply it to this?

DR. SCHMIDT: I think we are still in the early stages of doing some of our claims work. We have 2006 and 2007 drug claims information from Part D, and we hope to have some first cuts to look at that data, even by things like some elements of benefit design, a little later in the year. And it will take a little more doing beyond that. We're still trying to figure out how to maneuver some of these enormous files to get in some of the variables that you are most interested in.

But we are very interested in looking at those

questions, and we'll continue to try and work on them.

DR. CHERNEW: Part D has some, I think, offset effects on A and B. Bruce published a paper on the topic, I think it was on length of stay and health services research. We actually are working on a paper now in Part D. We find that at least in some clinical areas you find fewer hospitalizations in places where people gained more Part D coverage. But getting the actual Part D data is hard to get, and the data is not that recent, per earlier comments.

But I do think you would find the best evidence which suggests you would actually get some savings from better Part D coverage in selected populations. It wouldn't fully offset the extra drug spend, but it would offset some of the extra drug spend.

MR. HACKBARTH: I think we're done. Thank you, Chris.

We'll now have our public comment session.

MR. COBURN: I'm Ken Coburn --

MR. HACKBARTH: Before you start, let me just remind you of the ground rules. Please limit your comments to no more than a couple minutes and start by identifying yourself, as you were. If the light comes back on, it means

your time is up.

MR. COBURN: Thank you. Hi, I'm Ken Coburn. I'm the Medical Director and CEO of Health Quality Partners. We're a not-for-profit health care quality research and development organization. We are one of the two extended demonstration projects in the MCCD demo, and we're also one of the sites participating in the MCCPRN.

I just wanted to offer two brief clarifying comments relative to that, and I want to thank John Richardson, the staff, and the Commissioners for considering that, and seeing the opportunity to try to accelerate our R&D work with chronic care in Medicare.

Although my side is still participating in the ongoing MCCD, we see a huge need and opportunity to accelerate some of the research around chronic care in Medicare, and the two brief points I want to make are:

One issue was raised around why this self-selected starter group, which I think is a totally valid and important question. We've spent the last year with appropriation monies from Congress to do the pre-planning required to get a uniform intervention that can be implemented across multiple sites in ways that can be

readily adapted to those sites, and we have one more year of appropriation that we're working with Mathematica Policy Research and CMS to do that preparation work, the idea being that on day one of the launch of this, instead of the long lead time that you all referenced, we would be able to launch a uniform intervention, best practice model design across multiple sites and cut off that lead time.

The ability to change the membership of this network is envisioned. It is envisioned in the draft legislation we are proposing. The Secretary can remove sites for lack of performance. They can add sites to augment if they're missing sites that should be participating and could productively add to that. So I wanted to clarify that. The starter set is because we're doing two years of preparation work to be able to have a model to go out of the block.

The other point that I just wanted to make a quick comment on was in terms of the evaluation, internal-external. We envision both types of evaluation -- internal to get accomplished what many of you referenced as that rapid cycle change, so as data becomes available and changes in the model can productively be made and studied, that that

happens. But we also envision an external third-party evaluator to look at the long-term outcomes in terms of cost and quality so that that can be from a policy decision, not the cake bakers judging their own quality of the cake, but to have that external evaluation as well.

So I just wanted to clarify those in case those points failed to come across. Thank you.

MR. COHEN: Hi, I'm Rob Cohen from Excel Health. Earlier there was a question about risk adjustment during the MA discussion, and I just had a two-part follow-up question or comment.

One is, Do we have reason to believe that risk adjustment overpredicts costs for low-risk persons and underpredicts costs for high-risk persons? And if so, could there be substantial policy implications? For example, could the trust fund lose more dollars if plans disproportionately enroll healthy beneficiaries similar to that the trust fund could lose more money if plans disproportionately enroll beneficiaries in areas with high fee-for-service payments? So could the trust fund -- and then the end of that is: Could that also provide a disincentive to enroll the chronically ill and focus on

managing care, if, in fact, there is a bias in risk adjustment to overpay the healthy and underpay the chronically ill?

Thanks.

MR. DRUMMER: Good afternoon. My name is Robert Drummer. I represent the Promotional Products Association International out of Irving, Texas. My comments and questions today aren't necessarily related to your agenda today, more so to the report you recently released to Congress, specifically on one of your recommendations regarding the physicians payment issue and Senator Grassley's sunshine legislation.

Compared to last year's legislation, this year's legislation and your recommendations supported a $100 annual aggregate threshold for doctors and hospitals to report receipt of gifts and other items of transfer of value. And we're not sure what, if any, metrics or data or articles you utilized to come up with that number, that annual aggregate number, as opposed to at least last year's legislation provided for $25 per item de minimis.

I have, for example, an ink pen today -- I'm not sure who made, but it has a logo on it. It's by AFLAC.

Essentially, the companies that I represent are companies that produce these types of items really more so for advertisements, but not as a "gift." It's not like this is a Mont Blanc pen. But, nonetheless, those small businesses that provide these type of logo'd items, whether ink pens or coffee mugs, feel they'd potentially be adversely affected by the impact of companies having to make a decision about whether to go through the administrative burdens of recordkeeping of all the items that they provide to a doctor or a hospital in order to keep track and then actually report once they've reached that $100 annual threshold. So that is part of my comment.

My question, back to the Commission, is whether staff or the Commission took into account what is, I guess, the point of either a de minimis value and/or an aggregate to determine what would potentially create a conflict of interest for physicians subject to the intent of the legislation by Senator Grassley.

MR. HACKBARTH: Okay, just for your information, if you have questions that you want to discuss, the way to do that is with the staff. They go to great lengths to receive input from people and respond to questions. We

don't do that in this session.

Okay. We are adjourned for today. Let me remind Commissioners what time we start tomorrow: 8 o'clock in the morning.

[Whereupon, at 5:29 p.m., the meeting was recessed, to reconvene at 8:00 a.m. on Friday, March 13, 2009.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

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COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

MR. HACKBARTH: Okay, first up this morning is medical education.

MR. LISK: Good morning. I hope everybody has had their coffee and tea to get themselves going this morning. This is our first session since we had a panel back in October on whether we are training physicians for health care delivery in the 21st century, and were planning on having some more sessions in the future and from today.

Today, I'm going to start by reviewing some background information on Medicare support for the process of becoming a physician and the organization of accrediting agencies and Medicare subsidy for this.

Cristina is then going to discuss findings from a new study by RAND which MedPAC funded on curricula and residency programs with a focus on skills needed for delivery system reform. We will then turn to a discussion of the disincentives that are in place for non-hospital experiences during residency and finish with a discussion of future work topics on this issue.

Medicare provides substantial support for graduate medical education. Over 1,100 hospitals receive Medicare

payments in support of GME for approximately 90,000 residents and fellows. Support to hospitals comes from two payments: Direct graduate medical education payments are payments made to hospitals for costs associated with running a residency program such as the salary and benefit costs of residents, faculty supervisory cost, and program overhead expenses. Medicare payment for these expenses totaled $2.9 billion in 2007.

The indirect medical education adjustment is a payment to hospitals for higher patient care costs associated with being a teaching hospital, such as residents learning by doing and unmeasured differences in patient severity. The adjustment is made to inpatient payment rates and is currently sent more than twice the higher patient care cost associated with teaching activity. These payments totaled $6 billion in 2007.

Combined, each FTE resident recognized by Medicare provides hospitals with roughly $100,000 in revenues from the program, essentially covering what we might label as the full direct cost of the residence, Medicare itself funding that. These funds, however, are fungible and may be used for other activities other than residency training.

At the October meeting in our introduction, we showed you this graphic on the path to becoming a physician, which we also discuss in more detail in your briefing materials. What we focused on in just a little bit is on the left side on the accreditation process, but if you have questions on the processes involved, we'd be happy to answer them at the end of the presentation.

The medical education complex in this country is large. There are over 150 accredited allopathic and osteopathic medical schools with -- training about 86,000 students, medical students, with about 21,800 first-year students. There are new medical schools that are opening and class sizes are growing, so these numbers will be increasing.

Moving on to graduate medical education, there are over 9,000 ACGME or AOA approved residency training programs training about 110,000 residents and fellows in this country. While the vast majority of residents receive their training in US or Canadian medical schools -- their undergraduate medical training in US or Canadian medical schools -- over a quarter are international medical school graduates, graduates of medical schools outside the United

States or Canada. There are over 25,000 residents each year starting residency programs for the first time.

The accreditation of medical schools, graduate medical education programs, medical licensor specialty certification, and continuing medical education are handled by different organizations listed on this slide. As you may remember, Tom Nasca, from the ACGME, he was responsible for accrediting graduate medical education programs, was one of the participants on our panel back in October.

So, here we have a slide that shows the different things that need to be accredited in different accrediting bodies involving the accreditation and certifying process along the way to becoming a physician. Within each of these accrediting bodies are representatives from a number of other organizations involved in the education process such as the AAMC, which represents teaching hospitals and medical schools, and the American Medical Association who are represented in several of these accrediting bodies, the ones for medical schools, GME, and continuing medical education, for example.

There's been some cross-fertilization in terms of the groups, as ACGME and ABIM have worked in a complimentary

fashion integrating the core competencies into the accreditation and certification process. And if you remember, Dr. Nasca talked about those core competencies back in October, and we have some discussion of those in the paper.

Dr. Wickham, as you may recall from our October meeting stated that, with so many players, it makes it difficult to achieve consensus around system changes or reform and suggested there might be a role for an independent body here.

So, what does it take to have an accredited residency training program? Well, first, both the institutions sponsoring the training and the program itself need to be accredited. Site visits are performed every two to five years, and programs must meet the individual requirements of the residency review committees for individual specialties with movement to a competency-based education and outcomes-based education, which Dr. Nasca discussed at the October meeting.

Programs much show how residents have achieved competency-based education objectives and must also show how programs are using this information to improve the

educational experience of residents.

RRC members then review the site visit reports, then vote on the appropriate accreditation action, which would include the length of time until the next review.

With that, Cristina will talk about delivery system reform and other topics.

MS. BOCCUTI: So, in recent years MedPAC has recommended several changes to reform the delivery system to focus on beneficiaries, improve quality, and control spending. Several are listed on the slide up at the top but I'm not going to go through them, you've been talking about them for a couple of years.

I will mention that, for delivery system reform to work, it's crucial for medical education to equip students with the skills that they're going to need to deliver care under these new payment policies.

Medicare, as a major payer of medical education and healthcare, has an enormous stake at ensuring that physicians and healthcare professionals are adequately trained to provide efficient, coordinated, and high-quality care. Although accrediting agencies have instituted standards like Craig mentioned, Medicare has not played a

role in fostering goals and objectives in medical education curricula.

Many of you have asked or commented on the curricula and residency training programs, so we contracted with RAND researchers to conduct a very interesting study that I'm going to talk about for the next several slides. The study consisted of semi-structured interviews with directors of internal medicine residency programs. All were conducted by RAND's principal investigator who is a board certified internal medicine physician. Programs were selected randomly from a representative sampling frame. We examined several specific curricular duties within the broad topics that I listed there on the bottom of the slide, and we selected these topics for the relevance to delivery system reform. In brief, the main findings from the study are that, although most residency programs provide some training in these areas, there is tremendous variation and in general curriculum falls far short from that recommended by experts.

The first area we examined here is quality. The IOM states that physicians must be able to assess the quality of care they provide and implement changes in their

practice for improvement. This process is often referred to as practice-based learning.

The RAND researchers found that while most residency programs receive some exposure to quality assurance and system change, only a small share require residents to complete their own data analysis and data collection and resulting system change. This is important because delivery reforms to improve quality such as P4P demand that physicians really understand the underlying elements of quality improvement. Evidence-based medicine, as a tool for practiced improvement and comparative effectiveness initiatives appeared to be taught more consistently in residency programs through formal training, formal sessions and journal clubs.

While most programs reported teaching their residents to use clinical prediction tools such as a pneumonia severity index, only about a third have IT to support these tools in clinical practice.

Individual physicians work within a complex arrangement of health care delivery in the US. This complexity has led to fragmentation in care which has likely contributed to many hospitalizations for chronic conditions.

So, to counter this trend and unsustainable growth in spending, experts have introduced system-based practice. This calls for a better understanding of the components and costs of health care to improve coordination, spending, and safety. Several of the delivery system reforms that the Commission has discussed such as medical homes, bundling, they require providers to have these skills to succeed in those reforms.

RAND researchers found that formal training on many aspects of care coordination is limited or nonexistent, particularly in the outpatient setting. For the inpatient setting, many program directors stated that they have specific instructions on communicating patient status to other physicians when they're handing off a patient. However, less than half have formal instruction on hospital discharge.

This is concerning given the importance of this has on avoiding expensive readmissions, another area of recent interest for MedPAC.

We found further concerns on the topic of formal multidisciplinary training. About one-quarter do not have any formal experience in multidisciplinary teamwork with

other health professionals, but rather report that training on this topic is more informal. Less than a third reported formal multidisciplinary experiences in the outpatient setting.

Moving on to costs, only about one-quarter had formal methods for teaching about absolute and relative costs of diagnostic tests, treatments, and medications. Among those that did, they seemed to focus on inpatient costs such as hospital service costs, billing, coding, that sort of thing. Programs were similarly unlikely to instruct residents about patient share of medical charges. Among those that did it was typically during ambulatory experiences such as in a clinic that uses a sliding scale.

On to safety, all programs included some formal instruction in patient safety issues, for example, prevention of falls and proper patient identification in the hospital. However, only about a quarter teach basic safety design principles as recommended by the IOM. Safety design principles would be, say, a standardization methodology for implementing changes.

We know from published research that the quality of communication between patients and their physicians can

influence a patient's health outcomes. Thus, to maximize healthcare effectiveness, it's essential for physicians to communicate collaboratively with patients, their families, and other health professionals to determine appropriate diagnostic treatment and other regimens. The RAND researchers found that while half covered communication skills between healthcare providers, more included formal instruction on how to communicate clearly with patients about diagnosis and treatment plans. However, when looking at specific instructional activities, we find that formal teaching on how to engage in patients in their health care was rare. This is concerning because it's an integral part of improving patients' health, yet less than half of the programs formally trained residents how to counsel patients on regimen adherence and behavior change.

With respect to instruction on communication in special circumstances, there was somewhat better news. For example most, but not all, programs reported that residents received formal instruction on how to communicate end-of-life issues such as advance directives and most programs indicated that they have at least one session on cultural competency.

In a previous MedPAC report, we've discussed the importance of using HIT to improve the quality, safety, and efficiency of health care. The RAND researchers found that although all programs provide residents with some exposure to electronic medical records, in most cases the electronic medical records is not comprehensive but rather it's more partial. Some programs reported that none of their residents had experience with electronic medical records in the outpatient setting.

Lacking components of Health IT include computer order entry which allows physicians to write orders electronically for things like patient treatments and clinical decision support tools were also missing in these HIT systems, and less than half had experience using HIT from outpatient coordination functions.

Because most health care is provided in settings other than acute care hospitals, it's essential that residents gain experience in a variety of settings. The program directors stated clearly that residents have minimal training outside of the hospital. So even though most, but not all, programs include clinic or private practice experiences, this experience only accounts for a small

portion of their total residencies.

About half of the programs have their residents perform home visits and many require experience in a nursing home or a rehab facility. Many directors reported that managed-care patients were only a small share of the patients caseload in the outpatient setting. No directors reported that their residents have experience in designated medical homes; however, several directors indicated that their clinics have many of the features of one.

So, hold this thought about non-hospital setting. I'm going to get back to it in a minute but I want to complete the findings from the study.

RAND researchers reported that, in their interviews, residency program directors reported multiple positive and negative factors affecting their ability to train on the topics that we selected. The presence of IT was the most often cited resource for facilitating these topics. Conversely, the absence of IT was the most often cited barrier. Also, faculty quality and time were also factors.

Which brings me to the next bullet on institutional support. Residency programs are not always

able to compete with their sponsoring hospital on decisions about faculty hiring and faculty time. Also, Health IT exposure falls under the category of institutional support.

I should also mention that directors viewed program accreditation requirements as being crucial for obtaining institutional support for their curricular needs.

Directors noted that program locations and hospital types also provided opportunities and barriers. So, for example, some programs serve a diverse patient population but others do not.

Program directors also cited the level of residents incoming knowledge from medical schools as a factor in program strength, and they also noted a lack of inherent resident interest in topics, such as care coordination, is also a barrier, particularly when they're not a focus of Board certification exams.

Finally, program directors reported a dearth of information on the best educational methods for teaching residents of these kinds of topics.

So, just to summarize, from these interviews the RAND researchers reported that although most programs provide instruction on these topics, overall, the curricula

falls far short from that recommended by experts such as those on IOM reports. Of particular concern is the lack of formal training or enough experience in outpatient care coordination, multidisciplinary teamwork, awareness of health care costs, comprehensive Health IT, and patient care in non-hospital settings.

Specific topics that appeared to be covered more consistently in residency programs were evidence-based medicine and communicating with patients about end-of-life care. As I just mentioned, program directors reported multiple positive and negative factors that contribute to the circumstances.

So, now I'm going to get back to the issue of the limited time that residents spend in non-hospital settings. As Craig described, Medicare makes GME and IME patient payments only to teaching hospitals for medical education subsidies and residency programs are largely based in acute care teaching hospitals or medical schools that are tightly affiliated with teaching hospitals. Accordingly, residents spend most of their time involved with inpatient care, yet most of the medical conditions that practicing physicians confront are, and should be, managed in non-hospital

settings such as physician offices and nursing home facilities and patient homes. This misalignment of training highlights the need to examine the strong financial incentives that teaching hospitals face for keeping residency training in-house.

This slide reviews four such financial incentives. The first is a long-standing issue. Residents provide valuable services in the hospital, particularly on-call duties that may include writing timely prescription orders and conducting patient admissions. Letting residents train outside the hospital may mean hiring or contracting for other higher-wage staff to provide these activities. A second issue is that hospitals lose their direct GME payment proportional to the time that residents spend off-site in educational non-patient care activities. This regulation sounds a little tricky, so I'm going to explain it a little further.

Medicare pays for residents when they are conducting hands-on patient care, regardless of the setting, but outside of the hospital Medicare does not pay for the direct GME component for didactic or non-patient care activities. For example, Medicare does not count the time a

resident spends in an instructional meeting with an attending unless the meeting occurs within the teaching hospital's campus. A third barrier to outside placements is that hospitals lose both their direct GME and IME payments for time residents spend in settings that do not have a specified affiliation agreement. So, if a resident spent half their time in, say, a group practice that did not have this specific agreement, then the teaching hospital would only receive payments for half of that residency position.

So, what holds up such an agreement? Well, it's the regulatory requirement that teaching hospitals pay the outside setting for supervising the resident. It turns out that office-based physicians often prefer to volunteer their time rather than be paid by the teaching hospital. I know that sounds odd, it sounded odd to me, too, but I'll this further. First, these non-affiliated physicians want to avoid the paperwork involved with fulfilling that specific regulation. Also, they enjoy mentoring new physicians and view it as a professional responsibility. They may also see it as an opportunity to gain stature by being listed as an adjunct faculty with the medical school. And in addition they do, depending on the skills of the resident --

non-hospital sites could also gain in some clinical productivity from residents' care.

And finally, for the fourth bullet, to enforce these policies, teaching hospitals must track all of their residents' hours at various sites and submit logs of these to Medicare, which then can be audited. So the opportunity of this time creates another financial incentive to keep residents in-house.

This presentation has given some background information on two particular issues in medical education, curricula and non-hospital training. In forthcoming reports, you might consider further discussion on policy changes for these issues, such as ways to establish requirements or incentives for enhancing particular curricula and technology in the medical education continuum and mechanisms for ensuring more residency training in non-hospital settings.

So, to help you or think about and discuss these issues, we've put up that this slide just to illustrate that policy options can affect the components of Medicare's medical education subsidies differently. The top yellow boxes together represent total IME payments. The bottom

blue box represents direct GME payments. The top right extra box is not empirically derived, as Craig and other colleagues have discussed in prior meetings.

As you know, MedPAC has recommended that a portion of the IME funds for the extra bucks be used for P4P initiatives in hospitals. Medical education policies that you discuss today and in future meetings could also come from this box or such policies could affect how the funds in the left-hand boxes are used or distributed.

So, with that in mind, here are some more policy issues for further discussion. I'll give a brief sentence or two about each, but as you'll see, many could be the subject of an entire session or chapter, but we thought it would be useful as a starting place.

The first would involve linking Medicare's medical education subsidies to specific delivery reforms. So for example, hospitals that accepted bundling and readmission policies could see perhaps more favorable medical education payments.

Then, for the second bullet -- keeping in mind that Medicare is the largest contributor to medical education -- some have formed all payer proposals, and these

would explicitly require that other payers join in Medicare's support.

Third, given the interrelatedness of accrediting bodies that Craig raised, another proposal we've heard is to have an independent board preside over medical education funds. Also, the current construction of GME and IME has some small incentives to promote specific specialties such as primary care, but these incentives could certainly be strengthened.

Currently, Medicare does not specifically subsidize nursing education, but many reports show a significant need for nursing support, as they are essential professionals for effective and efficient health care delivery.

Given the small number of geriatricians in the US, some experts, like Chad Boult, that Jennie mentioned yesterday, suggest that all physicians be trained in some aspects in geriatric care.

Alleviating student debt through loan forgiveness policies might be another incentive-based policy to increase types of physicians and nurses in desired specialties and in certain underserved geographic areas.

Considering Medicare subsidy of $100,000 per resident, perhaps Medicare could require some public service in exchange. And finally, since almost all medical students become practicing physicians, efforts to increase diversity need to begin with the medical school admission criteria. And by diversity, I'm talking about racial, economic, and geographic diversity.

So there is a lot that we covered today and we are happy to answer your questions about all of this material.

MR. HACKBARTH: Thank you and good work. Could I see hands for first round clarifying questions?

MR. GEORGE MILLER: Thank you, Cristina and Craig. Very good work. I've got a question on the last statement you made about the demographics. Of the number of medical students, can you give us a demographic background or do you have that demographic breakdown currently so we have baseline to measure when the recommendations promote more diversity?

MR. LISK: Right now, if I recall, in terms of under represented minorities, which would be Hispanics and African-Americans and American Indians, there are about half of what they are in the general population.

Part of that also extends, though, from what happened at the undergraduate college education and also medical school, but there is some drop-off a from those populations, and we can provide you more information in the future on that.

MR. GEORGE MILLER: Just a follow up. In part of the RAND study, did they talk to traditional, historically Afro-American schools of medicine also?

MS. BOCCUTI: That was in the sampling frame.

MR. GEORGE MILLER: It was?

MS. BOCCUTI: Yes.

MR. GEORGE MILLER: Thank you.

DR. CASTELLANOS: Cristina and Craig, thank you very much, and excellent job, and thank you for bringing back onto the platform. I think medical education -- we have great opportunities. Just a clarifying question:

Cristina, you said we have the opportunity to set goals and directions for medical education. You were pretty silent on workforce issues and I see this as a direct opportunity to address some of the shortcomings in workforce. I'm just curious if you intend to use that as a future topic.

MS. BOCCUTI: I think it's on this slide, there is some sense of that in the fourth bullet, when you think about the mix of professionals. I think that because there is so much to cover and the Commission has talked a lot about the delivery reforms that we are first tackling issues about curriculum and the non-hospital setting that are somewhat related. And then, I think we're putting a lot of these topics up to see where the Commission wants us to go further. It was not focused on in this chapter because there's just other issues that we've got we should focus on first.

DR. CASTELLANOS: But perhaps you will be talking about that in the future?

MR. HACKBARTH: Ron, when you use the term workforce, what do you mean? The total number of physicians being trained or are you talking about specialty mix?

DR. CASTELLANOS: I'm talking about everything, both specialty mix where we have definite shortages within the physician community and the nursing community and allied health communities, and I'm also talking about the total number of the opportunities we have right now. We don't have enough work power to handle the direction we want to go

with medical home, with accountable care organizations. And if we don't started doing that now, it's going to be 10 to 12 years -- even if we start now -- before we can even address or solve some of these significant workforce problems.

DR. DEAN: One of the factors that is sometimes cited as to why hospitals pick the particular range of residencies that they choose to operate is the amount of income that the residents actually produce. Do you have any information about that? It's been argued that that's one of the negative incentives for primary-care residencies is they don't produce much income where some of the more procedurally-based residencies do.

Now, the residents and I've had contact with, the current Medicare rules are so stringent in terms of the involvement of the attending that I question whether they can generate all that much. But I wonder, did your study get at that at all? Maybe Karen, I see, is moving over there. She probably knows a lot more about this than we do.

DR. BORMAN: Just a couple of things that may relate to what you bring up, I think, Tom.

First off, it's important to know that a number of

-- other than primary care resident specialty residencies -- cannot exist in the absence of primary care residencies. For example, you cannot have a general surgery residency at the institution unless there's at least OB/GYN, internal medicine, pediatric -- I think it's two of the three of those. So actually, to some degree, the mix is driven by what residencies require others to pre-exist. Again, for example, a pathology residency would require that some sort of surgical activity go on in the hospital. So, that's one of the drivers go on.

A second one would be, in terms of the supervision piece, I would suggest to you that is probably is pretty across-the-board in terms of certainly compliant claims. A surgery attending is going to be there for the vast majority of any given procedure, certainly, a percentage equivalent to office visits. In fact, the only exemption to almost continuous presence relates to primary care clinics.

So, I think that those two things may be decided but are a little hard to say are a factor in what hospitals choose to sponsor.

MR. HACKBARTH: Could I just ask a follow-up on that? So, could you characterize the amount of billings

that a surgical resident generates compared to an attending? Is there some sort of...

DR. BORMAN: First off, a resident can't independently bill, as you know.

MR. HACKBARTH: Right.

DR. BORMAN: So to try and -- probably the function that you can attach a monetary equivalent to in the Medicare system might be the first assistant payment so that a case on which there is a resident attending probably doesn't have a second surgeon.

Now, remember that that payment currently is about 16 percent of the intern service part of the surgeon's fee, so it's a pretty small number, number one. Number two, that if you went by Medicare's list of procedures for which there is always an assistant at surgery, it's a pretty small fraction of those. So, the notion that every operation would have two surgeons if only residents weren't there would be a gross overestimation of the contribution. So, there probably is some contribution to a number of procedures but the flip side would be that it probably does add some time and expense by virtue of having residents and the corollary of students that generally come with it.

DR. REISCHAUER: Karen, that would save Medicare money, having the resident attending, but it doesn't save the hospital money does it? And the hospital is the decision-maker, or the medical school is a decision-maker here.

DR. BORMAN: To the extent that a resident costs more or less than a substitute personnel, it may or may not affect the hospital bottom line. For example, in our in first assistant cost more than a resident or so forth, then it might impact the finance piece.

MR. HACKBARTH: So what I'm -- I'll just a frame question and then we can come back to it later because I do one interrupt Tom's flow. What would be helpful for me to understand is the economic impact of having a training program on the hospital. Obviously, there's the direct the flow of dollars that comes from Medicare, but I'm talking about the secondary impact. That's all very murky to me.

DR. DEAN: That was basically what I was getting at, too. I know when we've had family medicine residents in our practice, if you follow the Medicare rules it's pretty tough because the rule says that every patient that they see, even third-year residents who are just about ready to

go out and practice, I would have to see those patients and write a note, even if it's a blood pressure check. I understand in a way why those rules got there, on the other hand, they're really restrictive and they really slow things down and there is a serious question if they have any educational value. I think it's more of an issue of preventing fraud and that kind of stuff.

I would just add, George, I've got a lot of data about the makeup of incoming medical school classes and it's very worrisome. They are becoming more and more majority, more and more higher income. The minority, rural, and low-income components of incoming medical students is going steadily downward which is a very worrisome trend.

MR. LISK: It's about I think only 5 percent of the medical students come from the bottom quintile of income or bottom quartile, but it’s small. Yes.

DR. MILSTEIN: In reflecting the degree to which we think Medicare could and should try to solve this problem, I reflected on the presentation that I think you set up for us in November and December from the two expert medical educators. My memory of that is that, in broad brush, their observation was that the problems that RAND has

done such a nice job of laying out have been visible and known to most parties including medical educators for quite awhile. But their message was that energy for change was the problem. They were very, very candid about indicating that they were very well aware, as were their colleagues, of the gap between what is and what would be of greatest benefit to the public and perhaps the Medicare program.

As I begin to reflect on what could we do about it, one of the things I also remember that the presentation -- and the two presenters, the point they made was that there was at least one other source of rescue above and beyond sense of professionalism on the part of the faculty which seems to be the problem in this situation. They said, well, if the boards, the certifying board, were to radically change the nature of what they test and certify for, that could be a major source for reform. So, as I reflect on what we should think about doing, can either of you tell me whether any imminent major intervention by the boards is something that we can count on?

MR. LISK: There have been changes taking place like ABIM for the certification of internal medical residents. It has been trying to incorporate more and

actually, in terms of the incorporation of recertification of physicians and stuff. So, there's efforts going on as to whether is it enough and how do you end up going about changing.

I think a lot of the problem, too, comes from -- and one of the things is faculty or faculty development -- what is their experience and how do you develop the faculty for some of these changes as well, so you get some of these things incorporated in, and that's a difficult thing. If you don't have the faculty trained to do that, that could be an issue.

DR. CHERNEW: You mentioned this briefly in the study limitations, but I just wanted to ask about the RAND study, and that is, I haven't taught residents but I've taught medical students, and the way in which they're evaluated matters enormously in terms of what they actually take in. And so, things are in the curriculum -- like me, they aren't really in the curriculum in some way because of the way the program is evaluated. So, I was wondering if in the RAND study there was any attempt to capture not just the intensity which you mention a little bit in the limitation section, but also other aspects of the programs about the

incentives -- in the spirit of Arnie's comment -- the incentives that the students face to actually do well at these particular things?

MS. BOCCUTI: Broadly, I don't think we can speak to what the feedback was from the instructors to sort of say whether they told the residents that -- how they motivated the residents to do better in these areas. We were trying to just get a baseline on what was really being required and what was formal and what was informally taught.

I didn't get into it enough, I think, but there are reasons why things should be informally taught versus formally taught. Some of the skills need to be done during a hands-on experience, but there's value to making them a requirement and formally taught in order to show that they are valued and important.

So, I think the most that I could say that there was a distinction within the confines of the study would be to say whether there was a formal or informal a focus to the curricula but there wasn't sort of -- other than the RAND researchers said, how well does your program, do you think -- does this. But I think that has so much judgment within it that it's better to report the actual presence or absence

of the activities and then get sort of a general picture. The final report will be forthcoming and maybe you'll get a better picture from that, too.

Does that answer your question?

DR. MARK MILLER: Yes, because the last thing I think is, when I was trying to process your question is, the way this is done is pretty much a presence or absence thing and then a discussion and, depending on which your view of that is, that means that even if you do something, no matter how -- if it's not very intense or not very integrated, it got onto the list. So in some ways you can look at what happened here as, if there was just something, then it got counted. Even doing it that way, there was sort of a conclusion of things falling short. I don't want to overstate that too strongly, but the other thing that you said in our conversations and I think you said here today is that people don't put as much effort into it unless they feel like it's going to be very much directly part of what they're tested and evaluated on. There seemed to be comments like that throughout the discussion. Yes, we do this, but it doesn't necessarily come up again and again and something that I'm going to be evaluated on.

MS. BOCCUTI: That goes to what Arnie was saying about the certification exam. Yes.

DR. CHERNEW: I was just asking, in the study you had -- do you have this, are they evaluated on it or how are there -- that I understand -- it seems like he did -- it was more of an open-ended discussion. If they mentioned that it came up, but it wasn't systematically collected by the RAND researchers.

MS. BOCCUTI: Right.

DR. SCANLON: Just a quick comment related to Tom's point on the economics of residency decision. Going back to our work on specialty hospitals, when we were looking at DRGs, we maybe need to think about what is the inpatient revenue impact in terms of a residency program, because what we saw was there was significant profit differences between DRGs, not just within a DRG. And while we've moved it to correct some of that, there is a question of, historically, what difference that made and what remains in terms of what the incentives might be.

MS. HANSEN: This is more of a question of the role that Medicare regulation has on any of the curriculum and the things that we can't do. Tom said certain things

you can't do because it's not allowed. So, how much of it is sorted out to some of the accreditation issues as compared to what Medicare is specifying?

For example, you only get counted if you do hands-on, for example. And how difficult is that to change? What level of decision-making is required to be ease that to make that shift?

MS. BOCCUTI: You mean regulatory versus statutory? Is that the kind of -- I just want to follow...

MS. HANSEN: It could well be. There are different levels of that. One is the statutory and the regulatory and then the professional itself in terms of how it gets defined. But when Medicare has this, is it at the statutory level or the regulatory level?

MS. BOCCUTI: I would say it's both, but there's been a lot of regulations over the last decade that have defined some of the specifics of the non-hospital setting supervision issues. I think Craig wants to jump in here.

MR. LISK: It is, as Cristina said -- it's kind of both. There is this language that came in the law that said Medicare should pay in the off-site and went Medicare pays all or substantially all the residency training program

costs. With that language, CMS interprets that as, well, they really have to pay for almost virtually everything.

In the past, though, they allowed for, let's say, direct GME reimbursement as long as the program was paying the resident salary in benefits, they allowed it. But when they changed the regulations to allow IME payments for residents' time when they were off-site to go to the hospital, they kind of changed the regulations. This gets to be a real weedy set of issues that goes on. So, the regulations kind of change and Congress had put in this substantially all or all language, and so CMS interpreted that in one way. So that is where some of the regulations come into play.

So, you have a statute issue from CMS's perspective. Congress has sometimes put in language saying, well, that's not necessarily what we mean but it's been in report language. So it's kind of a quagmire how you deal with it and who's really responsible, ultimately.

DR. MARK MILLER: This is just based on conversations with you guys and actually -- no, to some extent, some of the conversations we had with AAMC. My sense is there's a lot of regulatory underbrush here that

could correct some of these problems, particularly the in and out of hospitals. Probably not all of it, but there are steps that could be made that would make the situation -- and Cristina, if I'm way over --

MS. BOCCUTI: There are regulatory things that have changed so that sort of lies within CMS, but some of the financial incentives even override the regulatory ones.

So, I want to be clear that fixing -- let me take that word back -- changing the regulations may not in and of itself vastly change the incentives in keeping residents in the hospital.

MS. HANSEN: So, is it possible for future work with that in mind that there could be a way to outline where the statutory stuff comes from, the evolving regulatory kinds of issues that, in and of themselves are probably conflicting, and then the interpretive side of it which becomes, frankly, a staff issue sometimes, and then the financial piece that you just mentioned just so that we get -- we basically unpacked is a little bit so that we can see where are the decision points that really will allow us to do the best policy changes for this. So, from the accreditation to the payment issues to the regulatory world.

MS. BOCCUTI: Right. We'll try and make that a little bit more clear in this work. But I think also, because it's so technical, if we go forward on some of these ideas, there is a place to really get to the word for word language and how it might -- because then if the Commission were to start thinking about changes that those words get to be -- need to be thought about, too. So, we'll work on this now but it may also come up in the future.

MS. HANSEN: Let me clarify that because I don't want us to go to the weeds, that level; I appreciate that's not our role. I think part of it was just for an understanding of the complexity.

But then separately, this may be into round two, but it just leads so naturally, could we flip it around and take a look at what are the population needs of the Medicare population? And all of these initiatives are for the endpoint of quality, cost-effectiveness, and inclusive of safety and whatnot.

We could do it two ways: One is a structure as it is. The second one is how patients and beneficiaries should be getting care in the 21st century and then kind of begin to see where this is a bit archaic in order to achieve these

results. But we take it from a more beneficiary futuristic population base as to where our goals are meant to be.

MR. HACKBARTH: Understandably, we are sort of at round one and three-quarters, here. Let me just see the hands of people who have clarifying questions and make sure we get all those done first.

DR. REISCHAUER: I think I'm probably a one-and-a-half, so you can go to a pure one.

MR. HACKBARTH: Jack claims to be a true one here.

MR. EBELER: I think I'm a true one. And just follow up on Jennie's, on this question of regulatory framework, to the extent that one can get a signal in there of the regulations that come at you from the payment side and the regulations that came at you from the Inspector General side. My impression is that this is a world in which some cases -- my program does something inappropriate, the government comes out appropriately on me, but as a result, Tom and Karen and Peter are filling out forms for the rest of their life.

MS. BOCCUTI: Is there a question?

MR. EBELER: The question is that if you follow up on Jennie's -- that direction would --

MS. BOCCUTI: Tom sort of mentioned it when you are saying about the supervising activities, I thought we should probably put a little bit more of that kind of a burden in the chapter because we focus more on financial but there's sort of the financial -- the opportunity costs of what it takes to supervise.

MR. HACKBARTH: Before we go to round two, I just want to go back to two things that were raised in the first round.

The questions related to the financial impact of training programs on the institutions, Peter, I'd like to hear what you have to say about that. I understand that the direct dollar flow. What are the secondary effects in terms of having residency programs on the hospital? What are the costs and benefits, as it were? If you could say something about that.

Then, the other issue, I was going to ask Karen to address Arnie's question about what the boards are doing and how that process is evolving. Peter, do you want to talk about that?

MR. BUTLER: Let me see, I'll do it through my own specific experience and what occurred 22 years ago when I

was a newly-minted CEO of a community hospital, which affiliated at the time -- the first time I was with Rush and we inserted 12 internal medicine residents into the institution. I was highly aware of the formulas at that time. This won't be a comprehensive answer in terms of all of the impacts, but I said, I kind of wonder if this GME and IME is going to pay for the cost of the impact of all of this. My bottom line was about a wash, but let me give you some specific examples.

I wish I published this because I was using a second-year master's student in health care administration to pull together the data as a project. But in the one month that they occurred -- again, internal medicine residents are a little different than, say, a radiology resident. The radiology exams went up about 5 to 6 percent in volume after 1 month, lab tests went up about 39 percent. So that's a very visible impact of -- again, this was July 1, new residents coming in the door, encourage to diagnose and treat patients and maybe it's a community hospital that wasn't used to having quite the intensity, but you have these people around the clock. And so on the on utilization side, it did make it --

MR. HACKBARTH: These would fall under the indirect costs of medical education that IME is meant to --

MR. BUTLER: Exactly. There's one very visible example. And by the way, we need this test that's sent down, and you don't do it in-house, so you need to bring it in from somewhere. And some of these things were absolutely right. And they were further enabled by, say, the faculty that we now had to pay also to supervise the residents and they, too, had kind of overall service demands on the institution which were a different level and a different expectation than the typical community hospital.

And then, of course, the library that the community hospital had was not sufficient enough and so you had to have more publications and then you had to have certain technologies, and it kind of goes on from there. It really had kind of a cultural impact on the overall standards of the institution overall.

Now on the positive side, while there was additional costs and utilization, I think the presence of residents actually helped the care move along faster and better because the attendings in the community hospital would come around once a day in the morning and do their

thing, and particularly on weekends, you get the residents around, processes can move. Actually, we had a reduction in length-of-stay in our institution at that time.

Another benefit was that there were certain number of physicians that were splitters that say, well, you've got those residents around, now I'm going to admit more to your hospital. I have a feeling that you give higher quality and in general there are more people asking questions about the care than were occurring in a community hospital that didn't have anybody doing the types of peer review that should have been done.

MR. HACKBARTH: So, what I hear you saying is it potentially increases your market share, increases your referrals, makes people more likely to admit at your institution, and presumably also expands the capacity of the institution to handle more cases because you have the resident workforce?

MR. BUTLER: Yes, of course, that's injecting residents in a community hospital, which is sometimes viewed as very valuable to say -- in downtown academic medical centers, some of those same community physicians say, I'm not going to admit my patient down there, it's a

bureaucratic morass, the service isn't as good. They may have expertise but it's not a place -- I don't want to get on the staff there. So it's very different to have graduate medical education in the community hospital versus in the academic medical center, which is a whole different complex.

DR. DEAN: I understand that the supervisory requirements have changed quite dramatically, I think. Am I right, Karen, in the 20 years, at least, as I remember? And what's required now, the documentation of supervision. So, it's a little different environment than you describe.

MR. HACKBARTH: Do you want to talk about the evolution of boards and maintenance of certification?

DR. BORMAN: I think that the boards, for a variety of reasons, have broadened their thinking about what should be required and what should be evaluated for initial maintenance of certification and that reflects, number one, the general competencies presumably apply from the medical student through the experienced practitioner, number one; so it's a reflection of that.

Number two, it's a recognition of proving that what all of us who are board certified believe that is a quality marker, to try to make it more apparent to someone

not in what we do, that it is indeed a quality marker, so the interval, the intensity, of activity that's required.

I can only speak to detail from the board on which I Sit, which is the American Board of Surgery. We certainly have incorporated safety questions. We've incorporated system questions. We've incorporated ethics questions into the examination processes.

We and multiple other boards, I think, continue to seek better ways and potentially -- and valid ways, and there is a big chunk of the problem, of assessing some of the things that Cristina has brought up here in terms of interpersonal and communication skills, for example, would be one. And just to offer an example because I've heard their presentation, the American Board of Orthopedic Surgery has a very extensive process that when a diplomate is filing for recertification, they have to request peer evaluations that are from a broad variety of people, including chiefs of service at all of the hospitals that they work, the director of the OR at all the hospitals for which they work, a variety of people. So it's not just peer physicians. It's not your practice partners. It's people who presumably are in positions where they're aware of not only the medical

quality of your work but the nature of your interaction. If you regularly are unpleasant to the OR staff, it will come out in the evaluation of the chief or the administrator of the operating room.

One of the problems with that kind of thing and what the boards struggle with is that occupies 80 percent of the time of one of the executives of that board, just to service that process, because of the number of things. So, it's broadening the base of questioning; it's seeking other ways to get the input that is not so costly and time-consuming. Simulation may ultimately play some role in validating technical skills. For example, the American Board of Surgery in a couple of years, we will require that anyone for initial certification will have completed a number of well-validated skills curricula, including fundamentals in laproscopic surgery or the FLS curriculum. So, I would say, on a lot of fronts, the boards are moving.

MR. HACKBARTH: What I've seen and ABIM is that the maintenance of certification work, the development, the enriching of maintenance of certification is in fact focused on many these issues about improving actual practice performance and systems-based improvement and practice.

There is a lot of variability among the boards, some are more advanced in that than others. But Kevin Weiss, who is the new head of the American Board of Specialties -- the overall specialty board, his agenda is to deepen maintenance of certification, make it more substantial, and try to make it more consistent across the various specialties. That is sort of another force at work here.

MR. LISK: If we're still in round one, I have one technical issue just to clarify, and that's on the nurse training issue in terms of Medicare support for nurse training. Medicare does provide direct GME payments for hospital-based nursing programs, that's diploma programs. I just want to clarify that Medicare does provide some small amount of support for that, but those of the vast minority of nursing schools.

DR. CROSSON: Thank you very much for the presentation. I thought it was very good and very clear. I have to admit, when I read the first part of it, it made me tired and I wondered what I was thinking when I decided to become a physician.

In terms of the focus here for the work, I'd like to make the case that we strongly consider focusing on the

issue of training in non-hospital settings. As you said, Cristina, there is a lot of things we can do with this. As we've talked about this over the last few years, I've been a little queasy about exactly where we could go as a Commission in terms of making recommendations about the education process. I think, at least I feel, uncomfortable about that. But this particular one has some obvious regulatory barriers that I think we could comment on and it fits easily, at least for me, and to my conception of the work that we should be doing.

In thinking about it, there is a strong reason I think, just based on my own experience, for increasing the amount of time that residents spend in outpatient settings. You can argue, and I think the paper did very well, what some of those reasons are. The issue of having exposure to multidisciplinary coordination of care, certainly, not that that exists in all practice settings but it certainly does in some.

Obvious things, like the range of problems addressed -- that's sort of obvious on its face, the kinds of problems that are dealt with generally in the hospital are different from those that are dealt with, in general, in

the office.

The issue of role modeling. I think the role model in an academic medical center that medical students and residents are exposed to is quite a different role model than one is exposed to in a practice setting.

And I think all of those things feed into things like the selection of a specialty but also I think some more subtle psychological things which can end up influencing the pattern of practice of medicine for a career.

This is sort of an oversimplification, but the process of a hospitalization, for the most part, and the mental activities of the physician, are kind of focused on the diagnosis and treatment. What does this patient have? How can I figure that out most expeditiously? What's the proper treatment? And then, when can the patient long? And that's pretty much it. Now, I don't mean to say that there aren't follow-ups in clinics and all of the rest of that, but fundamentally the mental process and the acculturation of in-hospital training is that: diagnosis, treatment, end this case. Where the practice of medicine in the office is really very different from that. It's, in many cases, the management of the care of the patient over a very long

period of time. And properly done, focuses a lot on not just on diagnosis and treatment, but how to help an individual maintain their life over a period of time, how to manage high blood pressure and diet and exercise and how to do simple things like figure out what to do if you happen to be over 60 and have a meniscus tear from perhaps playing too much golf, and sort of like, well, what shoes should you wear? What sorts of activities are okay, how to know when you need to stop doing what you're doing, when you should take anti-inflammatory medicines, all those picky little things, which, added together, ultimately influence whether that individual is going to end up requiring higher intensive and more costly care. And those are things that you don't really learn in an in-hospital training session.

When I came out of my pediatric residency, I was a real hot ticket. I could put a catheter into a one millimeter space; It was unbelievable. But two days later I went into the Navy for two years at the end of the Vietnam war here at the Bethesda Naval Hospital and I realized, after spending an hour trying to understand how to put my uniform on, I realized in the first day or two that I didn't know anything about how to take care of their children and

their parents in the office setting. And I, in fact, learned the practice of pediatrics in the Navy and not in my residency training program. Enough of that.

I do think, though, that whatever we could do to help training programs get better reimbursed and to help interns and residents have more experience in the actual care of patients in the actual settings where most care is delivered would be a great contribution.

DR. REISCHAUER: Let the records show I was never a hot ticket.

[Laughter.]

DR. REISCHAUER: This is sort of a round one and a round two. The round one is a little refresher course for me, and that is, if I recall correctly, there is a cap for residents and we're over the cap. And so, there are some settings where the institution isn't being reimbursed. It might be interesting to look at where those are geographically, what specialties the people are in, and why that's going on if we want to get insight into the net cost of these programs or the benefits from them and whether the residency programs in those settings are significantly different from others where everybody is under the cap.

The round two comment has to do with IT, and I found that the most interesting part of this, in the sense that most training programs, post-undergraduate training programs, produce individuals that, in a sense, are at the cutting edge of methodology and technology and that's how it diffuses out into the economics or the sociology or at the business school profession, is these young people coming out just saying, I know how to use all these tools and all of these new methods.

What you're showing us here is that that's not true with respect to medicine and we've just passed legislation that's going to dump a whole lot of money into putting IT everywhere. I was wondering whether there was anything in that or the regulations that try to get the teaching component sort of where it is in all other professions and generating cadres of people who are ready to go and push the frontier, or they're going to come out and say, wow, now teach me this stuff that’s in the office or that’s in your hospital. It dumbfounds me that the hospitals running the big residency programs don't have all of the very sophisticated systems in which they train their people.

MS. BOCCUTI: I'll mention a couple things. First, regarding this stimulus bill you're talking about, I'm not aware that there's anything specifically for academic health centers. I think Jeff maybe has looked at this a little more specifically. It's available for hospitals, but I don't know that there is a distinguishing component related to whether they're a teaching hospital or not. I am getting this means probably not. So, I think that's a sort of what your question was about. We can talk more about what the IT similarities are, but I think maybe we've prepared something. We can talk about that later off-line.

I did want to mention that the VA system does have comprehensive EMRs. The RAND found that when residents could rotate through the VA, they did get those experiences, and that created the bulk of those that had comprehensive EMR experience.

MR. LISK: We focus on internal medicine here. There are also a lot of family practice programs, though, that do actually have these systems, and the residents actually, when they come out of those programs, frequently actually demand it from the practices that they go into,

because all of a sudden, they may have been using those, but then go into practices or hired by practices that don't have them or the practices they demand to go into are the ones that have them.

MS. BEHROOZI: Thanks. This was really great and actually kind of scary in a lot of ways, and Bob made a point about IT and that shocked me.

It does occur me that when we're talking about the things that, as you said, Cristina, have been so important in all of our other conversations like care coordination, communication around hospital discharge, patient communication, regimen adherence, all of those things that you've listed, and again, it's scary how little -- what a small place they seem to occupy in the preparation of doctors.

I know this is about doctor education, but it doesn't need to be if we're talking about those kinds of functions, right? Those kinds of functions really don't need to be always and only performed by doctors. It's good that doctors know they are important components of whole patient treatment. And in some settings it may be in incumbent on the doctor to do these things, but it does seem

to me that were in a little bit of a chasing-our-tail feedback loop kind of thing, because the payment system, which is doctor-centric, means that it's doctors who have to perform these functions or they won't be reimbursed. And I think we need to connect this back to our thinking about the payment system to be less doctor-centric. It's not just RNs either who can perform these functions; it can be much more diverse types of people and people with less expensive educations to have to support. Health educators, nursing assistants, and people with far less, as I said, expensive educations that can do these things. Not that we should necessarily say doctors shouldn't do these things and shouldn't know about it but I think that there's a little bit of a closed mindset that we're within a box, partly because of the payment system in looking at the educational issues.

But having said that, still, of course, we need doctors and we need lots of them and we need them to practice in the right areas and come from places that represent all of us. It's of tremendous concern how expensive an education is. Obviously, from the Medicare side, how much Medicare pays from it. From the hospitals

side, they still think they're losing money. They say that they're losing money even though MedPAC's analysis shows that the IME is not fully empirically justified.

But the students end up with a lot of uncompensated costs in the form of tremendous loans that they are only compensated if they choose to go into practice areas that are lucrative. And I think not only in terms of loan forgiveness, we should be looking at, or policymakers should be looking at trying to reduce the burden on students so that at the going-in end you have more economic and other kinds of diversity, but at the going-out end you have less pressure to focus on the lucrative specialties.

But also, and this came up in the panel last fall, if we're not teaching all of these care coordination and IT and all that good stuff that physicians should have, does it really need to take so long? Maybe there really is a core of things that doctors should be learning. And I'm talking about allopathic and not necessarily making everybody osteopathic, but that was something that was referred to in that panel, especially if we're not focusing on all of the right things.

DR. DEAN: Where to start? I have a lot of

interest in this topic.

First of all, it came up at the whole issue of what drives the curriculum, and my understanding, both from talking to medical school folks and talking to my son last night who is a fourth-year medical student and has a lot of opinions about these issues, one of the really worrisome and disturbing parts, although I think it is changing, is the national boards and that medical students have to pass at the second- and fourth-year are extremely rigid and extremely focused on relatively minor bits of information that students have to memorize.

Now, my understanding is that that is changing, because that has really dictated to faculty to what they can teach. In fact, my son said that for one course he had a college classmate who was at the University of Minnesota and he was in South Dakota. He said his college classmates sent him his notes, and they were the same thing we got. I had a student with me from Georgetown a while back and she said exactly the same thing, the same concern.

It really changes, really limits what -- any flexibility the faculty can have in bringing in some of these things, especially at an early stage that we think are

necessary. Now, my understanding is that's changing and so hopefully it's been a long time coming.

With regard to specialty choice in which residencies a hospital supports, it certainly seems -- I back up a minute. I understand that in the undergraduate area, Medicare doesn't have a whole lot of influence, although I think it's something maybe we should look at because what happens in these early years in medical school clearly has a huge influence on what happens later on where we are truly interested.

But anyway, a few years ago there was a group called COGME, I think it was Council On Graduate Medical Education that issued a recommendation which said that, in order to get Medicare reimbursement, teaching hospitals would have to have a mix of residencies that was consistent with the needs and the projected needs in their area. Now, obviously, that's not a simple thing to project, but at least it puts some emphasis that there should be some connection between when public funds are invested and it should have some relationship to the needs of the area. It isn't a straightforward thing, because obviously residents don't always stay in the same area and things change and all

that, but it seems to me that some requirement like that, even though it would have to be somewhat loose, would make sense.

I guess to respond to what Karen was saying, my impression from the Board of Family Medicine is similar to hers. I think the specialty boards maybe have been better at recognizing the needs for some of these changes then maybe the undergraduate testing activities although, again, I don't have data to support that.

Finally, we've alluded to it already, I am really worried about the admissions procedures of medical students and partly who is being admitted and the dead issue that goes along with that. The cost of medical school is scaring away many of the people we really desperately want to get into medical school. And also, it puts medical schools in a difficult bind, because many of the students come from areas where they are not guaranteed that they are going to be as successful as the majority of students that come from prestigious colleges and so forth; we know they're going to do well. And so, you understand, if you're in a medical school's admissions committee, that obviously those folks are going to stand out. On the other hand, the people that

are going to do the things and serve the roles that we really need to have served are going to come from other backgrounds and they're going to be a little less secure students, or a little less than -- going to be a little more risk on the part of the medical school. You don't blame medical schools for being hesitant. On the other hand, we've got to do something to push that forward. Otherwise, were going to have a complete mismatch in terms of the range of specialists we have compared with a range of needs we have.

DR. KANE: A couple points, and I think this is great and gives lots of opportunity for many more meetings and discussions I'm looking forward to.

One thing that's been brought up in different ways here but a lot of the training that we would like to see doesn't have to all happen in medical school or residency. In fact, quite a bit of it I think happens outside of that, as Jay mentioned, when you get your first real job, but also through continuing medical education of other activities.

I'm at a public health school but we get mostly -- probably two-thirds of our students are physicians seeking to add to their skills, including IT quality improvement,

and all of that. So, I think just saying all this has to happen in medical school or in residency training might be too narrow a scope for thinking about that.

And now that we've asked all continuing medical education organizations to be disclosed if they're receiving pharmaceutical funding, perhaps we should think about ways that they might be funded to provide more public purpose types of education around patient education, IT use, quality assurance, the kinds of topics that are here.

I think CME -- I have learned that the average age of the physicians in my executive ed program are 49 years old and they are wonderful students; they are lifelong learners. So, their brains don't go dead for learning after age 30, and I really recommend that we consider the lifelong learning opportunities and how can Medicare enhance those and potentially help either reimburse or foster the kind of CME that gets us the kind of skills we need. That also helps to educate the faculty and the older docs who are serving as role models for younger people.

The other issue I'd like to know more about and maybe have us talk about is that Medicare pays for education in places where Medicare patients go, particularly the IME

which is tied to an inpatient Medicare admission. I've been doing this safety net hospital work for the Commonwealth Fund and noting the payer mix for safety net hospitals has a very low Medicare, 20 percent, 15 percent, and yet the IME dollars are going to places that have the high Medicare payer mixes, inpatient. I just wonder if there isn't some kind of a mismatch when you tie IME to an impatient Medicare admission, particularly for communities of the minority and disadvantaged populations, which don't tend to bring it in that many Medicare inpatient admissions.

It is sort of like a disproportionate share going out the way it does. I'm wondering if the allocation formula itself doesn't harm the training grounds where a lot of our disadvantaged populations go to for their care and if we shouldn't start thinking more about how to reallocate IME on a different basis, and I guess that goes also to the concept of perhaps disassociating the support of medical education from caring for Medicare patients in the specific sites but rather having education go to where residents are educated and not necessarily where Medicare patients are. I'm not so sure that that makes sense to me, but that’s so tightly linked right now, and I think that's a topic that

I'd like to see us explore further in the future.

DR. BORMAN: I want to congratulate you on distilling out nice diagrams about a rather arcane process of educating a physician. I think it's very important that people have some literate place to go back to as opposed to entirely relying on Grey's Anatomy, House, and other vehicles for what they know about the education of physicians. It gives me some solace that you've laid that out.

I would point out that you don't have to finish a residency to get licensed. You have to do one year of some graduate medical education in order to sit for step three, which is basically what you're going to need to get a full and unrestricted license, and on your diagram, you had one to four years; it was just a little less clear in the text, I thought. So, I would just clarify that.

I'm having a little bit of the problem that Jack had yesterday in terms of the it that we're trying to get to here, because I think this is wonderfully provocative. But I think that, to move it forward, maybe we need to -- and Jay, I think, touched on a little bit of what is our it in doing this work and where we do want to go? Because this

could be a lifelong project for the Commission, way beyond any of our lifetimes, no matter how John projects them. So, I think we kind have to think about that a little bit.

If you look at our title, I would support that if what we're really looking at is education versus delivery reform, that that starts to take us down a huge -- the big workforce path consideration of the mix of education, sophistication, some of what Mitra referred to, and I'm just not sure that's where we intend to go but that's one place -- that's the ultimate view of all this, and where to parse out dollars in support of that.

Because I think that, instead, what we're sort of looking at and that gives me some concern is we think we've identified the needs over the next 5 to 10 years for some specific issues within the Medicare program. I'm going to submit to you that how you educate physicians, at least for the long-term, may need to have a little longer view.

Just to offer you some examples from my own discipline, when I was a resident and in a fair amount of my education -- and in fact a good chunk of operative experience -- related to management of peptic ulcer disease. Thirty years later, there's a bacteria, H pylori; it's

treated. The number of patients that we operate on for peptic ulcer disease, the natures of the operations that we do are just vanishingly -- they're hugely different. And there is some danger in tweaking curriculum to try and address a need. It would be like -- this is, off the top of my head, a bad analogy -- a particular plane crash where judged due to X and we then said every pilot must be trained in X to some nth degree to the exclusion of something else, that would not necessarily be a good thing. I think that one of the things we've got to remember here is that we're talking about people that are going to practice for 30 or 35 years, and the imperative is to give them a foundation on which to be those lifelong learners and continue to grow. We really need to be careful about tweaking for the short term. I am very concerned every time -- Jay's queasiness every time I see the curriculum word here and some implication that we will attempt to manipulate curriculum as a function of payment policy I think is a slippery slope and I really, really worry about that.

I do think if what we're talking about is how we best invest the dollars that we are currently putting into medical education, I think that one of the ways to build on

the system we have where the money is in fact going to the teaching hospitals, is to encourage and incentivize those entities to be the cutting edge people for us, in terms of the IT adoption.

In fact, Peter and I had a little sidebar, and most teaching hospitals are farther along than the average community hospital. Maybe we need to accelerate that, but I think that tying it to something like that -- faculties and universities tend to lend themselves to a structure that could more quickly morph to an accountable care organization. And should we use -- thinking about this to incentivize that kind of behavior, I'd much rather see that than tying it to some measure of how much did we teach geriatrics in the curriculum.

My last comment would be, one of the things that did trouble me about the study a little bit -- and I think it's a very fascinating study -- I'd love to see, number one, to ask the residents the same questions to see what they think they were taught and perhaps to do a procedural discipline for a comparison. But you made a lot of statements about they don't get formal training in this, formal training in that, formal training in whatever. As

was mentioned, some of the more formal piece, that's undergraduate medical education; that's medical school. Residency is, in large measure, experiential-based learning and it's the next step towards adult learning and it's more effective.

So, I want to be real careful that we don't start to use as a measure how many lectures or things there were about a given topic as a measure of addressing it. When I operate with a resident or I'm in clinic with a resident, we oftentimes talk about how to do those things.

Surgery residents, for example, log their cases by using CPT codes. So, they start learning about some of that and some of the implications. So, I think we just need to be a little bit careful.

MR. HACKBARTH: That's helpful, Karen. We're actually at the end of our time on this. I'm going to go through the rest of the list, but it would be really helpful if we can convert this into a round two-and-a-half and use Karen's comment as a jumping off point.

We're trying to figure out what the it is here and even know whether we do anything. So, this is a first very exploratory discussion. Some of the candidates that are on

the table for the it are, should we be trying to alter what is taught, the curriculum question, who -- we're producing the specialty mix sort of question.

Where they're taught, inpatient versus ambulatory settings, or the qualitative characteristics. Should we use these dollars to make sure our new doctors are taught in institutions that have the latest IT, they're involved in delivery system innovations, and the like? Those are four possibilities that I've heard floating around.

If, as the remainder of the people make their comments, if you could say something about where you think what the it is, that would be helpful.

DR. MARK MILLER: I was also keeping a list. I think there's also the notion of public service and loan forgiveness requirements either on people coming out or things to support physicians.

There was kind of this question, and it came from a comment a ways back and it gets to your point of whether at all. The other thing is, maybe it's not graduate medical education, maybe it's delivery reform and you use the money to try to drive this set of institutions in the direction of delivery reform and teaching or residency training will

follow that.

And then, finally, just big, really big financing questions like, are we talking Medicare only or all payer?

MS. HANSEN: Well, I appreciate the framing that both you and Mark did, Glenn, because the it is perhaps conceptually approached different ways. So it's not about the general medical education but it's graduate medical education.

So, the delivery system reforms that we're focused on here belie the fact that behaviors will have to change that oftentimes are prerequisite with some area of knowledge and since this is adult education, meaning clinical, my question is how we can assure the tools will happen.

So, the delivery system reform doesn't just happen by itself. There are some prerequisites along the way. I have no direct solutions at the moment but I don't want to forget that. It does need to be thought of maybe systematically, and to see whether or not some of the regulatory issues, frankly, get in the way, so that one consideration of calling it maybe more outcome-based education for the population of Medicare beneficiaries in the future as compared to a place-based education which is

where it's within the four corners of an institution. So that may be something as a concept.

The only other comment I'll add right now is -- actually it's a question, one, and we can answer it later. Is licensing kind of consistent across all of the states? If not, then what does that add to it structurally in terms of getting the quality of care outcome?

And then, finally, whether or not there is any opportunity from the RAND study to do a part two of it, because this first RAND study was really the state of affairs as we know it now. And then, we have graduate-level practice places of excellence in certain areas of academic medical centers and so forth. Of the things that we're looking for in delivery reform, whether it's IT, whether it's care coordination or transitions of care, is there a way to understand how those leaders are looking at what's necessary in order to have delivery reform follow? So, if there's a way that they can be fleshed out a little bit more.

MS. BOCCUTI: I don't want to take up your time. I will say we are going to continue working with RAND and we'll see if we can do a little bit more. The contract is -

- we thought we might look at some innovative programs, so we'll look at that. But I want you all to be able to have a chance to use up the time.

DR. MILSTEIN: Five points. First, as has already been said, this is a long-tailed problem, right? If you don't get it right the first time -- we might hope that continuing education might rise to the job, but it certainly isn't now. And so, with a fuel great schools exempted, but it's not happening. Because I think there's some urgency here, because it's a long-tailed problem, you miss it.

I think Jay's comment, maybe a few years ago, was it takes good delivery systems about two years to remove wrong contents before you get back to level, so that's problem one, point one.

Point two is that the problem of -- in some ways you think about where the nature of the absent content or the missing content on the RAND evaluation, it directly bears on how much IME costs. If you don't train the residents, there's no role models around for efficient workups, if people believe what I believed when I was in training which is a shotgun workup for the months of July, August, and September is just fine, then it does cost a lot

more. So, a second rationale for moving on this is it could, I think, substantially reduce the cost of IME.

The third point is that I think that the -- I think this is Ralph Mueller's point -- although I am anxious to find ways of finding ways of solving the problem of the mix of residents that we manufacture, I'm not sure this is the way to do it. I think we have better ways of doing it having to do with how much we pay different specialties.

A fourth point is that the problem runs deep. The problem is not that -- and many of these -- I suspect that when these training programs, when they had their exit conference with RAND, I'm sure they nodded. In my experience at the two medical schools where I am, where I play this role of unpaid clinical faculty, the problem is that there's almost nobody on the faculty who knows this stuff. And when faculty positions come up, they're not allocated for these purposes; they're allocated to replicate who is currently in place. That's reality.

So, all that being said, I think we should consider relatively salient policies to draw attention to this. This has been known and this problem was signaled in the IOM blue-ribbon report 11 years ago and we don't have a

lot of action and that was acknowledged by the people who came to testify in December.

In terms of the what or the how, we do have a process now for auditing these residency programs, right? We have an organization that does that for us. One way of thinking about this would be to begin to -- not begin to mandate curriculum, as Karen was cautioning us about, but rather specify the nature of the disciplines that have to be part of that auditing and then begin to link the audit results to how much Medicare pays.

DR. CASTELLANOS: I'm sitting here thinking, what's the it? Medicare really pays for the benefit of society, for the needs of society and the benefit. What we really need talk about is a health care delivery system, which we've been talking about. But we're really focusing just on the physician. I can't sit here as a physician and say I'm responsible for this. I'm only as good as the people that surround me and I need the help of everybody in the health care delivery system. And I'm sure, Karen, you feel the same way. Tom, I know you feel the same way. Jay felt, just like when he finished his residency, he was the hottest thing available, but you soon came out and realized

you didn't know very much and you really had to learn from a lot of people.

So, I know we want to focus on the physician, but I don't want you to forget that the whole care delivery system, the hospital administrators, the nurses, the care coordinators, is as important as a physician in dealing with the care and the public.

MR. GEORGE MILLER: Thank you. I'd like to go back to the frame you put together and the overall frame about whether this is under the umbrella of the sustainability issue or are we talking about investment in medical education for the future, and it may be a combination of all of those things. And so, dealing with these issues we've got to make sure that we understand the overarching goal and the framework you put this under.

One of the challenges I think Bob mentioned is that there are caps and many hospitals are under those caps. And then the off-site training is not reimbursed by hospitals. So, there is some financial pressure there for those hospitals; Peter illuminated to that.

And if my information is correct as I understand it -- I never worked at a teaching hospital -- but part of

the problem is that the capital -- and I think Karen mentioned that some of the teaching hospitals are further along on IT and that's because recently they've had additional dollars for IT and could afford it versus community hospitals that did not have that. And as I understand that recently the capital has been decreased, so there still may be some financial pressure.

The other issue I want to discuss going forward is, I'm concerned about the cultural competencies, the makeup of medical schools, and still, the disparity issue. How are we going to deal with that in the long term, especially those vulnerable hospitals, safety net hospitals in poorer communities. So, I think the issues of loan forgiveness and requirements of public service may help address that issue.

Hospital CEOs, whether they're community hospitals or academic centers are taught, quite frankly, to follow the money. So, wherever there's financial incentives they will follow that path and we've got to make sure that we designed a system that deals with all of these issues.

Finally, I am always entertained and appreciate what Jay talks about, but I would like to introduce just a

new acronym is WTMI, when he talked about what he could do, and that's way too much information.

[Laughter.]

MR. GEORGE MILLER: Thank you.

MR. BUTLER: I won't pass. Having spent my whole career in academic medical centers, I have to make a couple comments, but I'll try to be crisp. I have four things I like and five things I would suggest that would improve this.

First, I like the idea of having a chapter at this time if we can, even if it doesn't have recommendations. I think it's a great companion piece at the end of the book to kind of the reform issues that we've had in the last day. So if we can get to a point of having a chapter, I'm for it and I think it gets this issue importantly on the table, because these are the people that will impact the system of the future more than any others.

Secondly, I like the idea that it looks at lifelong learning and it doesn't just highlight in the chapter those years that Medicare is involved in financing. So, don't lose that.

Third, I like the idea that the chapter does a lot

of education and I think that it could even do more. I think that the pathway of how you become a physician is good, I think the accreditation table really assembles things nicely, and I think that the text box on the residency education and how that works is good.

What's buried in there that is extremely important is, in 1999, ACGME took on core competencies required of all residency programs. I was on ACGME at the time. It is an extremely tedious but important thing. If you look at those competencies, which there are five of them, including things like practice-based learning, systems approach, it's a perfect vehicle where we perhaps could build on that and say not what do we want in the curriculum but what are the competencies that we're looking for. And you have a vehicle where we could perhaps help find provide some additional insights into the competencies. So, I would bring that to light a little bit more as a foundation that we could contribute to.

Lastly, I like the regulatory issue. That is a theme and there are some early wins. You mentioned if you go off campus for didactic, you don't get -- if you go to medical school across the street, it doesn't even count.

You can be on campus. But I think there are some early wins that aren't necessarily financial issues that we could advance in recommendations fairly quickly and would help everybody.

What could be better? I think the clear identification of the difference between GME in IME is done in the textbooks, but right in the front of -- we pay $9 billion for training. Well, these are very different. You asked a very important question. We need to bring to light -- I think even in the chapter -- a little bit more the mystery around IME. I mentioned utilization and ordering by internal medicine residents.

There's also new technologies. In fact, some of the kinds of things we're going to discuss in the next session are often introduced in teaching hospitals more than any other without reimbursement associated with them. Whether that's right or wrong, the reimbursement system doesn't catch up and it doesn't always catch up in the right way, but that's an added cost.

Secondly, when you go and do further work with RAND, I think programs in internal medicine directors as a starting point because there are critical. But you might

want to go to what is called the DIOs, the Designated Institutional Officers. They're the people in the institutions that oversee all of the residency programs. They are the ones that can create the interdisciplinary teamwork and issues. So, it's a different position in the organization that you probably ought to talk to them, not just one program.

Third, I think there's a certain tone of this, including in the title, that says, we better match at this year's training to this year's need or health care reform agenda. So there's a little bit of a tone that should be -- I think this is already said -- that we're training people for many years out, not just for this year's agenda. So it needs to be a little bit longer thinking in how that's presented, and maybe it could be in a different title.

The IT thing I like a lot in terms of another area where we could advance some recommendations sooner rather than later. I think in the chapter it talks a little too much about you need to be able to do CPOE or be adept. I think it misses the point of transforming care.

When we put in CPOE, we spent a lot of time with our residents coming up with 240 order sets that get

embedded in the technologies that guide the care that reduce variations and eliminate error; that's the issue, not having the technology per se.

So, I think the power of engaging residents in those kinds of guidelines that happen to use technology to implement them is the issue, not the technology itself. So, make sure that that's highlighted.

And lastly, in terms of the couple of these other issues that came up, I think that the -- Mark, you and some like the medical school admission criteria and loan forgiveness -- I think it's extremely important, I just don't think it's our domain. I think similarly on the specialty side, I think we can tweak and influence the mix of specialties, but I agree with Arnie's comment and then half of Ralph, I guess. The payment system in the end is going to do more to put people into the specialties rather than this piece of the action. We shouldn't ignore it, but I don't think it should be the heart of what we want to work on.

But overall, I think it's time to bring it forward as a chapter in time to get some baseline education that we could advance some recommendations on in the future.

MR. HACKBARTH: Okay thank you. This is a good start and I think we made some progress in giving some shape to the it, but still much more to be done.

The next subject is follow up biologics.

Just a word about the schedule. We are starting about 20 minutes late, but what I'm going to do is extend this session until 11:15, so we will have just about the entire time that we had budgeted, and then we will start the public comment period at 11:15 and have that run to 11:30. I'm going to have to leave to catch a plane right at 11:15, but Jack will oversee the public comment period.

DR. SOKOLOVSKY: Good morning. Today we're going to talk about follow-on biologics, an issue that is new to the Commission, although as you may remember, we have discussed since the summer putting this on our agenda. Because the subject is new to us with an unfamiliar vocabulary and concepts, we're going to spend some time today going over those key concepts and issues. And I want to mention at the outset that we convened an expert panel to help us with this subject by providing their perspectives on the issues involved, and their insights are in reflected throughout this presentation.

Spending on biologics has been increasing rapidly, totaling over $40 billion in the U.S. for 2007, and about one-third of all drugs currently in development are biologics. CBO estimates that if the Congress established an approval pathway for follow-on biologics, the Federal Government could save as much as $12 billion over the next 10 years, and much of that things would accrue to a Medicare. Further, providing a lower-cost alternative to some very expensive biologics could increase patient access to needed medications.

We're going to present today some of the key definitions and concepts concerning follow-on biologics or, as I'll refer to them today, FOBs. First, we'll cover the difference between biologics and other drugs, and we'll look briefly at the patent system and the FDA approval process -- two separate processes, but both of which have implications for when an FOB can enter the market. We'll look at the issue of data exclusivity, the period of time before a follow-on manufacturer can submit an application for approval to the FDA based on the innovator's data.

Another key issue for the FDA is to define standards for approval when an FOB is comparable to the

innovator. An even higher standard that we'll talk about briefly is interchangeability.

After this background, Kim will look at FOBs and Medicare Part B, and Nancy will talk more broadly about ways in which Medicare could better reflect value in the payment system.

Biologics are drug products derived from living organisms. Unlike the kind of drugs that most people are familiar with, these products are large, as you can see, complex molecules that generally are injected or infused directly into the body. They include proteins like vaccines, insulin, and hormones but also products engineered through biotechnology like many of the new products used to treat cancer, anemia, rheumatoid arthritis, and MS.

Right now there is no expedite pathway for approval of these follow-on versions of biologics, so the prices of these new products, which tend to be high to begin with, have not fallen over time.

Biologics are also different from other drugs because manufacturers cannot produce a follow-on product that is exactly identical to the reference product. That's why we talk about follow-ons and not generic versions of

biologics.

Like all drugs, biologics have safety issues associated with them. For example, most biologics have some immunogenicity, which is the ability of the substance to stimulate the body's immune system, which generates antibodies. For many biologics, this doesn't result in any clinically relevant efforts, but for others the response can diminish the efficacy of the product. And in the most severe cases, immunogenicity can cause severe adverse reactions in some individuals, including life-threatening effects.

Any biologic has to meet tests of immunogenicity. However, severe adverse reactions in individuals may be very rare, and even using large-scale clinical trials for any specific product, whether it's the innovator or the follow-on, they may not be big enough to uncover the problem before a product is approved for marketing. Some analysts have suggested that post-marketing surveillance for biologics may be warranted.

I need to stop her again and give a little bit more background. All new drugs, including biologics, go through two completely separate processes: the patent

process, which protects an innovation from competition for a set period; and the drug approval process, which allows a drug to be marketed.

Different organizations have responsibility for the patent system and drug approvals. Patents are awarded under the Patent Act and administered by the Patent Office. The FDA has the responsibility to approve drugs for sale. These two processes have different requirements and award different protections. Examiners at the Patent Office award patents to any invention on the basis of utility and novelty and what they refer to as "non-obviousness," which I take to mean somebody could invent toothpaste, someone else could invent a toothbrush, but you couldn't get a patent for telling somebody to put the toothpaste on the brush.

MR. EBELER: Don't be so technical.

[Laughter.]

DR. SOKOLOVSKY: I'm trying.

Patent holders can exclude competitors from the market for a period of 20 years from the date the application was filed. In the case of drugs, the inventor generally files for patent protection well before a product is approved for sale by the FDA.

The FDA approves drugs that meet standards for safety and efficacy. Manufacturers of new products must support this application with clinical data, safety reports, manufacturing standards, and other relevant information. Manufacturers may market their products after they receive FDA approval, but the FDA also provides extra protection against generic competitors by awarding a period of data exclusivity, and that's something I'll talk about a minute.

Patent protection generally occurs concurrently with the FDA approval process. If FDA approval takes a long time, there are provisions for patent restoration. The patent process for biologics and drugs in general has a number of issues that can delay entry of generics or follow-ons to the market. Some of them are discussed in your mailing materials. In the interest of time, I'm not going to go into them now, but I would be happy to discuss them on question. For the rest of my part of the presentation, I'll be talking about the FDA process.

Two of the very contentious issues in the FDA process are how long a period of data exclusivity new biologics should get and what kinds of tests the FDA should require to determine that FOBs are comparable to the

original products.

Currently, in cases where a drug's patent expires before or soon after approval for marketing, an innovator is granted five years of data exclusivity. That's a period without generic competition. Data exclusivity is the period of time after FDA approval before a follow-on or generic competitor can submit an application for approval to the FDA that relies on the innovator's data on safety and efficacy. That means essentially that they don't have to do large-scale clinical trials.

At issue here is how long a period of data exclusivity is necessary to promote innovation and foster competition in the biologics market. Some argue that manufacturers need a long period of data exclusivity to recoup the development costs of a new biologic. For example, innovative companies argue that at least 14 years of data exclusivity is essential to provide adequate incentive for new inventions. They say investors will be reluctant to enter this market without the guarantee of a sufficient period of time.

Others argue that lengthy exclusivity provisions, longer that the five years that's included for generic

drugs, would both delay entry of low-cost competitors and discourage competition. They argue that brand companies don't have very much incentive to develop new products without the threat of imminent competition.

The second issue is that of comparability. To approve an FOB, the FDA has to determined that the follow-on product is comparable to the reference product, and comparability here means that the safety, the identity, the purity, and the potency of the FOB is unchanged from the innovative product.

Currently the FDA has comparability protocols that it uses to assure that when a manufacturer changes its own product, either by changing the production site or the process, the new product will be comparable to the old one. And remember, with biologics, even if it's the same company, the new product will not be identical to the old one.

The protocols outline a series of tests required on a case-by-case basis to ensure that manufacturing changes haven't compromised the safety and efficacy of the product. The FDA determines whether differences between the products are significant enough to require additional testing. Sometimes they want some clinical testing to see, for

example, how the product affects blood levels and various tissues, or they want to see the short-term impact of the product on animals or humans. These tests are clinical, but they're not the same thing as long-term clinical outcome studies.

At any stage of this process, the FDA may determine that the two products are not comparable and end the tests. Analysts disagree about whether the FDA can improve FOBs based on this case-by-case approach or whether there should be a uniform series of tests that should be required of all products.

An even higher standard of comparison is interchangeability. Interchangeability means that an individual patient can switch back and forth between the innovative product and the FOB without any clinical effect. Like if you get a prescription and take it to the drugstore for a generic drug you don't know which manufacturer has made that pill that particular time.

This is an issue that our expert panel spent a long time discussing. Analysts disagree about whether the science currently exists to demonstrate interchangeability. It's not clear that even if the FDA was given this authority

they would use it, but many of our panelists thought the FDA should have the authority so that when the science does exist they can make this determination. They also agreed that comparability was the standard for approval for an FOB.

Panelists did note some instances where the FDA declared biologics interchangeable for public health reasons, and here they referred to the example of Hurricane Katrina, where physicians and patients wouldn't have access necessarily to their usual pharmacies, and so the FDA said if you need insulin, just get whatever insulin is available, you don't have to worry about whether it's the same brand as you were using before. This determination was made despite the fact that there hadn't been any head-to-head tests between the products. It was a public health decision.

If the FDA designates products as interchangeable, it will have implications for costs and competition. In the small molecule market, most states have procedures where generic product can be substituted for the brand product without the prescriber having to intervene. With comparability it would be the prescriber's decision which product was used. And if the FDA declares that an FOB is comparable to the reference product, we still assume that

the FOB would compete in the market with the innovator and there still would be savings.

Next, Kim is going to talk to you about how competition might play out with Medicare Part B if FOBs do enter the market.

MS. NEUMAN: Biologics play a large role in Medicare Part B. The top six Part B-covered drugs in terms of spending are all biologics. These six biologics alone account for $7 billion or 43 percent of all Medicare Part B spending on separately paid drugs.

Follow-on biologics have important implications for Medicare Part B as they offer potential opportunities for savings to the Medicare program and beneficiaries. Lowering the cost of expensive biologics also may increase access to these products for some patients. The amount of Medicare Part B savings that are likely to result from follow-on biologics would depend on a number of factors, including how follow-on biologics are treated under the Medicare Part B payment system.

Next, I'll discuss how the Medicare Part B payment system works for drugs and provide an example of the competitive dynamics that work when generic drugs enter the

market and then discuss implications for follow-on biologics.

As you'll recall, most Part B-covered drugs are administered by physicians. Physicians purchase the drugs in the marketplace, and Medicare pays them 106 percent of the average sales price, or ASP. A drug's ASP reflects the manufacturer's average price for sales to all purchasers, with certain exceptions, net of rebates, discounts, and price concessions. Under the ASP payment system, physicians have the incentive to seek the lowest price available for a drug because they are paid 106 percent of ASP, regardless of the actual price they pay for the product.

This next slide gets into some of the more detailed mechanics of how Medicare pays for drugs and how this affects competition among products.

Medicare makes payment for Part B drugs using billing codes. A billing code typically refers to a unique form and strength of a chemical or biological entity. All products in the same billing code receive the same payment rate based on the volume-weighted ASP for the products in the code.

Generic and brand versions of a small molecule

drug are placed in the same billing code, which fosters competition. Because the payment rate for the billing code is based on the average ASP for all products in the code, physicians have the incentive to seek the lowest price version of the drug available. This in turn causes volume to move toward the lower-priced products and brings down the volume-weighted ASP over time.

Also, there is a two-quarter lag in the ASP payment system which further incentivizes use of generics. Because of the lag, for the first two quarters generics are on the market, they are paid only based on the higher ASP for the brand product, which creates a substantial incentive for generic adoption.

For biologics and drugs without generic alternatives, often referred to as single-source drugs, coding and payment work somewhat differently. The MMA required that each biologic and single-source drug be paid based on its own ASP, not averaged with other products, so each has its own billing code. The MMA, however, made an exception for a small number of closely related biologics and single-source drugs that had been placed in the same billing code prior to the MMA. The MMA grandfathered these

products, requiring that they continue to be grouped together and paid a rate based on the average ASP for the products in the code. Note that the FDA has not made a determination regarding the comparability or interchangeability of these grandfathered products.

This next slide provides an example of some of the competitive dynamics at work under the ASP payment system when a generic drug enters the market. This example illustrates how coding and payment play a role in the degree of price competition among products.

This slide shows four intravenous anti-nausea drugs in the same therapeutic class that compete with one another. Each of the four drugs is a different chemical entity and has its own billing code. In late 2006, one of the drugs, shown in blue in the chart, went generic. As you can see by the steep decline in the blue line, there was a substantial decrease in the Medicare payment rate for this drug after it went generic as the generic and brand versions of the drug were placed in the same billing code and received a payment rate based on the average ASP for all products in the code.

We also saw more moderate declines in the payment

rates for the other three drugs in the therapeutic class, each of which continue to be paid in its own billing code based on its own ASP.

It is important to keep in mind that we would not expect follow-on biologics to result in as large a price decrease as we see for generic drugs. Nevertheless, some of the same competitive dynamics apply.

Follow-on biologics are expected to generate savings for Medicare Part B, and how they are coded would affect the level of savings. Placing follow-on biologics and innovator biologics in the same billing code would lead to more competition and greater savings than if they were in separate billing codes.

Clinical appropriateness of coding decisions, however, is an important consideration. Placing follow-on biologics and innovator products in the same code would create financial incentives for the use of the lower-priced product. Given some of the safety issues associated with biologics that Joan discussed earlier, there may be reasons why financial incentives for the use of the lower-priced product may not be clinically appropriate in all instances.

If policymakers wish to put follow-on biologics in

the same billing code as the innovator product, there are several ways that it could be structured to address the goals of ensuring patient safety and achieving savings. For example, placement in the same billing code be contingent on an FDA determination of interchangeability. Another potential approach is to permit the Secretary to place follow-on biologics in the same billing code as the innovator product after input from an advisory committee of scientific and medical experts or a public comment process. A third approach might be to require follow-on biologics and innovator products to be placed in the same billing code, but permit the Secretary to make exceptions if there is evidence that this is not clinically appropriate for a particular product.

As we walk down this list of approaches on the slide, it is likely that the number of follow-on biologics and innovator products placed in the same billing code would increase, and as a result savings would increase. I would be happy to discuss these approaches in more detail in the Q&A if there is interest.

Now I am going to turn it over to Nancy who is going to talk about innovative pricing strategies that might

improve the value of Medicare payment systems for Medicare services more broadly, including drugs and biologics.

MS. RAY: Implementing a process to approve follow-on biologics may increase competition and lower Medicare payment rates for these products. To help Medicare become a more astute purchaser of health care services, policymakers could consider other changes. One such change concerns how Medicare sets the payment rates for biologics and drugs as well as medical services, devices, surgical procedures, and diagnostic services.

Medicare rarely considers clinical evidence in the rate-setting process. Consequently, instances exist in which the program pays more for a service when there is no evidence showing that it is better than currently available treatments.

Some policy experts have concluded that Medicare should use comparative effectiveness information when setting providers' payment rates. Some have also suggested that Medicare not pay more for a new service without evidence that shows that it is better than currently available treatments.

Your mailing materials give three examples of

pricing mechanisms that would improve the value of Medicare spending that makes use of clinical evidence. I'm going to spend a couple of minutes here talking about these approaches.

The first is reference pricing. Payment for a service under this strategy is often set at the price of the least costly service among all those that are clinically comparable. That is, payers cover the cost of the lowest-priced alternative. Patients can pay the difference if they and their providers decide on a higher-priced item. The rationale is that payers should not reimburse more for one service when a similar service can be used to treat the same condition and produce the same outcome but at a lower cost. This concept is a little different than what Kim was discussing. What we are discussing here is, for example, two innovator products, two innovator drugs or medical services, for example, that are in separate codes. One is more costly than the other, but there is no evidence that the more costly item produces better outcomes. Reference pricing could also be used if the decision is made to put follow-on biologics in different codes from the innovator biologic.

Medicare has some experience with reference pricing strategies, referred to as least costly alternative policies that are used to set the payment rate of selected drugs and supplies. However, a recent court decision pertaining to drugs might discourage its widespread use.

The second strategy is performance-based pricing. This approach explicitly links payment to patient outcomes through risk-sharing with providers and manufacturers. This is also referred to as payment by results. The basis of risk is the effectiveness of the product as measured by agreed-upon objective outcomes. This strategy shifts some of the financial risk from the payer to the provider and manufacturer.

Some have suggested that performance-based pricing might be particularly appropriate for services and products that are high-priced but whose clinical effectiveness is now well studied for all patients.

One example is a risk-sharing scheme that began in 2002 in the United Kingdom between the Department of Health and four manufacturers of products used to treat multiple sclerosis. The outcomes of about 5,000 patients with MS are being monitored for 10 years. The price that is being paid

for each drug may be adjusted based on the drug's clinical effectiveness at two-year intervals to ensure that the drugs remain cost effectiveness.

The third pricing strategy is bundling. Under this approach, providers are paid a set rate for a group, a bundle of services that they furnish during the treatment of a chronic disease or illness or during an event, such as surrounding an inpatient hospitalization. The Commission is certainly familiar with this strategy. You discussed bundling all services associated with an inpatient stay in our June 2008 report.

I would like to point out here that widespread implementation of these approaches might take a change in the statute. Some researchers have concluded that the statutes that set forth particular prospective payment systems and fee schedules would have to be amended before Medicare could broadly use such pricing strategies.

This concludes our presentation. Some of this discussion of follow-on biologics was complex and introduced new topics. We are happy to answer any questions you have about the material we presented this morning and anything in your mailing materials that we did not present. We are

interested in suggestions for topics for future analysis.

In April, we will present an analysis of Part D spending of biologics and discuss how the approval of follow-on biologics might affect this trend. For the June report, we plan on including an informational chapter on follow-on biologics.

MR. HACKBARTH: Thank you. I thought I'd see Bruce's hand up here early. So first-round clarify questions.

DR. STUART: This is a very dynamic market for biologics, and as you know, the pipelines for these products among the major manufacturers are fairly deep and long. So the question here, the first question I'd like to ask, is: Did you look at the follow-on biologics in the context of a dynamic market? In other words, it's going to take awhile for these products to be approved, if FDA gets the authority to do this. But the market itself is going to continue to operate in terms of new products coming on the line. Are the FOBs going to be obsolete by the time they get through the market? I guess that is really my question.

DR. SOKOLOVSKY: I guess that I can't say that because, as you know, a third of the drugs in development

right now are biologics, but we don't know how many of them will actually make it to the market. So, on that basis, I don't really think -- as you say, it's a very dynamic market. I don't think I could answer that.

DR. STUART: I haven't read the GAO report. Did it address this issue?

DR. SOKOLOVSKY: It talked about drug development in general.

DR. KANE: I'm finding it a little confusing to understand quite what the criteria for bundling into the same billing code options are. So if you look at page 14, I think, one option is, I guess, to put them in the same billing code if they're interchangeable; another is to put them in the same billing code I guess if they're comparable. And is that middle bullet putting them in the same billing code on some other basis?

MS. NEUMAN: The middle bullet gives sort of an intermediate option in the sense that you could under the middle bullet put things in the same code if, for example, they're interchangeable. And perhaps there may be circumstances where an interchangeability determination hasn't been made, but something has been on the market for a

fair amount of time, and there's consensus that they're pretty much the same, and for whatever reason there's not an interchangeability determination.

It would allow the flexibility to sort of take into consideration the specific circumstances of a product and, you know, sort of what the common consensus is among the medical community about its use. So it would give wiggle room and discretion to the Secretary.

DR. KANE: I guess I'm a little uncomfortable understanding what other type of evidence besides these two standard -- and maybe a related question is: Does what other countries do with that drug have any bearing on what we do? Would that help set the standard that isn't the same as comparable or interchangeable, but yet it's in wide use in England or something?

DR. SOKOLOVSKY: There are on the market now about 15 follow-on biologics in Europe. The EU, which has the overall responsibility for approving follow-on biologics, makes determinations of comparability. It leaves determination of interchangeability to the individual countries, and, in general, they are not making that determination.

DR. DEAN: I'm going to say this, but I obviously could be wrong. The way I organize this to my mind when we were talking it through is the first one is the highest standard. It's sort of interchangeability, you only put them in the same code if there has been a determination of interchangeability. And that's a fairly high standard. Try to track your mind back to some of the things that Joan was saying in terms of being able to determine particular -- all right.

The other two I see as more -- you could use different determinations, but those are more comparability standards, and it's just a question of kind of going through a process and deciding there's enough evidence to put them into the same code.

Is that a fair break between the first and the second two?

MS. NEUMAN: I think that is a fair break, and you could see a need for sort of the second or third if you had questions about whether FDA would exercise the interchangeability determination.

DR. KANE: So the second two are sort of ways of deciding whether they are comparable?

MS. NEUMAN: Ways of deciding whether they are comparable, yes.

DR. MARK MILLER: Are you sure, Kim? Because, I mean, I said that, not you. So --

[Laughter.]

DR. SOKOLOVSKY: It's the FDA that decides that they're comparable. This is a coding decision that CMS would make, and CMS --

DR. MARK MILLER: And that's what I was trying to say. At a minimum, there would be a comparability determination.

DR. KANE: But not by the FDA.

MS. NEUMAN: Let me step back for a second. If a follow-on biologic is approved, assuming there's a pathway, that would connote that the FDA has determined that the two products are comparable in terms of safety or efficacy. So any of the products that there would be consideration about whether to put in the same billing code or not would have been determined to be comparable by the FDA. The question is whether that alone makes you comfortable putting them in the same billing code or if there are other concerns that would make you want them to stay in separate codes.

DR. KANE: Okay. So step two and three are really just ways to avoid having a comparable put in the same billing code if there are concerns that are beyond the comparability determination.

MS. NEUMAN: Yes.

DR. CROSSON: My question of clarification was exactly the same as Nancy's.

DR. CHERNEW: I had a question about Slide 16, and, in particular, were you intending these to go well beyond biologics and be a broad discussion of Medicare payment policy that could be used in Part A or Part B? Or is this ways of thinking about it just within the context of prescription drugs?

MS. RAY: More broadly, Part A and Part B.

DR. CHERNEW: I'll save my round-two follow-up question.

MR. BUTLER: Just another clarification, because the chapter is titled "Biologics," and you do get into in the end the pricing for new technologies. So you use, for example, IMRT and CTA which are really not biologics per se, or we could go back over drug-eluting stents and some of the other things and how those have been handled.

What is your thinking about how that fits with the rest of the discussion around biologics? Because they're a little bit different. They're both important, but...

DR. MARK MILLER: It's always complicated trying to organize the material that we go through here. There has been some discussion on at least a couple of these strategies in the past, the reference pricing strategy and the bundling strategy for sure. Biologics introduces another place where it was a good place to talk about these kinds of tactics.

The middle one, although you might potentially apply it to other things, my sense -- and, again, because I am not as close to this as you guys -- is pretty much that one has been talked about only in the drug world that I'm aware of.

So I think what we're trying to do is we're trying to do a couple of things here. Biologics and those follow-on biologics matter to Medicare, and it's probably worth knowing what they are, number one. Number two, there are some very specific Part B issues that might pertain. Then there are some broader payment strategies that we should be talking about generally that could very much play a role in

the biologics world but probably go past that.

I see your point that these may have different permutations depending on what we're talking about. We're just trying to organize it close to something where you can get your head around it and go, oh, I see what these concepts -- how they could be used.

DR. REISCHAUER: This might be more a question for Bruce or some of the physicians here than you folks, but comparing biologics to small molecule drugs, is the effectiveness of any biologic more likely to vary with genetic makeup than is the case with small molecule drugs? Because we could be on the cusp of a period where we're going to say, well, you know, all of us have the same condition, but biologic A is best for me and biologic C is best for Bruce, and so sort of trying to lump together just before we get to the scientific application that says this is not appropriate may be not the way to go.

DR. SOKOLOVSKY: If no one else wants to take a crack at that, I will give -- a couple of years ago, you may remember, we did a mandated report on physicians that used Part B drugs, and one of the examples was rheumatologists. There are four biologics -- well, actually, there are four

Part D biologics and two Part B biologics that rheumatologists use, most of them in the same class called TNF inhibitors. I was told virtually to a person by the rheumatologists that all of these drugs essentially perform the same purpose; there isn't a particular reason to favor one over the other going in, but that each one of them won't work for a certain percentage of people, and if you move them to another one, it may work. So that implies a certain -- I don't know that I want to compare it to small molecule drugs, but it certainly supports the idea that there is a some individual reaction that's important to take into account.

DR. MARK MILLER: The thing that I try to carry around in my head is, again, it goes to the interchangeability and the comparability. If you could get to an interchangeability standard in the sciences, you know, is in question. That notion there is it's getting a lot closer to what a generic is.

But setting that aside, because the standard may be a very high and hard to hit, is the question of comparability. And there the difference one way -- and you said this -- is whether you go to the pharmacy and somebody

simply just substitutes a drug or one biologic for another, you wouldn't be doing that. In a comparability situation, your physician would be making that decision.

DR. CROSSON: Just a little bit on Bob's question, there's two moving pieces here. One is for the small molecule drugs which say -- let's say it contains 20 or 25 atoms; the generic drug has got same 20 or 25 atoms. They're the same. So then you have genetic diversity in the population in the sense of how one person versus another person responds to that group of 25 atoms.

The issue here with respect to the biologics is you've got molecules of perhaps hundreds or in some cases thousands of amino acids all combined in a ball of yarn like that diagram suggested. And it's possible to construct -- as a matter of fact, it is most likely that when others try to construct the same molecule, they're going to have, say, a few amino acid sequences that are different.

It is possible, although I don't know that there's any evidence, that those differences between the two molecules that are slightly different could play into the genetic differences that are present in the population, even for more simple formulations of pharmaceuticals. But I

don't know that there's any evidence that it's more likely.

DR. DEAN: Just to follow up on the same thing, what Joan said is certainly right, but it's also true of a lot of small molecule drugs. It's true of non-steroidal anti-inflammatory drugs, it's true of antidepressants. So there is a lot of variation. I think we just really don't understand it, I mean, just on the verge of -- but I would suggest that I think it's true of all drugs.

MR. HACKBARTH: I am struggling -- and we're going to get to round two here in just a second. Maybe this is the first round two. I am still struggling with the question of where MedPAC might enter into this conversation. It seems to me, if I understand this correctly -- and I may not -- that there are a bunch of issues for the FDA about how it deals with follow-on products in this area and very important questions to be answered there. And then there's a series of questions about how Medicare would pay for biologics and, more broadly, new technology of various types.

I understand that focusing on biologics gives us an example of broader "How do we pay for new technology?" questions. But given how many moving parts there are in

biologics, I wonder if it's a good case for us to be using to address the Medicare new technology questions. That's a question, not an answer, but that's what I'm struggling with.

Let me see hands for round two.

DR. STUART: This is partly a question -- well, a comment and then a question. There is one opportunity that's not on here, and that's coverage determination. So you decide whether you're going to cover it or not.

Now, this is certainly a very underused aspect of at least drug coverage under Part B. But that's not to say that it can't be done, and there are some other countries that have done this with biologics. What that comes back to, then, is having a mechanism for determining comparability, which is really what were kind of struggling with here.

That leads to my question. Of the $1.1 billion in stimulus funding for comparative effectiveness, $400 billion of that ended up in NIH, and $300 billion is going to be in AHRQ, and $300 billion is at the discretion of the Secretary. My question is: Has there been any talk about that $300 billion being funneled in some way for comparative

effectiveness that might lead ultimately to coverage decisions under Medicare? I know this is an atomic issue. It's a huge issue, but you're closer to it than I am.

MS. RAY: Just to clarify, the comparative effectiveness funding totals $1.1 billion; $400 million goes to NIH, $300 million goes to AHRQ, and $300 million is at the discretion of the Secretary.

This slide and the mailing materials were designed not to be comprehensive but just to provide examples. I think we focused on payment as opposed to coverage because of concerns raised in the past with coverage and trying to include value in the national coverage decisionmaking process. And that leads to a yes and no decision versus on the payment side where you don't have that same yes or no decision.

In terms of the $1.1 billion funding in stimulus and the coverage, I think it remains to be seen how that goes.

DR. MARK MILLER: My take on the second part of your question would have been -- I mean, they're going to motivate studies, and those studies may potentially shed light on coverage decisions. But I don't know that there is

a hard linkage between the money and coverage decisions. I think the money is directed more towards studying things.

DR. STUART: I'm sure there is no direct linkage. It was simply a question about whether the discretion is likely to lead to some efforts to clarify what is a very messy area here. And I frankly would put coverage determination in there even if you don't spend a lot of time talking about it, because I know private insurers, private payers, are looking particularly at some of these new chemotherapy agents that are coming down the line. According to the trial, it gives you another week to live as opposed to the next best agent. You know, are we going to pay for that? So I think it ought to be on the table.

MR. HACKBARTH: Nancy, can I just ask one more round-one question? The CBO had in its Options Book a policy related to biologics. In fact,, the President's budget also has one, and they have some specific number of savings, $9 billion or something over 10 years. Is that a proposal or the CBO option about changing the FDA process, or is it about changing Medicare payment, or some combination of the two?

DR. SOKOLOVSKY: It reflects both the FDA and the

coding issues that Kim brought up, depending on your assumptions what the savings would be. One range of assumptions is what are you assuming about data exclusivity. Another set of assumptions are about this coding issue that Kim is talking about.

DR. KANE: It would be interesting to know -- for these biologics that may be harder to get generic substitutes for, for a variety of reasons -- how they're priced in other developing countries and how our average sales price relates to that. I am not saying necessarily that Medicare should go negotiate directly around the price, but perhaps the global developed country average sales price should play our role or have an influence over. I would just like to know what that differential is, if there is, in fact, a big differential, and that we might want that to inform our decision on how much we're willing to pay.

You know, maybe we are using -- ASP works when there is a competitive market, but when there isn't one, it doesn't work, and some countries might even be looking at what's a reasonable ROR or how long should we leave it on the market before we arbitrarily say that.

I just think we're trying to price this thing when

there's clearly some scientific reasons why there is no competitive market, and we shouldn't remove from the table the option of saying, okay, when there's no competitive market, we're going to use more regulated or administrative pricing mechanisms. I would like to see us explore that if we can.

MR. BERTKO: I'd like to have us, I think, be perhaps on two levels. One, the spending on this is already high, and I think a third of the new drugs in the pipeline do come on, some portion of them. It is probably going to get higher much faster. These are very expensive drugs, as I think we know -- $10,000, $50,000, $100,000 for a course of treatment. And so the thought would be should we be as the Commission generally supportive to the FDA of speeding up the process somehow. I'm not sure I know how to specify it, but just that we would lend our support.

Then, secondly, I think you guys have laid out some nice options there in terms of the payment principles, and this was one where I think we really need to pound through, particularly on drugs. As far as I know, there's really no other cost control mechanisms out there today, as I think Bruce or Nancy were saying. When the drugs come in,

we pay for them, that's it. And so anything we can do to support the cost controls I think is worthwhile.

MS. BEHROOZI: It occurred to me, Glenn, that -- by the way, I learned a lot from this. Thank you so much, and I'm so impressed with how much you guys know about this obscure corner of the world, becoming less obscure actually as we spend more money on it. I was thinking, as you were saying, Glenn, what is it that MedPAC should be thinking about in terms of Medicare payment policy. It struck me it's either rather narrow; it's, you know, whether we should include various drugs in the same code; or it's really broad, like should we reform the entire payment system.

As I was thinking about this, I was thinking about our problems and paying for biologics, and what we've been doing is taking them off our physician fee schedule and moving to specialty pharmacy management by our PBM. And so it does seem to me that we are constrained by the fact that these are Part B drugs rather than being able to put them into Part D where, no, Medicare can't negotiate; so far Medicare is relying on the innovation of private payers. Well, maybe we should let them innovate about biologics, and I bet they'd be a lot less -- they'd feel a lot less

constrained by just paying ASP plus 6 percent versus an entirely new payment structure. I bet they'd come up with ways to determine comparability, step therapy, all kinds of things that are imposed in the private sector that we're not talking about here.

MR. HACKBARTH: Although part of what I thought I hear John saying is that private payers feel powerless in this case.

MR. BERTKO: I agree. Step therapy is there, but once the drug is indicated, you're done. You just pay $100,000.

MS. BEHROOZI: Well, except, like I said, we've moved it out of the physician payment fee schedule that we use, which is based on Medicare, into a specialty pharmacy where there is some negotiation going on by the large PBMs that have a lot more pricing power certainly than we do. And I anticipate that they will be innovating and be more aggressive about things like their own version of comparative effectiveness and things like that, as we do with other drugs.

I thought the point that Jay made was so important. It's not just biologics where people say that

there are differential impacts on people. Right now we have reference pricing for generics, and there are still physicians and there are patients who say, yes, but in this particular case, I need this brand drug. And we have a clinical review process to make exceptions, which was referred to in the paper as a possibility.

So I feel like we could be treating biologics a little more like other drugs except we don't deal with drugs in Medicare, except for Part D.

DR. CROSSON: Thank you. I'd like to compliment you, the staff, particularly Joan, on this presentation. It's one of the more complex, I think, technical things that we've taken on in the time I've been on the Commission. As usual, you have made it seem simple. So thank you for that.

The other thing is I think it is something that we should take up. We have thought a lot about this, made some cost projections of our own, given the state of the technology. And I would have to say, just based on our own cost estimates, the ones that we saw in the paper are somewhat of an underestimate based on what we think is going to happen, at least over the next 10 years.

The question is what do we want to do, you know,

if we are going to move towards recommendation, how technical do we really feel that we can get here? I'm not sure, I think we have some more thinking to do.

It would seem to me that if I were thinking about recommendations right now, it might be something like, well, given the potential impact on the Medicare program and our responsibility for trying to guard that as a fiduciary, we might decide to conclude that there probably does need to be a pathway for the approval of biogenerics without necessarily saying exactly what that would be. Because I guess that's one of the questions, whether there should be one at all or not. I would certainly come down on the side of there being one.

Second, something that might have to do with whether or not Congress should consider the necessity of expanding in any way the authority of the FDA -- perhaps it doesn't need to be, but examining and expanding the authority of the FDA to deal with this new complexity of issues. Whether or not there needs to be some sort of case-by-case work done or not would be part of that.

And then, lastly, the issue of the marketing exclusivity period. I guess maybe we might say something

along the lines that as Congress considers the issue of the marketing exclusivity period, it should take into consideration, among other things, for sure the impact on the cost of the Medicare program, the cost of these drugs in terms of out-of-pocket costs for Medicare beneficiaries, and then also perhaps even the impact of these on out-of-pocket costs for non-Medicare beneficiaries because there is a derivative cost. Many of these drugs are put into the highest-cost tier by insurers, and when you're talking about drugs that cost $100,000 a year, 25-percent co-payment, pretty soon it adds up to real money. So there are economic issues that go beyond the Medicare program.

So I have been thinking about us ending up somewhere in an area like that.

DR. CHERNEW: I'm struggling with the scope of this in a specific way. I see three topics that are sort of spinning around. One of them is biologics, which is a range of issues. One of them is Part B drugs, which certainly includes biologics but is definitely not limited to just biologics, and that has a separate set of issues of how we pay. And the third is all new technology.

So first let me say I think how we pay for all new

technology, which is a fascinatingly important question, I think needs to be somewhat beyond the scope of how we deal with this. I think there is a lot of -- I think that's going to differ in different areas. I think applying this to new imaging is just somehow different than applying it to new services that might be a new medical service or a new clinical service. It's just different. I think it's too hard to think about how to think about some of your Slide 16 concepts across the whole array of different types of new technologies. And some of the things, like bundling, is important for things well beyond issues of new technology. So I think that, in my mind, just has to be separate.

I think the Part B focus versus the biologics focus again illustrates this complex problem we commonly have, which is we're organized A, B, C, D, but we think about disease and services, and we often get confused.

So I like discussions about how we might solve some of the problems and rationalize across the programs where we have issues, and I think this issue of what consumers pay matters a lot.

What makes this interesting to me is there are some really fundamental questions that arise in this case

technically that have ramifications and also some philosophical issues. One of them that hasn't been raised very much is many of these biologics, I understand, are designed for a very small number of people and that they tailor treatment in very specific ways for very specific people. They'll look at exactly your cancer, your type of cancer, and they'll do the genetic testing and decide this is the right one for you, more so than I think they've done for others. They have a lot of small market biologics -- I believe that to be true -- which has ramifications for price.

What often happens, I believe, in those cases is they can demonstrate in some cases there is some measure of better quality. How much better quality, whether it's a week or a month, is a separate issue. But I think throughout this it raises the question of how we decide to pay for quality. And my opinion regarding some of these things, for example, when we talk about coverage, I think coverage is particularly clunky in these areas because you might find some subsets of people for whom it works, but if you cover it, it's hard to limit it to just those people.

I think this is an area where there is a strong

role for aspects of consumer incentives as we talked about before. I think we have to think about novel designs. I think we have problems with across-the-board cost-sharing. I think we have problems with coverage limits, because many of these people are going to hit their coverage max, and then everything is free about that. On the other hand, I think really would make none of us feel still good -- I know would make me feel horrible -- if we had a system where you had to pay 25 percent of all specialty drugs when there were some that were really, really high value in certain people.

So I think this is really going to challenge our sense of how we use consumer incentives to allow people to decide they want something that we don't want to pay for, how we decide what quality we will pay for.

The last related point that I want to make, which I think is a wonderful change from the last several meetings we've had, is we often have discussions around the table in a paradigm of what does it cost, what should we pay, how do we did the margin right? And as the medical education discussion illustrated and as this discussion illustrated, our discussions are actually much more broad about how we can make the health care system better for Medicare

beneficiaries, and then particularly in the medical education discussion, overall how can we make the health care system better, which, of course, would benefit Medicare beneficiaries?

I think that broader paradigm is actually really useful in thinking about how we go forward and how we do this. And I think as we talk going forward about payment, a payment paradigm that is fundamentally based on what's the cost of this, how shall we pay for it, is different than a paradigm that is broader. And I enjoy and I think it is a better role in some cases if we can, recognizing our more limited charge, to have that broader paradigm.

DR. CASTELLANOS: We all wear a lot of hats, so let me wear a physician hat for a second. I think we're a little out front. I think we need the science before we talk about reimbursement, and I think we all agree on that. Whether interchangeability and compatibility are consistent, we need the scientists to help us. So before we think about reimbursement, we really need the help from them.

Again, with the physician hat, Mitra, you mentioned about drugs and Medicare. Well, these drugs are Part B drugs, and these come directly out of the SGR. And

every physician, whether he's a pediatrician or a primary care director or a urologist, pay for this under the SGR. So if the oncologist is using these billion-dollar drugs, it affects every physician and his reimbursement.

This has been brought up on several occasions. I don't need to beat up on the SGR. We've all thought about taking this out. But it does affect that.

I guess the big point I want to make is that we do need to look at reimbursement. Urology was directly involved with a Part B drug called LHRH agonists. And we were getting paid under AWP. And it was outrageous the money we were making. I didn't set the rules up, but did I collect the money? Yes. But it was outrageous, and we as a committee made some decisions and did the right thing. And I think we can do the same thing for these drugs, too.

I really believe that we have the ability to make some changes to correct some of the inadequacies or inaccuracies in the reimbursement system.

DR. MARK MILLER: Can I ask one thing? Ron, in your opening comment, you said policy needed to wait for science. And then in your last two examples, you suggested -- yes, policy needed to wait for science. And then your

last two examples kind of pointed to the need for reimbursement to address some of these issues.

DR. CASTELLANOS: I guess the point I was making, we first need science for the policy as far as whether these are interchangeable or not and whether they can be used. But once they are approved, then we need reimbursement policies. And I think we have that ability to do it, and we have done it.

DR. MARK MILLER: [off microphone] So you're not asking us to wait on making those decisions?

DR. CASTELLANOS: I'm talking as a physician. Before I use these drugs, I want the science first. But we should be working at things together.

DR. STUART: This is a follow-up. I think it has implications for what you're talking about. The reimbursement is going to forth regardless of the science, and Mitra was indicating that what she sees is that these drugs are being put -- they're taken out of the medical side, they're put on the drug side, they're a specialty tier and presumably very high co-insurance. No? All right. Well, but this is -- I don't want to steal your thunder for next month because you're going to be talking about this.

But to the extent that these drugs are on the D side, they are increasingly being put on specialty tiers, and I think you said the average reimbursement rate is somewhere around 33, 35 percent.

Well, the difference between D and B is that D has a company. And so, in essence, when you take one of these very expensive drugs, if somebody is in the standard plan, the price doesn't matter, because you just zip right up to the catastrophic cap almost instantly; whereas, if it is a B drug, there is no maximum. And then it becomes the issue of, well, what does the Medicare supplemental plan do, what does the employer plan do.

John, maybe you can answer this -- well, I know you can answer it better than I can. That is, what are the supplementary payers doing with respect to Be coverage for biologics?

MR. BERTKO: The answer is pretty much as I indicated before. You run through as many things as Mitra said -- and step therapy in particular -- and then you pay. And they use specialty pharmacies, but even the specialty pharmacies -- you're right, Mitra, they do try to negotiate, and I'll emphasize the verb "try" as opposed to "achieve"

negotiated prices.

DR. STUART: I was thinking in terms of patient cost-sharing.

MR. BERTKO: They pay.

DR. STUART: So they'll just pay. All right.

MR. BERTKO: They have to just pay.

DR. STUART: So there is no move that you see toward D is doing in terms of segregating these into a separate your tier with higher co-insurance that would not be paid by the supplemental policy.

MR. BERTKO: Well, there are very few people in Medigap D coverage, so that's very small. And if you're in an ESI, employer-sponsored insurance, retiree fund, then you most likely have a regular four-tier cost-sharing with the 25 percent. But that's becoming increasingly -- well, it's diminishing.

MR. HACKBARTH: But if it's a B drug as opposed to a D, they're just paying all the cost-sharing?

MR. BERTKO: Yes. In a supplement, if it's a Medigap B, they're just paying. And probably, as far as I'm aware of, most of the Medigap payers use relatively few specialty pharmacies. I mean, compared to what Mitra's

group does, they're on top of the game, and these guys are, let's say, slow.

MS. BEHROOZI: If you're talking about Medigap, then you're talking about wrap-around payments, so you've got two different payers in the mix. So that's another problem, another issue. If you move it to the drug payment side, you've got one payer, and that's where you have some negotiating power. And maybe it hasn't proved effective yet, but there's more opportunity when you've got one payer paying from whatever dollar they pay from, then splitting it between two -- just, you know, as a theoretical model. I understand it hasn't played out yet.

MR. HACKBARTH: Although if it's a B drug, one of the payers is Medicare, which has lots of power -- not necessarily used at this point, but it has the potential to have more market power than any individual private carrier.

MS. BEHROOZI: Sure, as long as we're paying ASP, whatever that is, at 106 percent, as you said, no power being exercised.

MS. HANSEN: This is related to the Part D side. Did I recall -- and I forget whether it was this time or before -- that the people who are dual eligibles or they're

covered, that the use of biologics has been disproportionately higher for them?

DR. SOKOLOVSKY: You're absolutely right, yes, and that is some of what we're going to present next month.

MS. HANSEN: It struck me when we talk about the co-pay with somebody paying the 25 percent, or whatever it is. But when you are on Part D and you're subsidized, the beneficiary doesn't necessarily have a co-pay. And so there seems to be some corresponding disproportionate use of the biologics with the people who don't have a co-pay.

DR. SOKOLOVSKY: Just to clarify, they do have a co-pay but it's much --

MS. HANSEN: It's much smaller.

MR. HACKBARTH: Any other questions, comments, suggestions for direction?

MR. BUTLER: Just to reinforce that Mike's point that the direction we're headed towards a narrow focus, I vote for that.

DR. STUART: I think narrow is good, too.

This is a question that you may have addressed here, but I didn't see it, and that is, how does the VA pay for biologics?

DR. SOKOLOVSKY: That's a very good question, and, unfortunately, it didn't occur to me until yesterday, so I can't give you much clear data. But I wanted to see if the PA used any formulary process for those rheumatoid arthritis drugs, the TNFs, which, as far as I could see, Part D plans have all of them on their formularies, although it's not actually a protected class. But for all the various reasons that we've talked about, they have them all.

The VA, as a plan that has a national formulary and is much stronger in using them, I wondered if they had a formulary, but I found that cover them all as well. But what they pay I don't know.

DR. STUART: But you're planning on adding that to the chapter?

DR. SOKOLOVSKY: Yes.

MR. HACKBARTH: Thank you very much. Good job.

Now we will have our public comment period.

The ground rules are please first state your name and organization and limit yourself to no more than two minutes.

MS. TODD: Good morning. My name is Laurel Todd. I'm Director of Reimbursement and Economic Policy at BIO,

the Biotechnology Industry Organization. We appreciate the opportunity to comment this morning.

BIO is the largest trade association to serve and represent the biotechnology industry in the U.S. and around the glove. BIO represents more than 1,200 technology companies, academic institutions, state biotechnology centers, and related organizations in the U.S.

BIO strongly supports the creation of a regulatory approval pathway for biosimilars and believes that Congress should pass the right bill as soon as possible. This legislation should be based on sound science and recognize that biologic products are fundamentally different from traditional small molecule drugs in their complexity, development, and production processes, and that biosimilars are not generic drugs.

In addition, BIO believes that such a pathway must fully address both how to ensure patient safety and how to maintain incentives that spark continued investment that leads to future medical advancements and breakthroughs.

One of the many important positions that BIO has articulated during the legislative discussions surrounding the establishment of a regulatory approval pathway for

biosimilars relates to interchangeability and the importance of maintaining the physician/patient relationship. As the FDA has noted on numerous occasions, there is a known significant risk to repeatedly switching between products and a resulting negative impact on both patient safety and effectiveness.

Therefore, in light of the current scientific limitations on the ability to make determinations of interchangeability, and because it is critical to protect patient safety, BIO agrees with the FDA's position that patients should not be switched from the innovator biological product to a product that is only similar and vice versa without the express consent and advice of the patient's physician, and legislation should not allow for determinations of interchangeability at this time.

BIO has worked with legislators in Congress for a number of years to ensure that these critical goals are met by any biosimilars legislation. BIO looks forward to working constructively with MedPAC, as we have with Congress, as MedPAC reviews the many complexities of a regulatory biosimilar approval pathway, as well as the implications for the Medicare and Medicaid programs

following the passage of a new regulatory pathway.

Thanks.

MS. BIRMINGHAM: Good morning. My name is Maya Birmingham. I'm a Senior Assistant General Counsel with PhRMA. I'm representing PhRMA today and would like to thank you for the opportunity to present a short statement concerning follow-on biologics in Medicare.

As many of you know, PhRMA represents the country's pharmaceutical research and biotechnology companies which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

It is in this spirit that PhRMA supports establishing a pathway to approve follow-on biologics that is science-based, open and transparent, puts patient safety first, and promotes incentives for innovation.

As you were all discussing today, there has been much discussion about the appropriate abbreviated approval pathway for FOBs. However, there is little consensus and much controversy about the correct approach. Just this week Chairman Waxman introduced new FOB legislation, which raises more questions than it answers.

While we are still reviewing the legislation, we believe that there are a number of patient safety, regulatory, clinical, and intellectual property issues that remain unresolved. The resolution of these issues is critical to understanding the market and reimbursement implications of any proposed changes.

Consequently, it is difficult to speculate whether and to what effect coverage and reimbursement policies, how they may affect pricing and competition. For that reason, PhRMA believes that it's premature for MedPAC to make recommendations before the regulatory approval pathway for FOBs is appropriately designed, described, and defined.

However, once a pathway is established, we firmly believe that market dynamics should be given time to play out before Congress and/or regulatory entities intervene and formulate policies that may result in unintended consequences.

Thank you very much.

MS. FISHER: Hi, Karen Fisher with the Association of American Medical Colleges, AAMC. We represent all of the medical schools in the country as well as all of the major teaching hospitals.

We, too, were glad to see the Commission interest and discussion on medical education and the role of delivery system reform. It's obviously something that we're paying a lot of attention to within the academic medical center community.

Let me first say that we really appreciate Cristina and Craig's efforts to meet with us, and Mark and the other staff, and have dialogue about a lot of these issues. That's been very helpful.

The one thing I would say is that it is important to remember that a lot of the people who do this work, and the program directors, and the DIOs that Peter Butler mentioned are really committed to educating people for the future and looking forward at delivery system reforms. There is a lot of effort and emphasis on core competencies by the accrediting body and by academic medicine to do exactly what you folks are talking about, and that is to set people up for lifelong learning to be able to deal with the changes that are going to come about in medicine throughout their whole careers.

It is important that that be a major focus. That's why our association is very much behind the ACGME

core competencies and we're involved with that. Many of our members are devoting a lot of time and effort and cost to implementing those core competencies.

So we do urge the Commission to look at those core competencies, to opine on them, to see if you think they're going in the right direction or not. Because a lot of our members are spending effort on that and we would not like to see a parallel process go in opposite directions. It's not the right message to give them.

We do appreciate and met with MedPAC staff on the RAND study and the survey. Part of the problem -- and we're part of the problem with it, too -- is that there's not enough information about what's going on in the 9,000 residency programs. We need to do a better job. Twenty-seven gives you some information. It's not enough. We're going to be going out to our GME leaders and asking them questions similar to what the RAND study asked and we're happy to work with MedPAC staff to get more information in that arena.

Let me finish up with the non-hospital site issue on the regulatory side. We do think that's an area where the Commission could make some major impact to the

regulatory agency about the regulations that are going on. It is demoralizing for our GME people who are trying to place people out into these settings to see the regulations that they must go through to be able to do that, and for me to get questions on the phone saying our residents are training in school-based clinics. They're going out to the jail. They want to go out to public health departments. They want to ride along with the ambulance people. What do we have to do there?

The incentives are so negative in that area that it's quite demoralizing. Despite the fact, though, that they're still doing it, in part because they think it's important and in part because the accrediting bodies say you must do it. So they're going to do it. But it's demoralizing and I think the Commission could make some real progress in that area by saying something to CMS about the necessity of some of these regulatory burdens.

Thank you.

MR. HACKBARTH: Okay, we're adjourned. See you in April.

[Whereupon, at 11:07 a.m., the meeting was adjourned.]