MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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COMMISSIONERS PRESENT:

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P R O C E E D I N G S

MR. HACKBARTH: Welcome to our first session in this new cycle. Many, although not all, of the sessions today are going to be oriented around -- at least initially -- updates of what happened in the recent Medicare legislation and its implications for MedPAC's agenda. Over the next couple of days there are some exceptions to that, an important one being tomorrow we will have an expert panel with three guests on research on the use of imaging services, a subject that we have touched on frequently in the last couple of years.

So our first session today is on the initial draft of our content character that goes at the beginning of the March report each year. And Evan is going to lead that presentation.

MR. CHRISTMAN: Good morning. As Glenn mentioned, this presentation is going to review the broad economic and financing challenges facing the Medicare program. The purpose of this presentation is to frame the issues facing the Medicare program and the challenges driving future policy choices.

A key financing challenge is that growth in health

care costs for all players has exceeded growth in the gross domestic product. You can see that on this table on the second slide. In a recent analysis, CBO covered the growth in health care spending per capita to the growth in GDP adjusting for changes in demographics. The analysis found that over a 30-year period health care spending has exceeded per capita GDP growth by more than two points.

For these reasons, health care spending has grown as a share of our nation's GDP and it is expected to continue to do so. You can see that on the next graph. In 1980, health care costs were about 9 percent of GDP and they rose to about 16 percent in 2005. And 2017 they are expected to be over 19 percent of GDP. The upper three areas are public spending such as Medicare and Medicaid and other public spending. The gray bar is private sector spending.

Public spending by Federal, state, and local governments has risen to about half of all health care spending and it is expected to grow faster than private spending over the next nine years. About three-quarters of the public spending is Medicare and Medicaid.

For Medicare I would note that these projections

assume the SGR mechanism requiring negative updates is not overridden.

The rising share of public spending does not suggest that it is less efficient in controlling costs and other sectors. For Medicare the comparison is sensitive to the periods compared. However, over longer periods of time the rates of growth for Medicare and private health insurance have been remarkably similar.

While the growth in health care as a share of GDP may raise affordability concerns, from an allocation perspective it is not clear that there is a correct level of spending on health care. Some analysts have suggested that a nation as prosperous as the U.S. should spend up to 30 percent of its income on health care. However others would note that allowing spending to rise to this level could require increases in borrowing or taxes that could reduce the total economic output.

In addition, other skeptics might argue that much of the growth is due to inefficiency in the delivery of care and inappropriate incentives that raise volume. To the extent that these factors account for growth, the increasing share of GDP committed to health care may not reflect

society's preferences.

This graph highlights how Medicare's share of GDP has changed. Again, I would note that these projections assume the SGR remains as in current law with negative updates.

In 1970, Medicare was three-fourths of 1 percent of GDP and by 2005 it was 2,7 percent. In the long run the Medicare Trustees assume that the rate by which Medicare spending growth exceeds growth in GDP will gradually decline and by the end of their 75-year projection period, Medicare per capita growth will equal growth in GDP. However, even with this assumption the share of the economy committed to Medicare will grow. By 2040 its share will triple to 8 percent of GDP. I would also note that this graph shows the long-run impact of Medicare Part D. In 2030 Part D increases Medicare's share of GDP by about 20 percent.

This next slide reviews some of the major factors driving growth. Most analysts believe that many of the same factors drive growth for both Medicare and other sectors of the health care system. This highlights some of the major factors that researchers have identified. They are probably familiar to you.

The first is technology. Most analysts believe that 50 percent or more of the long-run increase in spending is attributable to technology. New technologies and medical technique can yield improvements in health but they can also yield new costs and inefficiencies if they are targeted inappropriately. As the Commission has noted, there is not an adequate evidence base to allow providers and beneficiaries to select treatments based on their comparative clinical effectiveness.

Another factor is income. The nation's income has been rising. Many analysts suggest that it is natural for people to demand more health care as incomes improve, as the marginal value of increased life span or function may be worth more than other goods.

Insurance has provided beneficiaries with financial protection from the costs of ill health but it has also insulated beneficiaries from the full cost of care. Consequently, some beneficiaries may consume more care and some providers may deliver more care than they would have otherwise. A special issue in Medicare is the availability of supplemental insurance that covers the beneficiary cost sharing for Part A and B. Estimates suggest that the

availability of this insurance may raise Medicare spending by 10 percent or more.

Another factor is prices. Changes in prices are particularly important in the U.S. system because so much of our care is provided through the private sector. Prices provide the incentive that can affect what services and regions are served, what technologies are developed, and the specialties physicians in training select. Every year as a part of our Congressional mandate the Commission reviews the reimbursement for Medicare providers to ensure that payment levels are adequate to cover the costs of an efficient provider and provide adequate access to care.

Changes in demographics and longevity also have an impact on health care spending, particularly for Medicare. With the retirement of the baby boom population, the elderly are projected to grow as a share of the population. In addition, life spans are expected to continue to increase. These factors will cause Medicare spending to grow and CBO has estimated that they will account for approximately 30 percent of the growth in future years.

Trends in disease morbidity also affect health

care spending. One analysis suggested that much of the growth in per capita Medicare spending since 1987 has been due to the increase in treatment for chronic conditions. However, it is not clear how much of this increase is attributable to an increase in the prevalence of these diseases or an increase in the rates of the treatment for these diseases.

Each of these six major individual factors is important, but in practice we observe how they act together in the delivery system. For example, the availability of insurance can result in higher demand for services, which could result in higher prices and encourage the use of more advanced medical technology. These interactions, combined with fee-for-service payment, reward providers for delivering more services, not necessarily for delivering more value.

This next slide looks at total health care spending for the nation as compared to other industrialized countries. As you can see, relative to those countries the U.S. spends more per capita than any other country in the world. This comparison shows exactly how much in 2006, about $6,700, significantly more than even the other higher

spending countries.

As you can see, the green bar on the left is the United States and to the right are the next four highest spending OECD countries, which are still significantly positively lower than the U.S. The final bar on the right is the average of all 30 OECD countries, about $2,800, which is less than half of what the United States spends.

In addition to international differences, there is variation within the U.S. in how much care the average Medicare fee-for-service beneficiary receives. This map shows how spending varies among regions and the wide variation in Medicare spending is further evidence of the questionable efficiency of some of the program's current spending. Studies of regional differences in Medicare spending have found that areas with more spending do not have improved patient health or satisfaction. And other work suggests that the broader health care sector has similar problems. Various studies that have examined the efficiency of the entire U.S. health care system have estimated that 25 percent or more of the care delivered could be eliminated with no detrimental impact on health outcomes.

In addition, the quality of care provided in the U.S. has been found to be deficient. A study by the RAND Corporation found that patients received only about half of the care that would have been expected under evidence-based guidelines. All of these findings indicate that the current system is inefficient and often inefficacious and opportunity exists to reduce expenditure growth and increase the value of care provided.

To the extent that inefficiencies drive Medicare's increased costs, they have important consequences for the solvency of the program. The Hospital Insurance Trust Fund is projected to be exhausted in 2019. At this point it will have sufficient funds to pay only 80 percent of benefits due. This gap between the fund's resources will gradually widen and by 2050 the fund will have the resources to pay only 40 percent of benefits due.

The financial burden of Part B and D will also grow. The Supplementary Medical Insurance Trust Fund, which funds these two benefits, is funded primarily through premiums and a contribution from the general fund. The general fund, which constitutes the majority of funding for these benefits, equals about 12.5 percent of all corporate

and personal income taxes in 2008 and will grow significantly in future years.

Medicare's darkening financial prognosis is creating near-term challenges for both beneficiaries and policymakers. Rising Medicare spending will impact beneficiaries directly as an increase in premiums and cost sharing. In 2008 Medicare cost sharing is expected to equal about 26 percent of the average Social Security benefit and by 2019 the burden is expected to rise to 30 percent of the average Social Security benefit.

Finally, the 45 percent trigger was also tripped again in 2008. This mechanism, created in the MMA, requires the trustees to issue a warning if two consecutive trustees reports find that general revenue will fund more than 45 percent of Medicare spending in the next seven years. Since the trustees made a similar finding in 2007, the President will be required to submit legislation next year to address the warning. The trustees issued a similar warning last year and consistent with the law the President submitted legislation this year but the Congress opted to not act on it.

In summary, Medicare and other health care sectors

face many of the same challenges that will become more serious if action is not taken soon. All health care payers will have to decide how much more of an increase in health spending they are willing to allow, carefully considering the trade-offs with other priorities and the well documented deficiencies in efficiency and value of the current system.

Addressing growth for all sectors will be challenging because there is no single cause and no single solution. Multiple strategies that enlist the efforts of many stakeholders are likely to be required.

In addition to pressure on financing, there will be pressure to improve the efficiency and quality of care. Addressing these issues will also require tackling the challenges of a fragmented system.

The Commission has considered several ideas to confront these challenges but more work remains. The system we have today evolved over many years and addressing these issues will take a sustained effort over time and hopefully the Commission's work can serve as a starting point. However, all of these data underscore the importance of starting on reforms soon so future generations have the tools they need.

I look forward to your discussion. Let me know if you have any questions.

MR. HACKBARTH: Thank you, Evan. We will open it up for discussion and, as we have discussed what I would like to do is use the following ground rules. We will go around once, give everybody an initial opportunity to comment. I would urge you to make your comments brief. When I say brief, I'm talking about no more than two minutes. If you think 17 times two, that's 34 minutes. We've consumed a big hunk of our discussion time. So please no more than two minutes. And I will start gesticulating and jumping up and down and looking unhappy if it goes on much longer than that.

When you make that initial comment, if possible what I'd like you to do is say I like the general direction of this or I don't like the general direction of this and here are two or three brief additional points. But we want to be sure in that initial round to get your general sense of direction if at all possible.

Then once we've finished the first round, what Jack and I will be trying to do as it goes on is identify a small number of topics that came up during the first round

for further discussion in a second round so we can really hone in on a few things in that second round.

So that's the basic approach. And with that, let me see a show of hands of who wants to go in that initial round. We will just go down the row here. Karen, do you want to lead off?

DR. BORMAN: Generally, I found this a very helpful way to start thinking about it. Two questions or comments. One is that I think one segment that we've left out of this, as you say, are the other aspects of the fiscal and economic challenges. I think it's understanding the expectations of patients or society has health care consumers. Because I think that is evolving and that is, in part, triggering the demand. I think, for example, if you knew how much of this was totally discretionary -- cosmetic surgery for example and going forward, just to pick something out of the air that is discretionary -- starts to give you a hint as to what are the changes that are going on in expectations. I think what you expect versus what the government provides as a baseline may, in fact, be two different things and we need to be sure not to ignore the piece that the beneficiary/patient plays in this in terms of

expectation, in terms of adherence, and in terms of access -- I think all of those things -- would be very important to me to add to the conversation here.

My second thing would be in our discussion of geographic variation, I would like to see us couple with that that one of the challenges is to understand the reasons for the variation. We tend to fall to some interpretations that I'm not sure the data yet tell us. We can make some things about correlations but not necessarily causality. And I think one of our commitments here needs to be better understanding the reasons for the variation.

DR. STUART: An observation and then a couple of questions. The observation is that if we go back to slide number two, the emphasis here is on per capita growth in spending comparing Medicare, Medicaid, and other private spending. When we move to slides three and four, it looks like this is total program growth.

So my question is -- in this one in particular -- how much of that green bar is due to -- the growth in the size of that green bar -- is due to demographic changes? And how much is due to the per capita increase?

The reason I think that's important is that there

has been, in the public perception, the expectation is that Medicare and Social Security are going to grow because of the number of people that are coming onto the rolls. And so I think it's really important in terms of trying to understand this is how much of this is mutable and how much isn't. Because clearly you're not going to have -- you don't have control over the growth in terms of the number of individuals who will be receiving these services. So it would be useful to distinguish the source of the growth in that third slide.

And the fourth slide, and this really is a question, the next one. It looks as though the projections have Part D as becoming a larger proportion of the total spending, certainly relative to Part B. So if I look at 2010 Part D looks like a third or so of Part B. And when you get up to 2080 there, it looks like it's a much larger proportion. The growth in Part D has actually been relatively modest compared to other aspects of the program, at least since 2006. So I'm wondering, what's the basis for that expectation, that Part D is going to grow?

MR. CHRISTMAN: I'm less familiar with Part D's long-term piece so I'd have to think about it. But my

understanding was, at least for a period of time -- and this may have changed -- that in the long run they expected those to grow a little faster than B and A. But past a certain point all of these go to the same growth rate.

DR. STUART: Well, I think that was true initially, before the benefit was passed. So part of the question, I guess, is where these numbers come from. This is the 2008 Trustees' report. It struck me that the growth in Part D actually had declined or the expectations of growth had declined.

MR. CHRISTMAN: And I don't know that they have rethought their long-term yet. We can look at that.

DR. CHERNEW: A few comments. The first one is I like generally the chapter and where it's going. A few specific comments. One is I think a stronger distinction between the level of spending and the growth of spending would be important. For example, the U.S. has higher spending than other places, than other countries that doesn't necessarily have more rapid growth. Areas on the Dartmouth Atlas Chart that have high spending don't necessarily have more rapid growth. Interventions that may reduce the level of spending may not reduce the rate of

growth in spending. So I think a stronger conceptualization of the distinction between the level and the growth of spending would be useful.

My second comment is that I think more attention to distributional issues matter, particularly with regards to income and health status. Whatever we think is going to be problematic with higher cost-sharing and premiums relative to average Social Security benefits, if you look for certain subsets of the population I think the problems are even more challenging. And I think that that separation within the system I think is an important thing to point out.

The third comment is it would be interesting for me to understand how much of the higher out-of-pocket burden that you mentioned is due to greater use of care which people could presumably deal with through substitution or utilization patterns as opposed to through increases in things like the deductible, the amount they're asked to pay for use of a particular service.

And finally, at the end of the chapter there is a section on different proposals. The whole chapter starts about cost, then there's a bunch of proposals, then there's

a paragraph that says but of course these things might be good but they really may not address cost, which is how the whole thing was set up.

And I think thinking through in the chapter the interventions related to cost versus the interventions related to quality would help it hang better.

DR. CASTELLANOS: I like the direction we are going. I think we all agree that the spiraling costs of the Medicare system needs to have better control. We also need to think about efficiency and we need to think about quality delivered.

One of the points I would like to make is I'm not sure what society's expectations are. Maybe they don't mind spending more money if they can get it on a better delivery system, more efficient with better quality. I think the 45 percent rule is arbitrary and I think linking everything to GDP perhaps may be arbitrary.

When we look at responsibilities or how we're going to look at it, I think we have to look at all the providers plus the beneficiaries. Beneficiaries in our society definitely have some responsibilities in controlling the costs, not just to mention their lifestyle, the obesity

rate, smoking, et cetera.

DR. CROSSON: First, I'd like to compliment Evan on the completeness of this analysis of the problem statement. I think the bibliography itself is worth coming to the meeting.

But I do have a problem I think beyond that in terms of what we're trying to do with the chapter, and it's similar to Mike's final comment. I'll use the medical analogy, I did a biopsy of the chapter. And what I found was the first 22 pages were the diagnosis and the last three-and-a-half pages were the treatment. In fact, the last three-and-a-half pages are sort of a categorical listing of various approaches.

I would like to see one of two things: either we simply make the chapter a thorough academic analysis of the problem, or we -- and this would be my preference -- we have a more balanced chapter which does some of both. By shortening the diagnosis part, providing some general context to what we think as a Commission the general approaches to solving the problem ought to be, linking those to some of the parts of the chapter that describe the problem, and make this a piece which is a context for

Medicare policy in our mental construct.

In other words, this is not just an academic statement of what the problem is. This is our view of what the problem is, and at least some general thoughts about directions to solving it. So that would be my thought.

DR. SCANLON: I am supportive of the general direction and the content. What I would like to suggest is that we beef up what we say about the issue of the beneficiary and their out-of-pocket burdens because I think the problem is current, not just sort of in the future. It's current for the subset that end up with catastrophic costs.

Considering Medicare from a big picture perspective, I think we have to always remind ourselves this is a program that doesn't provide catastrophic protection, that you have unlimited Part B copay liability. Part A is less of an issue but on the Part B side, particularly for chemotherapies where those drugs are administered through Part B, that this is an issue.

We've talked about this in other context before. Here when we start to talk about Medicare supplemental insurance it provides kind of a different direct link to the

issue. Why would someone want to have Medicare supplemental insurance? It's because you'd want to buy catastrophic protection. But the other reality is that the current supplemental insurance may produce too much use because of the first dollar coverage. And first dollar coverage is a bad deal. To pay somebody 40 cents to write a check for $1 for you is not a good purchase.

So the idea would be to try and talk about this -- when we're thinking about bigger reforms for Medicare in the future, be thinking about it also from the beneficiary perspective and catastrophic protection.

DR. KANE: I like the chapter and actually I've used parts of it -- because some of it is from prior times we've written it -- to help scare my students and other people when they want to know what MedPAC is working on.

A couple of things that are at least of great interest to me, I don't know if they are to anybody else. But I think it's coming up more often now that what the private sector does affects Medicare and vice versa, and that we really need to, I think, delve a little more deeply into how the two sectors can better collaborate.

That leads me to thinking it would be useful to go

back and do a literature review of what was good and what didn't work about the old all-payer systems and get a better sense of what that means and how we might -- that's the most direct way of creating a collaboration with the private sector. There's obviously less -- what's it called -- rigorous ways to do that, but that may also have value. So I'd like to see us delve more deeply into how we can get the private sector to be more on the same page on us more on the same page with them, as well.

The other thought that came up as I read the paper was at the very end, and also related to what I know about the history of Medicare. In the very end there's a table on page 40 about the tools that Medicare has and that the private sector has and the differences between them. One of the things that's on the Medicare side of the page says that we are prohibited by Federal law from interfering in the practice of medicine. I know that's been there since 1966. But I'm very interested in knowing what does that mean? And how does that play out as we evolve into episodes and pay for performance and bundling A and B and medical homes? How will that play out? Is that going to go away? Is that going to come back and haunt us? And how should we be

addressing clarification of that provision in the law?

MR. BERTKO: Like everybody else, I am going to echo that this is a good chapter. It's well written, and I think in comparison with a lot of similar things, it's thorough and it's readable.

My big suggestion would be in that introductory chapter summary section, it would follow up on some of Jay's comments here, that the last paragraph says here are some solutions such as...

On slide five, for example, you did a great job in the chapter taking apart those factors. But there could be something that says technology, can use comparative effectiveness. Insurance, like Bill was suggesting, can make adjustments to Medigap. And having a list of those in there, because I think there will be some readers that really get stopped by the introduction. It's a good chapter but there's a lot of meat to it.

MR. BUTLER: I think that we shouldn't underestimate the importance of the chapter. As a new commissioner, when I was preparing for this -- this is the first chapter that I read some several months ago and I was very impressed by it. So it is probably the first thing

that people read and we ought to take it seriously and I know we do.

I also was impressed how well it was done then and how well it's done now.

I did do though a comparison because I said I think I read this before. I went back and it is basically, an awful lot of it is a repeat of last year. So I tried to say what is different? And I did note that the six areas or so that we're focusing on in value -- where a value can be added is new. Part of it is a question, is that our declaration of the important areas that we're going to suggest reform in ultimately?

If it is, and that's our working agenda, then I'd like to know that. I think it's a good list, but I'd like some clarification around that.

Now specifically with Mike's point, which was exactly mine that I wanted to make is in the specific recommendation. If you look at the charts -- and a lot of times people don't read the words, they look at the charts. Every single chart is growth trajectory. And there's nothing on the current level of the distribution of current resources.

So specifically a Dartmouth Atlas Chart or specifically the charts that show that 25 percent of the beneficiaries use 86 percent of the money, the variation kinds of issues are at the heart of where dollars ultimately can be saved I think could show up in a couple of charts rather than just having the charts show the trajectory of the spending.

MS. BEHROOZI: A lot of it sounded familiar even though it's only been a couple of years I've been here reading it again. I feel like maybe it's partly new, but I feel like there's a little more of a sense of urgency in painting the picture of the health care system in the United States, in particular the Medicare program.

But I think to really complete the picture or to enhance that picture, I would suggest a couple of additional points that I think of as along the lines of myth busting, to help get people ready for the fact that we need to make major changes. And just a couple of ways in which I think that the presentation can be beefed up a little.

On slide six and in the paper you talk about U.S. spending compares to other OECD countries' spending and you talk about regional variation within the United States not

being correlated to quality and the RAND study that says people receive only about half of the appropriate recommended care.

But I think it would be very stark to show where the U.S. lines up in that -- I think it was a Commonwealth Fund study -- of OECD countries in our quality scores overall and on certain measures that kind of pop out at you. I think that would be very dramatic to help people understand this vaunted U.S. health care system that people from all over the world come here for -- all of that, look at how we compare to places that spend less. I think that would be very stark.

I think another point that you make, it was actually on page 18 of the paper, about how you say numerous measures indicate that low income individuals and some minority groups have greater difficulty in obtaining appropriate care. Often people say, in response to looking at costs in other countries, oh but care is rationed there.

Well, I would submit -- sorry, I'm talking like a lawyer now here -- that we have rationing of care in this country too, except it's done by income and socioeconomic status. People forgo care because they cannot afford it.

That is becoming increasingly true, even for those who are insured, whether private insurance in the under-65 marketplace or with Medicare as cost-sharing rises. And I wonder if we can look at whether as Part B premiums rise fewer people purchase it. I don't know, that's probably easily obtainable.

But in general, the Part D information that we'll will about later talks about how people, when they get to the doughnut hole, the most common way of responding to that is by not taking their medication. So that's rationing.

DR. DEAN: A couple of brief comments. First of all, I would certainly echo what people said. I found the chapter very useful and well written and helpful. And I think it's a good introduction to the problems we face. It's a little scary.

A couple of brief comments. First of all, in response to Bruce's comment about Part D growing, there is a projection that, in fact, pharmaceutical costs are going to grow rapidly because of the introduction of a whole new category of drugs, the biologics, that at least some people project are going to be sort of an order of magnitude jump in terms of cost. So I don't know whether that was factored

in here, but there is a belief that that's a whole new approach to care that's going to be extremely expensive and maybe that accounts for -- I don't know whether it was factored in here or not. But it's certainly right that Part D costs less than the initial projections but there are some new things on the horizon that may change that. So I don't know.

Secondly, the issue in these projections of leaving out and just ignoring the whole SGR thing, I think is a mistake. Because at some point that's going to have to be dealt with as I understand it. I realize you have no idea how that's going to be dealt with. But at least in some sort of pretty bold faced footnote I would say it needs to be mentioned that that's getting to be a big enough -- the fix of it is a big enough cost that it at least needs to be noted. Now you can't put it on the graph probably but it can't be ignored forever, I don't think. I don't know. They've done a pretty good job so far.

And finally, to Mitra's comment, I would certainly support that as well. The recent reports that the parameter of mortality amenable to health care, the data showed that we've actually gotten worse in the last three or four years.

And to put that ranking beside the spending rankings I think would probably make the point even more boldly than it is there now.

Thank you.

DR. MILSTEIN: I also am very supportive of the general direction and think that the current chapter draft is strong. My specific suggestions are that I do think we could substantially increase the value of this chapter if, for each of our prescriptions or treatment recommendations at the end, we could give the readers at least a range of notion as to what we think this might be worth if well implemented.

We address this, for example, when the comparative effectiveness people have come to talk with us periodically and we've fleshed them out in our questions and said in the best case scenario if tomorrow, whenever there were treatment options of equal expected clinical outcome, we always chose the less costly treatment, what would that be worth on a total Medicare spend or total national spend basis?

And I think that same information, even if it was a rough estimate based on implementation in other countries

or by private sector payers, would be a very useful addition to readers in terms of understanding what are these different interventions worth on a static aesthetic basis, on a one-time basis. That's comment one.

Suggestion two would be I think it would also be nice for the readers if we could make the point that in relation to at least some of the interventions on this list that they can be conceptualized either as a one-time static opportunity to reset the base lower or they could be designed and implemented in a way that would create favorable dynamic changes, that is continuous effort on the part of the American delivery system to generate more health with less spending. You can take almost any one of these recommended interventions and help the reader understand how they would have to be implemented if your goal was dynamic impacts, that is continued impacts on rate of growth in spending as opposed to a one-time lowering of the amount of spending.

It doesn't apply to all of them, obviously. For example quality standards for imaging, I think that primarily as a static advantage, a one-time reset. But a number of things, like how you design a pay-for-performance

program, could be implemented in a way that they would generate perpetual improvements in performance, both cost and quality.

DR. REISCHAUER: I support this chapter and I think that over the years it's evolved to become a stronger and stronger case. But I have the sense that we are offering half a loaf, that what this chapter does is it says long-term this program is unsustainable, puts heavy pressure on the budget. Here are the reasons why health care costs are going a whole lot. Here are the consequences of that.

But then it doesn't say what I would say next, which is the rest of this report is going to be about unit prices. And even if we moderate the growth of unit prices in drastic ways that will irritate every provider in the United States, that's not going to solve the problem here. We have another bunch of sort of reforms that we advocate. And while Arnie has a lot of ways of extending them and implementing them, we haven't recommended those and most of what we've recommended from a cost standpoint, in a sense, is really rearranging the deck chairs on the Titanic.

We are all for pay for performance but it's budget neutral. We are going to have a pilot project on medical

homes. I wouldn't put billions of dollars of savings on that. Comparative effectiveness, I'm all for that but we haven't drawn the next step which is you have to have the guidelines, you have to use this in the payment system, et cetera, et cetera, have reference pricing or something.

So Nancy can scare her students and Tom can be scared in his office reading this, but the real message is to scare people a lot more. And that is we're going to have to consider some more fundamental changes if we really want to address this. And they're going to have to affect not just Medicare but Medicaid and the private sector, as well.

It needn't be more than a paragraph saying that, but you're sort of left with the impression that we have some reasonable ways of getting out of the unsustainability here when, in fact, we really don't.

MR. HACKBARTH: We've got roughly 15 minutes here. What I would like to propose is that we focus on three areas which I hear in the comments.

One, several of you suggested ideas for strengthening the discussion of the beneficiary connection here. One take on that is the beneficiary's role in driving the cost increase, namely their expectations for quality and

access, convenience, et cetera. The other side of it is what are the implications of financial burden on beneficiaries? And surely there are other takes as well, but that would be one potential area for enhancement, the beneficiary connection.

The second that people touched on in various ways was related to the basic structure of the chapter. Jay raised this initially by talking about how many pages are devoted to the problem statement as opposed to the solution, and several people followed in a similar vein, asking for enhancement of the solution discussion. So that's one potential path.

Another, and they're not necessarily mutually exclusive, would be to use this as a document each year for a statement of MedPAC's agenda, as Peter proposed. Commissioners who have served on the Commission for a while know that we're always looking for ways, in fact struggling to find ways, to better tell our story so that -- we may call these individual recommendations, but sometimes the themes, the story, how they link together, is lost in the detail of individual recommendations. We could use this chapter to tell the story of the MedPAC agenda, where we've

been and where we see it going.

A third idea that came up here, Bob just touched on, which is to be more pointed in our take on this context, on all this data, on how bad the problem is. Bob's take is the tools that we've got, even if you enact all of our recommendations, the tools are pretty meager relative to the scale of this problem. And we could use this chapter to tell a story about the context that's much sharper.

In fact, in the extreme you could say we're going to cut out a lot of these detailed data or put them someplace else. And what we want to do is tell a story that really heightens urgency. In this case, to lengthen the detail almost has a dulling effect. I've seen all this before. I know all of this, yada, yada, yada, it almost causes the reader to turn it off as opposed to really hitting him between the eyes. Maybe a short three or four page statement that really was focused on the urgency of this and made some sharp comments would draw more attention to the problem than a 30-page chapter.

So there are some different ideas about how to make this more pointed and effective.

Then the third theme that I heard in various

comments was the quality dimension and there's a lot of talk about rapid growth in costs, a little allusion to quality especially in the geographic variation. I think we say the quality is not well correlated with costs. But that could be made much more pointed using international comparisons, as Mitra Tom suggested. Indeed, as Tom says, there are some Commonwealth data that suggests that the U.S. is falling further down the ranks in the international quality comparisons, even while our costs soar. So we could enhance the quality piece of this.

Now these are not mutually exclusive ideas by any stretch. He could easily do the beneficiary strengthening and the quality piece.

I think the one that is more fundamental, what are we trying to do with this chapter, is how much time do we want to spend talking about the statistics about the problem versus what we want to do about it or statements that would really create a more powerful sense of urgency. That really, I think, could change fundamentally the character of the chapter.

So with that prelude, let's do a second round of comments.

DR. BORMAN: With regards to the beneficiary theme, as we look at the piece of out-of-pocket and burden I think it might be helpful to break that down into a couple of groups because I think there are haves and have-nots in this very clearly. I think we've tended to use the duals as a measure of sort of the most vulnerable, the most have-nots, and that's a group we can continue to look at.

I think we do have an evolving sort of higher end group and as we think through this we're going to have to look at structuring the benefit, whether you want to talk about it in terms of tiered benefit or whatever you want to call it. So we need to have an understanding of sort of the size of maybe the high-end and low-end groups so we can think going forward about matching the beneficiary to the benefit, to the premium maybe a little bit better over time.

So as we look at the beneficiary analysis, it's probably not in this chapter. I think as Glenn is saying, there's a lot of merit to making this a conceptual or philosophic chapter and let the details play out in other chapters. My recollection is that we have that an ongoing 21st Century beneficiary project and maybe that's the place to start moving some of this beneficiary discussion as a

chapter and as a focal point would help me, I think.

One comment about as we get into the international variation in quality piece, perhaps we could find a few things in which we do rather well. I think a wholly negative picture kind of turns a lot of people off to start with. And I think in all honesty there are some things we do reasonably well. And so I would work to find a few things.

And some of it is acute care things. Like we probably do have very good care for appendicitis, for example, some of those kinds of things. So let's find a few positives here to balance. And maybe that helps us know why are we doing well at this and things we're not doing well at that we'd like to do well at? Is it because of the nature of the care and the technology and some of those things? So it may be informative to help that.

And then the other pieces, I would like to see us highlight a little bit the high administrative cost because that's something that certainly at an individual practitioner office -- I've got a different form for every policy almost, much less a given company, that I have to deal with. And yet in the end, I think people on both sides

of the equation want to give and share the same information. And why we can't get to that as a part of the benefit as moving toward IT standardizing, we do have an opportunity I think for recouping some of the administrative cost. And I think this would be a hopeful place. Whether this is the right chapter to highlight it or not, I think it does flow from this comparison of costs.

DR. CHERNEW: As I said before, I think the oddity in this chapter is the disconnect between the strong call to focus on costs and the problems associated with costs in the beginning and then the recommendations at the end where I come down in the camp I think with Bob that we don't know a lot about them being able to address the cost issue at all. And so my view, for starters, is that the first two paragraphs on page 26 have to be -- they're way too optimistic for my taste.

And in that spirit, I would prefer a more focused chapter, perhaps other chapters related to other issues, but maybe a more focused chapter that maybe makes the cost issue that people know well very clear.

And then instead of saying here's a solution in some optimistic way, which is sort of the way that I read it

now, say there's a lot of things we can do. They can affect quality, which is a wonderful thing. But they don't address really much beyond a bump the way they're currently implemented the problems we have just laid out. And I think the chapter has to make very clear that doing all of these things that we can all rally behind -- myself included -- are wonderful things but they don't solve the problem that the original part of the chapter. And I think too often we have the tendency to say costs are a big problem, here are some good things, let's do them, without connecting those things. And I think this chapter has to do that.

Now Arnie may be more optimistic in ways to make these things control costs, and I wouldn't mind a conclusion that says we have to take these basic tools and make them control costs. But I think this chapter can't be the chapter which says we have to find a better way to get to improve quality. We can have another chapter about how we need to improve quality. But if you start out with costs as this crushing problem, I think the conclusion has to be a call to how to deal with the cost problem better. Quality obviously matters but it's a distraction, in my opinion.

MR. HACKBARTH: Let me raise a question for people

to react to it as we go around. There's something that doesn't quite seem right to me about using the context the chapter, as we've called it, as the place to describe solutions. What we're supposed to do is develop recommendations supported by analysis that we vote on. And to use this as saying here are the answers seems to be a shortcut to where we're supposed to be going. We're supposed to develop recommendations on what the solutions are, as opposed to lay them out in the first chapter of the book.

Now of course, we've recommended certain things in the past, so we've got a history that we can refer to. But even if we're optimists, to say here are the solutions to this grave problem just doesn't seem right in a context chapter. So that's one thought.

And then a second that I'd ask people to react to is maybe what we need is actually two distinct chapters. Mark tells me that the context chapter has an audience, that people use this material for various reasons, writing speeches for their Senator or Congressman. There are people who look for this every year, the updated information. And so we want to continue to meet that demand.

But maybe what we need to do is separate out into a shorter statement something about solutions or a statement about the urgency of the problem, that the content would vary each year. But it's a much more sort of pointed essay view that is a little bit more hard hitting as a way to get attention. So those are some thoughts that I would welcome reactions to.

DR. CASTELLANOS: Just a couple of points, specifically with the beneficiary. I would like to think more of a cultural change where we can change the culture of the beneficiaries or at least try to impact, that new and better is not always the best way to do, shiny and bright. Sometimes the old ways are just as good. We need to talk about lifestyle changes. They have a responsibility and they need to think about what society's expectations were, and I think I mentioned it briefly.

Getting on Jay's point, I think we've made the diagnosis. Now we need to think about treatments. We need to get away from just again hammering the diagnosis but how we can go ahead and treat the problems that we've diagnosed, speaking as a physician.

We have to involve all the Medicare providers and

the beneficiaries, as I said. Being a physician, I'd like to stress a little bit on the physician community. And we talked briefly about this last year and we've talked again this year. I think the fee-for-service provides perverse incentives. And this is what's causing the behavior that we see in the hospital community and what we see in the physician community. And until we have some change in the payment system, this is going to be a continued problem.

Now I understand that pay for performance, accountable care organizations, and bundling has a downstream effect but I think we need to get and hit the problem within the physician community as far as a payment system change.

MR. BERTKO: I'm going to support your last call, Glenn, for something on urgency whether it's part of the current context chapter or a new one. And in the line of there is, in my mind, a clock ticking. In 2009 it will be 10 years. While the 45 percent trigger, I think, is a useful warning, some people criticize it as being arbitrary, which it is. But in 2019 there's not going to be anything arbitrary. Part A will run out of money.

The second part of this urgency is that, I think

everybody around this table knows and others, that many of these options for fixing the costs in Part A would be multiple years to roll out, two, three, four years to get through what CMS does to get there. We ought to bring that to people's attention.

MR. BUTLER: Three comments. One was related to what you said, which was where I was headed to. By definition the title, context for Medicare policy, does suggest it's a diagnosis chapter, it's not a solutions chapter. And I think we ought to keep it that way and handle the solutions elsewhere. So I'm reinforcing that.

Secondly, with respect to the charts that I was recommending, I have a greater appreciation now that some people just expect these annually and they want their charts for this year. Having said that, my point was really around, when I said I referenced Mike or Arnie saying there's 10 percent right of the base that we ought to be looking at as opposed to just the projected. If there was a kind of two or three charts where we continue to track that kind of base level spending that is an opportunity where there's over utilization, I think that would be a helpful part of the diagnosis.

The last comment, you made reference to me wanting to maybe perhaps be the place where we display the MedPAC agenda which some would think needs greater clarity. I certainly would like to have it clear. But having said that, maybe this isn't the place to put it exactly for the reason that this is the diagnosis.

If we do put in it here, my point was I want to know that that's what it is. It's not just that well, we might do these things. Because it's not clear whether that is the agenda or not.

So I probably would suggest that, given your comments, that that gets lifted out of the chapter rather than put in because it starts to dabble into the solution side.

DR. DEAN: In terms of the comments about whether we should include responses or solutions or however you characterize it, it seems to me that there is a value in at least laying out and trying to take these responses that are listed pretty briefly at the end of the chapter and making some sort of comment about what MedPAC believes are the potential benefits of each of those responses so that some priority as to which ones are likely to have the biggest

payoff and some comment in terms of -- maybe it follows on what Peter just said -- what the priorities or the direction of the Commission will be, not to get to specific solutions but which of these is likely to be most useful in responding.

I think part of the reason that we have failed to make any progress in any sort of real reform -- and as an aside, I'd certainly support everything that Ron said about the perverse incentives that exist in the current payment system -- but anyway, there is no single fix. And it's such an intimidating problem, even for those of us that live with it a lot, let alone the general public. If we're going to make any progress, we need to make a point first of all that there is no single one of these that's going to solve the problem. But there probably are differences in terms of which ones will have the biggest return. And I think it would be useful to at least go out on a limb in a way. We don't know but where do we think the payoff may lie?

DR. CHERNEW: Those solutions strike me as solving a different problem and I think that's the problem in the chapter, is how to get those solutions to solve this problem.

DR. CROSSON: Just a similar comment. I said initially that the strength of the chapter was the completeness of the analysis of the problem. The weakness was the little tail at the end which was just a listing of solutions, as Mike said, out of context necessarily for specific parts of the problem statement. But I also think it kind of understates the work of the Commission, which is a lot about recommendations about what Medicare policy should be to solve the problems.

So I look at the same words, context for Medicare policy, and I don't necessarily see just diagnosis. I see diagnosis and our thoughts about relative treatments. And it might be, as Bob said, that a lot of the stuff that we're discussing and working on is very good but it isn't going to solve the fundamental problem. We need to say that, as well as suggest perhaps more radical ideas that we haven't worked on yet.

It might be though, for the purposes of continuity, that that would best be done by creating two context chapters or two parts of a context chapter: one which is more traditional which in fact ends at page 22 and says the context for Medicare policy is something like the

issue of financial sustainability. And then a second context for Medicare policy, the range of future solutions or something like that. And make those distinct but connected in terms of the way they're written and the way the content flows.

MR. HACKBARTH: So the problem number one in chapter two, so to speak, is where we've been, where we're going, and some commentary on the strength of our toolkit, whatever else we want to fit in that heading.

So let us work with a little bit of a restructuring along those lines for next time.

Thank you, Evan. Good job on the first draft.

Our next session and the last before lunch is one of our MIPPA updates, this one specifically on the provisions on physician resource use measurement. Jennifer is going to do that.

For the audience, we are scheduled to do this one for 45 minutes and then have our public comment period. So that would mean shortly after 12:30 we'd be at the public comment period.

MS. PODULKA: Thanks. As Glenn mentioned earlier, today you'll be hearing several presentations on the recent

Medicare Improvements for Patients and Providers Act of 2008, or MIPPA as we refer to think it. This is the first one and one that I'm particularly excited to talk to you about.

You may recall back in our March 2005 report to the Congress we recommended that Medicare measure physician resource use and give confidential feedback back to physicians. I'm pleased to tell you that the recommendation has been enacted by MIPPA which requires that the Secretary of Health and Human Services establish a physician feedback program using claims data to provide confidential feedback reports to physicians measuring the resources used to provide care to Medicare beneficiaries.

The program must begin by January 1, 2009, this coming January, and the Secretary must conduct education and outreach activities to prepare physicians. The Government Accountability Office must evaluate the program by March 2011.

MIPPA grants the Secretary flexibility on several characteristics of the physician feedback program. The Secretary may choose to use other data in addition to claims, provide feedback to physician groups in addition to

individual physicians, and include feedback on the quality of care. The resources measured can be done so on a per episode or a per capita basis or both and the Secretary may choose to adjust data for beneficiaries' health status and other characteristics.

Additionally, MIPPA grants the Secretary flexibility to focus the physician feedback program on several items. First, 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 practicing in certain geographic areas; and finally, physicians who treat a least a minimum number of Medicare beneficiaries.

Even before MIPPA was enacted, CMS had already begun work that they refer to as the Resource Use Report pilot program which will comply with the law's physician feedback requirement. Phase I of the RUR pilot will use two commercially available episode grouper software packages, Episode Treatment Groups or ETGs developed by Symmetry Health Data Systems and Medical Episode Groups or MEGs by Thomson Reuters, which was formerly Thomson MedStat.

Just a quick reminder here, episode groupers are software packages that use clinical logic to assign all types of health care claims to clinically distinct episodes of care which are a series of clinically-related health care services over a defined time period, such as all claims related to a beneficiaries' diabetes over a year.

Then these episodes are attributed to physicians based on patterns in the claims data. And then each physician's pattern of resource use is compared to the average resource use. Physician's patterns of resource use are compared with the average resource use for similar episodes by peers. The comparison can be made both in aggregate by specific episodes or types of services.

For example, a physician might treat all diabetic patients in a more resource intensive manner than their peers or they might generally use more intensive imaging services. Providing detailed information in addition to aggregate measures makes physician feedback more actionable by identifying differences in practice patterns that influence overall results.

Continuing back on the slide there, both episode groupers will be used to analyze Medicare claims, produce

alternative research use reports for several acute and chronic conditions, provide confidential feedback to selected physicians, and conduct one-on-one interviews with a sample of these physicians who receive feedback. The pilot will test several different characteristics of both the measurement methodology and the feedback format.

Phase I of the pilot will focus on four acute conditions and four chronic conditions, as indicated on the screen, designed to capture a range of specialties and conditions.

Phase I of the pilot will test several different characteristics of the measurement methodology. I laid these out in some detail in the paper so I'm not going to go through anything but some examples here, however I'm happy to discuss anything in more detail if you'd like on question.

The pilot will test three risk adjustment approaches to account for differences among patients. It will test six approaches for attributing episodes to physicians, including both attributing to a single physician and attributing to multiple physicians, and it will test several different benchmarking approaches.

First, it will explore multiple cut points for defining both cost efficient and cost inefficient physicians. For example, two standard deviations from the mean, the top or bottom decile, and others.

It will also test multiple comparison groups used to measure physicians' efficiency. Generally a physician's resource use for a given episode must be compared with an expected value, often determined by the average of comparable physicians' resource use. Remember that in our past analysis we compared physicians with other physicians in the same market area and in the same specialty. The pilot will test additional geographic areas and specialty groupings.

The field test of the Resource Use Report to gather physician input, CMS and its contractor for the pilot, Mathematica Policy Research Inc., will distribute RURs to a large sample of physicians in the same 12 sites that are used for the community tracking survey, as indicated here. CMS and Mathematica will conduct one-on-one interviews with small samples of physicians who receive feedback in three ways. Physicians will be asked their opinions of the alternative RURs and the methodologies.

I'd like to note that a pretest of the one-on-one interviews and feedback with physicians was conducted the week of August 18th in the Baltimore-Washington area. The RURs tested in this wave used per capita measures exclusively. The next wave of RURs will be field-tested later this month continuing through October and these will include per episode measures. Eventually, RURs may include both per episode and per capita measures.

CMS will revise the RURs based on the feedback that they receive from physicians in the interviews and based on the results of the phase I part of the pilot, CMS may implement a Phase II, which could expand the evaluation of physician feedback by including additional specialties, conditions, geographic area, and feedback on quality measures.

Before I move on to the next slide, I'd really like to make the observation that CMS has been pursuing these efforts for a few years now at least in part at the urging of this Commission. The Agency is especially well-positioned to execute this part of the MIPPA very nearly immediately upon its passage. And speaking at least at the staff level, the pilot encompasses a thoughtful and thorough

research design that could move Medicare in a direction that we and the Congress have been pushing them for some time now.

Moving along to our planned work, to gather both your views and to complement CMS's feedback pilot we will continue to explore best practices for building an environment for effective physician resource use measurement and feedback. We will do so by reviewing the literature and conducting structured interviews with individuals and organizations involved in these efforts. We will, of course, present these findings and discuss potential principles that should be adopted by any future Medicare efforts at future meetings this year.

Our structured interviews will be augmented by additional data analyses, by analyzing Medicare claims using episode grouper software for four or five years now, 2001 through 2006. After we do so we will address the following questions: first, do physicians' efficiency scores, which are their measures of their resource utilization compared to their peers, tend to remain stable over time? Second, what effect do different attribution methods -- single, multiple and others -- have on the types of physicians that are

assigned responsibility for episodes and what their resulting efficiency scores are?

Also, we will explore the integration of quality and resource use measures. In addition, as some of you have suggested in the past, we will focus our analysis on the most common expensive conditions or episodes to address the following questions: are their episodes or conditions with fewer physicians involved, both for attribution and for the total care? And for conditions with multiple physicians involved, what types of specialties are represented? Are they duplicated throughout the episode? And finally, which specialities tend to be attributed responsibility for episodes?

Hopefully answers to these questions will give us a more qualitative understanding of what happens in a resource use measurement environment.

That concludes my presentation and I look forward to especially your feedback on our work plan for the coming year.

MR. HACKBARTH: Let me see hands of people want to comment during our initial two-minute round. Karen, you've got the lead.

DR. BORMAN: I share with you and the staff some warm and fuzzies about moving in this direction because I do think it can be a productive one, because I think it can have intangible effect on the provider community that I think may be very helpful and rewards professionalism, for taking information about yourself, using it to modify your practice and move forward. And so I think that's a good thing.

In fact, there may be value in a subset of this in exploring how to provide these data in a way that an individual practitioner might be able to submit them almost directly as part of maintenance of certification process, which some if you are familiar with in terms of how to maintain your specialty certification and is essentially a universal requirement now going forward.

So to take this and give it a context that a physician can use in another setting that is personal improvement that impacts on their patients I think could be a very good thing. So I'm supportive of this being a significant work project for the staff.

Two specific things about the data. Number one, again because we all have so many reservations about our

ability to identify good data, can we at least identify outliers? I think that's very helpful. It's a place we can rally around. It would be a very useful thing. I'd like to continue to see that be part of the work.

DR. CROSSON: I also support the work. I think that we've talked about it in the past and come to recognize that at least some portion of variation in practice style is simply due to lack of awareness from one physician or one practice to the other of the fact that there is a difference and providing physicians, albeit all of the difficulties in the data and concerns that will be brought forward about the data is not right, et cetera. The general experience has been that for many physicians when presented with information that suggests that that individual is an outlier, it results in some thoughtfulness and change of practice. It seems like if the cost of doing this is not overwhelming, it's likely to yield some good results.

I had one specific question and that has to do with whether it's possible in this analysis to take a look at the practice setting also. That is, we are going to look at specialties. Is it possible with the data available to also look at the type of practice setting, group practice,

large, small, solo practice, single specialty group -- is that attribution possible with the data that exists?

MS. PODULKA: That's actually a good point. For our analysis, speaking for the MedPAC staff, not the CMS pilot. But for our analysis, we can definitely try and incorporate that. Like many things, it's going to be a little fuzzy because we'll have to match on some other data sets. But I think that's something that we can pursue.

MR. BERTKO: First of all, I'd like to recognize CMS's efforts on this part. We sometimes don't give them credit for really getting going and coming out of the gate on this one. They've obviously been listening to at least some of us saying this.

The second part is I'm really thrilled about the emphasis on looking at the various benchmarking. MedPAC and you guys on staff have done a lot of good work on attribution rules and some of the other parts. But how do you apply this and what are the appropriate benchmarks? They have been thoughtful about what they're looking at and I think maybe, Jennifer you guys and staff can maybe add to that with them. I would encourage you to think along those lines a little more.

DR. KANE: I am just going to do my broken record part about is there going to be drug claims involved in defining the costs? I know there isn't right away because it's not going to be available. But I was wondering if there was a possibility of even just focusing on congestive heart failure and trying to make the effort to just get drug claims linked to the congestive heart failure episodes as soon as is possible. Only because some of these are much more drug intensive types of episodes than perhaps hip fracture, in terms of the proportion of resources and the importance of how those resources are used for controlling the episode.

So I just wonder if we couldn't selectively pick one or two and see what happens when you bring it in when it comes. I know we're going to come to that later. Because I think it's going to be really hard to know what's going on congestive heart failure, for instance, without drug claims.

DR. MARK MILLER: One thing is you have mentioned this a couple of times...today. I didn't say that, just for the record. That was Bob.

Actually, there are some good things to say here and it's worth saying out loud. I think I said it to you

guys in the executive session. We kind of carried on for a number of years about the need to get access to the data. The most recent change in the law has opened that gate and data has begun to move. In the last session tomorrow, the second session tomorrow we discuss it more detail.

I want you to know, whether you say it or not, we are aware of the need to do that. We will fold it in over time but I also, as always, want to dampen expectations. We've just gotten the data. The first year has probably got some issues with it.

But yes, our long-term plan is to fold it into the groupers. We can certainly do it on a selective basis and look at condition specifics.

But the other thing I want to say is CMS has also -- not only on this demo but on the delivery of the data -- stepped up to the plate. We got the request to them and they delivered it and they worked very quickly to get it done.

DR. DEAN: Just a real brief comment. First of all, I think this is a really important thing and I think it really needs to be pursued out although it's going to be difficult.

One very specific question, does this method have a way of attributing costs? When I see a patient who has three or four diagnoses, one of which relates to say a recent hospitalization -- the other three do not -- which is the usual thing -- I rarely see, dealing mostly with older patients and most of them have multiple conditions. And I would probably deal with three or four diagnoses at a given setting. It may be a trivial issue but I suspect there's no way of doing that.

MS. PODULKA: Both software packages have numerous settings where the user of the software package can make a determination. They generally try and attribute, for instance an E&M visit to a specific episode. You're absolutely right. Frequently there's multiple conditions being discussed in that E&M. That's definitely one of the things that CMS, in a separate effort, is evaluating the sort of clinical logic and how they operate with Medicare data. There's always going to be a little fuzzy factor in this but they're definitely aware of it and trying to work on it.

MR. BUTLER: Building a little bit on Jay's comment about practice setting, I think there are actually

three variables, not to further confuse your study because you're looking for the impact of feedback. It is the are you in an organized multispecialty group practice at one end? But also are you accepting risk in the payment stream is another very important variable. I'm not saying you can do all of these but I would think these all have big impacts. And do you have electronic health records?

Those three things at one extreme versus a solo practitioner, family practice with manual charts and in a fee-for-service environment are very different kinds of settings and it would be interesting to see what impact those have, in your spare time.

MS. PODULKA: Those are actually interesting and I'm cringing. I'm not sure, I'll have to go back and think about a dataset that could do that. Practice setting, I know the data. This seems a little more trickier but almost a more interesting breakout on the findings.

MR. EBELER: Thank you, Jennifer. This is really interesting work. One question about whether we can relate this to some of our other recommendations. We've talked about medical homes. We've talked about hospital bundling and have specific recommendations and we're exploring ACOs.

Can our work here link to and inform some of that policy work? Because it strikes me that knowing something about efficiency within what one would think of as a medical home dealing with chronic conditions would really help us get there. So it's really a linkage question, can we do some of this work in ways that informs those policy streams, as well?

MS. PODULKA: That's a really good question, not one I've thought a lot about. Medical home might be uniquely suited to an episode measurement approach because one of our big issues in the Medicare arena is attributing these episodes to physicians. But that's partially solved by a medical home -- partially not entirely -- but the physician is indicating a willingness to assume responsibility for this patient's care.

So I could see fairly shortly down the road integrating measurement with medical home, if that helps answer your question.

DR. MARK MILLER: The other way that the -- and I see the way I think you're pitching it -- is if we looked at this could we use this to kind of shape policy directions we are going? I would just remind all of you and anyone else,

the other way we've made the linkage is kind of the reverse where when we've talked about this -- and some of this went on in the SGR report -- of if you had these other organizations, an ACO or a medical home, to be sure that this information can be used and supplied to those organizations so that they understand within those structures what their practice of medicine is and how it compares to other places.

So we've made the linkage kind of in the opposite direction. But I see what you're saying and we can think about it that way.

MR. GEORGE MILLER: Thank you, Mr. Chairman. I think this is important work also and I'd like to link to what both Jay and Peter said about the setting and the source of the patients. And that is -- I don't know if it's appropriate but I'll ask the question. Do you also look at if that patient comes from the emergency room and if hospitals are also paying a physician to be on call and what impact that may have as you do feedback?

And also along the lines where a particular physician may refer to a hospitalist or internist first and then ask to be consulted, versus taking that patient in the

beginning, what impact that may have.

DR. CASTELLANOS: I think this is a good topic to look at, variations in practice patterns. I'm a little hesitant about some of the issues until we can look at the details. Risk adjustment is going to be a significant problem here. In urinary tract infections, some are life-threatening and some are so called benign, unless you have it.

The other concern is practice settings is really important. If you're a urologist in the middle of South Dakota, you don't have the resources available to you that perhaps a urologist has at the Mayo Clinic or at one of the cancer hospitals.

There's going to be a tremendous geographic variation and I think this may be due to some of the resources that are available. But I'm a little concerned. We had a lesson with PQRI. That was set up real quick. There was no lead time for CMS. And the data that's coming out that, that should been out of that this summer has never come out or it has come out incompletely.

I guess the question I have is what is MedPAC or CMS going to do to allow the physician some feedback on the

data that is collected? And an issue is is there going to be a time limit that you're allowed to look at the data and comment on it in a timely fashion?

MS. PODULKA: The CMS pilot design includes sending the Resource Use Reports to large samples of physicians in the 12 communities used for the Community Tracking Survey. I'm not sure exactly how much time but they will give them time to review the report. And then they're going to have, instead of focus groups with everyone in the room at the same time, one-on-one interviews with those physicians where they're going to ask physicians questions about was this useful to you? Was it understandable? Are there things you would change?

Presumably at that time, physicians could certainly indicate this is too much information for me to process in the little time you gave me. I need more assistance, more time, more something.

There is a contractor evaluation of the overall pilot which will go to the Agency. I can't promise when that will be out. But as soon as it is we will share that with the Commission and with the public.

MR. HACKBARTH: Jennifer, is public disclosure

part of the pilot?

MS. PODULKA: No. I do want to absolutely make clear. This is all confidential feedback.

MR. HACKBARTH: This is one-to-one with the physician at this point, Ron. It's confidential.

DR. REISCHAUER: Start with a question to John. Haven't some large insurers done this?

MR. BERTKO: Yes, but not necessarily in this thorough of detail.

DR. REISCHAUER: That's what I thought. What I was wondering is whether there was going to be any effort on CMS's part compare, contrast, piggyback on, offer similar stuff for large insurers in some of these markets to use themselves? Because you could get a much richer dataset if one went that direction.

MR. BERTKO: I think there are at least four companies, major ones, with big dominant groups of people, members, that could contribute to that.

DR. CHERNEW: First, just to pick up on that point, I think the motivation behind developing the groupers that are used in this was other organizations that wanted to do the activities so that they could then report back. I

think the other activities are actually stronger than this.

The comment that I wanted to make was that I think as we think through this we have to distinguish between two things. One of them is using this information as a study of variation and efficiency, as a study of factors that relate to higher income use, things that might cause variation one way or another, and studying that. That is one activity but I don't think it's the focus of what this is.

I think the focus of this is just to collect this data, however flawed they may be, and give it back confidentially to the physician and see if the mere conveyance of that information changes behavior.

I hope two things then are true. The first is, and it may be that you know the answer or you don't. I think it's crucial that the evaluation have some relatively strong study design so we can understand the impact of the conveyance of information as opposed to getting conflated in a range of things.

And I think it's important that the evaluation try and understand, particularly if there's not much of an effect, if there's not much of an effect because the physicians fundamentally didn't believe the data, there were

all of these things they didn't believe about the data, or because there was actually no teeth behind the giving of the data. So if you sent me my teacher's scores but told me no one else was going to say, that gives me a different incentive to change my teaching scores than a number of other systems.

And so I don't know how the evaluation is planned or how the evaluation goes. But in terms of understanding where to go from here, I think it's important that we make it clear that they do that well.

DR. MARK MILLER: Jennifer, my understanding -- and you're a lot closer to this than I am. My understanding is this isn't so much about will this information change their behavior, at least at this stage of the demonstration. It's more an exercise in how can we give you information in a way that's understandable and actionable? It's trying to figure out the physicians end of this transaction, I think. Is that fair?

I'm not sure I've heard -- and again, I haven't been as close as you are -- that there is an element to the evaluation that says and did it change their behavior? But I could be wrong.

MS. PODULKA: That's my understanding as well. Bob, you mentioned this as well. Many of the other users of this data have many, many more years of experience and they are, in fact, using the results for very different purposes than Medicare has at least thus far envisioned. They build high-performance networks. They build two-tiered networks. They have differential cost-sharing for their beneficiaries. None of these types of more teeth type items are currently considered for Medicare. They might be longer term.

So right now this is an instance where I think Medicare sees that they need to crawl before they can walk and then run.

This is somewhat unique, using Medicare claims data to create feedback on Medicare care. And yes, it's primarily designed to do a lot of sensitivity testing on the different methodologies, the attribution like I mentioned, and then the format of the report so that they can see, do physicians get this and then say this isn't helpful to me? Or there's things in here that are helpful, here's how to improve it.

So you were right, it's largely about the feedback on the report mechanism but also the content of that report

mechanism.

DR. MARK MILLER: I think the general thinking in this Commission, when we started making these recommendations a couple of years ago, was you've got to sort through this and figure out whether these things even work at all? We've been kind of grinding through that. Then work at it from the physician's perspective, how does the physician view this?

Then the next step is okay, first inform. And then the question then becomes, again for this Commission, should more teeth be added at that point? But I think my comments are narrowly about the CMS demo. I think they're just up to can we figure out how the physician is consuming this information and how to make that work?

MR. HACKBARTH: We have just about 10 minutes left.

What I heard in the first round is, not surprisingly, there's general support for this direction. It's not surprising inasmuch as we've made at least two recommendations on this topic before. I would add my voice to John and others who praise CMS's effort to get to this point. It's no small task and lord knows they've had a lot

of other things on their plate. So I'm delighted that we are as far along as we are right now.

The comments that I heard sort of fell into two broad categories. One group reiterated concerns that we've raised in the past. There are important issues to be resolved using these tools around attribution and risk adjustment and the like. We have, I think, consistently reiterated those concerns and recognize the challenges inherent, and I don't think we can say too often that these are difficult things. Part of what we're trying to do is figure out how well we can cope with these challenges.

The second set of comments were there were a number of specific requests, can we look at this and the effect of setting, for example, on behavior? We will do what we can on that, what the data permit us to do. I would add one item of my own to that list, and I've always wondered how much the scores for an individual physician vary if you first run the data or run the tools using Medicare data and then run the data using a private carrier's data for the same physician. It would obviously be very reassuring if we got consistent results, even though we're talking about different samples of the physician's

practice.

My fear has always been that you might get an A from Medicare and a C from Humana, in part just because of the differences in the population, small numbers, or something.

So if there's some way that we could look at that, maybe in conjunction with a private payer, run the data using the same tools for the same doc and see what happens, I'd be very interested in that result.

I saw at least one hand for a second comment, Karen. Is there anybody else who has another comment before we go to the public comment period?

DR. BORMAN: I just wanted to touch on something that relates to the benchmarking comparison kind of conversation. Recognizing the very informative first step nature of the CMS project, and also we're trying to ask what can you -- Commission staff -- invest time in that would be helpful. One of the things that occurred to me is utilizing datasets that are already available, not just the private payers. The VA has an incredible dataset. The VA is another part of our government, I think, and hopefully that means that getting those data might not be quite the uphill

battle that are others, although I'm not so sure that's true.

But at any rate, certainly some of these conditions are regularly treated in the veteran population and there might be just a way to give us that as sort of a reality check, sniff test, something else. We recognize that there are limitations to that population and the data and whatever, but they do have a fairly transparent data collection system. They do clearly have a fully electronic medical record. They have made a huge effort to have primary care networks.

I do think there are some features of the VA system that make it worthwhile to know what would these look like from the VA. It just seems to me those data might not be too difficult to get as a comparison dataset.

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

We will now have a brief public comment period.

Okay, that's brief enough. We are just about on time so we will reconvene at 1:30.

[Whereupon, at 12:29 p.m., the meeting was recessed, to reconvene at 1:30 p.m. this same day.]

AFTERNOON SESSION [1:35 p.m.]

MR. HACKBARTH: First up this afternoon is Medicare Advantage. Scott and Jennifer and Carlos are going to lead the way.

MS. PODULKA: Thanks. Carlos is here, he's not mentioned on the slide there but he's certainly available to answer questions and definitely helped in the preparation of this session.

As Glenn mentioned, this is another MIPPA update, specifically to Medicare Advantage. I'm going to be speaking to you first about special needs plans.

Special needs plans or SNPs were added as a type of MA plan by the 2003 MMA. They are paid the same as other MA plans but are allowed to limit their enrollment to certain beneficiaries. In our most recent March report to the Congress, we made a series of seven recommendations, several of which are enacted -- at least in spirit -- by MIPPA. If you want to know more about how those two match up, I can answer your questions at the end.

Originally, SNPs were set to expire at the end of 2008. They have already been extended through 2009 and MIPPA extends them one more year, through 2010. But unlike

our recommendation, it does not call for a subsequent evaluation of the SNPs.

Until MIPPA, SNPs could apply for approval from CMS to enroll non-special needs individuals. We, the Commission, recommended that this be limited. MIPPA says that beginning in January 2010 all new enrollees must meet the definition of special needs individuals.

Also, MIPPA adds two new requirements. SNPs must have in place an evidence-based care model with appropriate networks of providers and specialists, conduct an initial assessment and annual reassessment of each enrollees physical, psychosocial, and functional needs, and develop a plan that identifies goals and objectives, including measurable outcomes as well as specific services and benefits to be provided, and finally uses a care management team.

You may recall from last year's discussion that special needs plans targeted population include beneficiaries who are dually eligible for Medicare and Medicaid, residing in an institution or in the community with a nursing home certifiable designation, or who are chronically ill or disabled. MIPPA makes requirement

changes to all three types of SNPs.

First, for dual SNPs, they must limit their cost-sharing for dual and QMB enrollees to no more than they would be charged under their Medicaid plan. Dual SNPs cannot expand their service area unless they contract with a state in that area. And dual SNPs must give potential enrollees a written comparison of the Medicaid plan and their plan's benefits.

For institutional SNPs, which can serve beneficiaries in nursing homes and those in the community who are determined to require a similar level of care, MIPPA requires that that determination be made using a state-approved assessment tool applied by someone other than a SNP employee.

And then finally, for chronic condition SNPs, which were designed for beneficiaries with severe and disabling chronic conditions, these were not further defined by CMS after the original law was passed so MIPPA adds the following to their definition. These are those who have one or more comorbid and medically complex chronic conditions that are substantially disabling or life-threatening, have a high risk of hospitalization or other significant adverse

health outcomes, and requires specialized delivery systems across domains of care.

In addition, MIPPA calls for the Secretary to convene a panel of clinical advisers to determine conditions that should meet this definition and be appropriate for the chronic condition SNP designation. They will be announcing that next week, actually.

That concludes the update on SNPs.

DR. HARRISON: The Medicare Advantage payment system has resulted in Medicare duplicate payments for indirect medical education. The MA benchmarks, which are used to help determine Medicare's payments to MA plans include an allowance for IME spending for fee-for-service Medicare. The Medicare program also makes IME payments directly to teaching hospitals that treat Medicare Advantage plan enrollees.

IME spending raised the benchmarks for 2008 by about 2.5 percent. The Commission had recommended eliminating the effect of IME payments on the benchmarks to eliminate the double payments. MIPPA reduces the benchmarks to eliminate the double payment. Beginning in 2010, each county benchmark is reduced by 0.6 percent annually until

the total percentage reduction equals the percentage of total fee-for-service spending in the county which is attributable to IME payments to hospitals.

For example, if a county had 2 percent of its fee-for-service expenditures attributable to IME then in the first year the reduction in the benchmark would be 0.6 percent, then 1.2 percent in the second year, then 1.8 percent in the third, and then the full 2 percent thereafter. Thus, the phase-out will be gradual, with some counties having phaseout periods lasting a decade.

In the first year, however, the reduction will approximate an across-the-board cut as 92 percent of MA enrollees live in counties where the benchmark would be reduced by the 0.6 percent.

MIPPA will require major changes for private fee-for-service plans. Private fee-for-service plans differ from coordinated care plans because they do not need to have a provider network to pass CMS's network adequacy requirements. Instead, if they offer to pay providers the same rates as fee-for-service Medicare, they are considered to meet the network adequacy requirements.

The Commission has been concerned that rapid

enrollment growth in private fee-for-service plans was a manifestation that the benchmarks were high enough to allow plans to thrive even though they had limited ability to manage care or influence the quality of care.

Beginning in 2011, MIPPA requires that private fee-for-service plans maintain a contracted network of providers except in areas where there were fewer than two networked plans offered the previous year.

Employer private fee-for-service plans are not given the two plan exception. Employer private fee-for-service plans will have to maintain networks throughout their service areas. However, CMS policy changes will make it easier for employers to offer networked plans across the country, and I can give you more details on question.

Private fee-for-service plans will also have more rigorous quality requirements beginning in 2010. The law requires that private fee-for-service plans have quality improvement programs, as has been required for HMOs and PPOs. Also, the quality data reporting requirements for regional PPOs and private fee-for-service plans will be raised to the same level as those for local PPOs, though still not as high as those for HMOs.

MIPPA contains a few other MA provisions. MIPPA extends the cost reimbursed plans by one year, through 2009. After 2009 they are prohibited in areas where there are two or more organizations offering networked products that meet certain enrollment levels.

MIPPA also eliminates $1.8 billion, or all but $1, of funding for the regional PPO stabilization fund through 2014. The fund may be used at the discretion of the Secretary to raise benchmarks for regional PPOs to attract or stabilize regional PPO plan participation. The Commission had recommended elimination of the fund because it favored one plan type over others.

Finally, and of particular interest to us, the Act assigns MedPAC two MA studies. The first is a report on quality measures. The Commission has recommended that CMS collect and calculate clinical measures from the plans and from the fee-for-service program that would permit comparison across MA plans and between the fee-for-service program and MA plans. MIPPA requires a MedPAC study of performance measures and patient experience measures that can be used to make comparisons of the quality of care both across MA plans and between MA and traditional fee-for-

service. The study should address technical issues, such as data requirements and issues relating to the appropriate quality benchmarks. The report is to be completed by March 2010 and is to include recommendations for legislative or administrative changes, as appropriate.

We are also required to study and report on MA payments. The study needs to include three sets of analyses. The Commission is directed to study the correlation between MA plan costs to deliver the Parts A and B benefits, as reflected in plan bids, and county level per capita spending under fee-for-service Medicare. The provision also requires us to evaluate the accuracy and completeness of CMS's measurement of county level spending and, incorporating the findings from the first two tasks, we are to examine alternate approaches to MA payment other than the 100 percent of county level fee-for-service approach.

The report, along with any recommendations we deem appropriate, is due March 2010.

Thank you. Jennifer, Carlos, and I are happy to address any questions you have and look forward to your discussion.

MR. HACKBARTH: Round one questions or comments?

DR. REISCHAUER: Just a technical question. When you say that there has to be two or more networked plans, what exactly is the definition of a plan? If I'm Aetna and I offer a high and a low level plan, is that two plans or is it one?

DR. HARRISON: There is some discussion about that. The language was not as clear as it might have been. We do know that CBO scored it as if it were two organizations. So, for instance, Aetna would not be able to offer just the two plans. It would have to be Aetna and Humana or something like that.

MR. GEORGE MILLER: Another technical question. On page eight of your report, the three main tasks: study correlation between MA plan costs and county-wide level, are you also going to examine the fact that taxpayers do subsidize MA plans in itself? Will that be a part of the evaluation?

DR. HARRISON: We would expect that we would be looking at the different implicit subsidies or explicit subsidies in the different counties.

MR. GEORGE MILLER: Thank you.

DR. CROSSON: I think the two tasks we've been

given have probably created the most exciting situation that I've seen in a few years here, and I wonder how the staff feels about that.

But clearly, the one that is fascinating to me is the very last -- almost penultimate anyway -- bullet point which is to examine alternate payment approaches and make recommendations. Because that can mean -- that encompasses a potentially very wide spectrum from simply making some technical suggestions about how the existing county basis process should be made more accurate, more fair or whatever to fundamentally suggesting a redesign of the payment system which, in fact, serves the purpose of remaking the Medicare Advantage program because, depending on how the payment system is constructed, you could imagine a smaller program, a very much larger program, a program that for example is set out now to achieve goals in a practical way that were envisioned initially for the program or one that simply continues some of the trends that have existed over the last few years.

It would seem to me that -- one question is do we have a sense of what the intent of Congress was with respect to that spectrum?

And then secondly, I would hope that we would spend some time in the next couple of months at the meetings discussing what we think would be the mission of MedPAC with respect to that. Because I can imagine again anything from a relatively simple task to a relatively complex but potentially very impactful one.

MR. HACKBARTH: Scott, do you want to answer about Congressional intent? Or Mark, do you want to handle that?

DR. MARK MILLER: I'll take that. First of all, I want to tell you how excited we are. I've been dying to say that, ever since you...

[Laughter.]

DR. MARK MILLER: As any observer can see -- yourselves, the public, everybody -- we've had our recommendations out there for a while. The Congress has kind of stepped up to them in some draft legislation but there hasn't been a lot of enthusiasm to embrace them in their entirety. Some of the issue, and you've implicitly referred to it George, as kind of the distributional consequences of those decisions and how different equities work across the country. And I think that their intent is, in part, to say can you talk about options where underneath

whatever -- the aggregate spending, there are different ways equities are kind of worked through.

Again, some of this can get to things like if you had 100 percent of fee-for-service -- and let's just say for a moment that's a governing principle, just for the moment, although I think the Commission can decide to discuss that. You could still arrive at that differently by having a blend, for example, across the country.

And I think some of the Congressional intent was -- I think they truly do want a broad discussion of options. But I think part of what drove it is their own internal arguments about the distributional equities of the program.

MR. HACKBARTH: We will come back to this some more in round two, but for now let's get to round one.

DR. SCANLON: This probably adds to the excitement. We've made some real improvements in terms of risk adjustment, and we've also affected the selection process by creating this lock-in for enrollment. But I still have this question in my mind from some of the things we've heard over the years here about the inflation creep in terms of diagnoses that's not commensurate with reported health status.

And so in thinking about going back to some of the work that was done in the mid-90s about selection and how well risk adjustment adjusts for patients' health status I think might be a very good companion to looking at plan costs and fee-for-service and then thinking about what would you want to do in terms of a payment system. Because if you understand the limitations of your risk adjustment, that may influence what you want in terms of how you have the base payments set.

DR. CHERNEW: I want to make two quick comments. The first one is one of the things I would like us to think about in some ways broadly is how the Medicare program can become more clinically oriented in the way it thinks about things. So instead of thinking about A, B, D, it might think about heart disease or something like that. And so I think one issue related to the SNPs which is important and shouldn't be forgotten is it does at least give you a lens to begin to think about patients around the clinical connection as opposed to a type of service connection. I think that's important. And as we do our work on SNPs, I think that's an advantage of SNPs that transcends some of the administrative issues of how they're paid and what

happens. Having them enables us, perhaps, to move the system in a way that we may like.

The second comment I want to make relates to the particular issue of the reports and the MA and fee-for-service comparisons. And that is I think we need to be cognizant as we go through that that these are not simply two separate systems that operate independently, where you compare the costs of them like two different factories that are totally separate. The existence of one can influence the other. There are spillovers between them.

So in thinking about the merits and the payment and the whole series of things for the MA system, as you go through that report, I think it's important to recognize that the costs we might see in say a county that has a lot of MA in the fee-for-service system may be affected by the presence of the MA plans in that area. So that spillover, that connection, shouldn't be missed in the report that we do.

DR. STUART: I also have two brief comments but first I want to second what Bill said about selection. About a decade ago there were a number of studies that looked at pre-selection Medicare claims for people that

ended up in HMOs and didn't. I agree that that study ought to be done, particularly looking not just at those that end up in MA plans or stay in fee-for-service but also the characteristics of the MA plans that they go into. I think that's going to help us learn a little bit more about these private fee-for-service plans.

The second thing is a question. CMS recently promulgated a rule that requires that every MA plan provide event level data to all -- 100 percent event level data to CMS that would be used for this purpose, to develop new risk adjusters.

My question is will that data be available to you for this study?

DR. HARRISON: I don't think so because I don't think it would be collected until at least 2010.

DR. STUART: Because I think that's really an important point because if you're looking at cost, you're going to be comparing the cost reports presumably with fee-for-service reimbursement, which are going to be obviously an apples and oranges kind of issue. And so even if you don't have those data available, I think it would be really important to develop a research design that would use those

data when they become available.

MR. HACKBARTH: Just on this particular issue, could you just elaborate a little bit more about the data that you're referring to, Bruce? I think I understand but it's a relatively recent development so it may be helpful.

DR. STUART: Mark might be in a better position to do that than I. Mark?

DR. REISCHAUER: He might not.

DR. MARK MILLER: Again, let me say how excited I am to be here.

[Laughter.]

DR. MARK MILLER: Here's what I know, Bruce. And Scott, this is the stuff from the inpatient PPS rule, oddly enough. Right?

MR. ZARABOZO: It is the collection of encounter data from the health plans and our understanding is that CMS is going to work with the health plans to determine exactly what is to be submitted and how it is to be submitted. But the requirement is essentially encounter level data for both Medicare covered and non-Medicare covered services, is my understanding of the requirement.

DR. MARK MILLER: At this point it's true that we

don't have a sense of what and when CMS is going to do. We know from the rule that they have an intent to do it but we haven't lifted from the Agency yet exactly what and how and when they're going to proceed on this. And I think that is some of the caution you're hearing about how quickly this would be available.

DR. KANE: I've talked about this I think with Mark and some of the staff before. I'm wondering if we wouldn't also want to take a look at how the industry behaves with this extra payment above costs, above the 100 percent of cost piece. Where is the excess going?

One assumption is that it's going to serve low-income beneficiaries so they have access to benefits they otherwise would not be able to afford. But another possible place that the excess of payment above traditional cost is that it goes into other forms of competitive behavior, perhaps less need to raise premiums in the private sector or particularly the large group or the small group.

It turns out that the reporting of that is not great, so there may be a need to say we need to have better reporting of this. States now require -- some states moreso than others -- a lot more detailed reporting of the internal

cost -- almost like a Medicare cost report -- the internal cost structures and lines of business reporting of these plans.

We don't have that yet. But it seems to me that if there's going to be a big argument over time about whether the premium should be lowered to 100 percent of fee-for-service from where they are now, what is the impact? And if we don't have any idea where those excess monies have been going, people can claim anything, that they're supporting low-income people or whatever. But we don't have any way to independently verify that. We can look at the old orange blank NAIC forms. I know you've thought about that.

But maybe we need to do something better than that or ask for better data than that to be able to really address where are these excess above 100 percent dollars going? And that, I think, will help us with the next round of discussions in Congress about whether the premiums should be brought back down to fee-for-service other than just the equity issue.

DR. MARK MILLER: Right. And just to make sure everybody is in on the conversation, several months ago --

and I can't remember exactly what it was -- Nancy raised this hypothesis with us that is there some behavior that would be reflected on the private side in terms of premiums. Carlos and Scott got some data and took a look at that. We couldn't lift a real clear -- and we discussed it -- we couldn't lift a real clear pattern off of it.

One thing for sure in responding to your comment is we can certainly raise this as an issue and point to the need for information to explore it. I would defer to you guys if there is a different angle to go at that question. I think we came up a little dry but I don't know if there are other data sources that we can pursue.

When Mike said that spillover, spillover goes in a lot of different directions. And I think the notion of what the impacts are between MA, fee-for-service, the private sector is something that we should make as part of these reports.

DR. MILSTEIN: I share Jay's enthusiasm for these mandated reports and wanted to especially emphasize two points. One is the quality comparison. I think last spring we surfaced a heretofore I think underappreciated fact, which is a majority of these Medicare Advantage plans when

you look at health status of their populations they are actually scoring worse than expected relative to baseline two years earlier. That was something that was a very important fact and we had no clear way of following up. I think the mandated report on quality gives us a way of beginning to drill deeper and understand that better.

And then the second comment, I guess is really an elaboration on Nancy's point. Any shareholder of any Medicare Advantage plan knows what their Medicare medical loss ratio is, how much they're spending on medical care per Medicare beneficiary on a risk adjusted basis. They know it. It's not an area of ambiguity. Certainly there are differences in how plans count medical loss ratio but I'd say by and large in the majority it's a relatively standardized approach. There may be a few plans like Kaiser Permanente excepted.

And so I would hope if we are going to make well-informed recommendations on report item three, examine alternative payment approaches, that hard as it may be we should do what we can to service information on what is the Medicare medical loss ratio for Medicare Advantage plans? What's the distribution of it? It gives us, among other

things, a sense of how much opportunity there might be for efficiency gain.

MR. BUTLER: Just a logistical question. This report is due in March of 2010. It's got some big questions in here. There's obviously a lot of work between now and then. Historically, or more specifically in this case, is there interim reports or interim data that we look at as a Commission that can help guide us? Or do we kind of freeze in time until March 2010, and only kind of collectively look at the report?

MR. HACKBARTH: Let me take a crack at that, Mark, and then you can as well.

The normal process in doing a report like this is that there will be frequent discussions. On one that has a 2010 report date, normally it would come back six or seven times where you get interim reports, data analysis, further opportunity to refine the questions, et cetera.

MR. BUTLER: Now I'm even getting excited. Okay.

[Laughter.]

MR. HACKBARTH: They don't just go off and bring a semifinal draft. You see it build up from the ground over time. Is it responsive to your question?

MR. BUTLER: That is. And then the second piece, do we even taking advantage of that as we think about our annual responsibilities here and take that data into account?

MR. HACKBARTH: Sure.

MR. BUTLER: I would think so.

MR. HACKBARTH: Sure.

So another question I detected there was is there any precedent for us issuing a series of reports here to Congress? So as Jay pointed out at the beginning, you could define this big or you could define it small. And so the gist of the conversation I've heard to this point is bigger, bigger, bigger. We're sort of adding new dimension.

On the other hand, there's been at least some interest from the Hill in well, could you report earlier? Conceivably, we could do both in the sense of having an interim report on a narrower question and say future installments are planned on X, Y, and Z and will be rolled out over time.

I can't remember a case where we've ever used that approach but I wouldn't necessarily rule it out. Is that responsive?

Is there anything you wanted to add on that, Mark?

DR. MARK MILLER: You'll have multiple opportunities. A common thing you'll see us as a result of this conversation, we'll try and come back with a work plan. For everybody, this is the way the Commission works. It happens in public. We come through. We do the presentation. People react. We take things in different directions.

It is getting bigger as the comments go out. So there's always a work management issue. We have to respond to the mandate and we have always been on time and always been responsive. So if it gets so big where we're going to have to really decide what part of it is going to meet the mandate.

And remember, just because this is a mandated report, you can as a Commission choose to take up these issues. This is a nice vehicle to start to build around those. But we'll have to say stay focused on meeting the mandate and the timing of that mandate and then other stuff as you guys see fit.

MR. HACKBARTH: So to kick off the second round, let me ask a question. My understanding of the

Congressional request and interest has been that at least implicitly they want to hold open the possibility of further MA savings, but they want some guidance on how that might be accomplished while dealing with issues of geographic equity that have troubled them. And so can we move towards 100 percent on an aggregate basis in another way other than county level that might result in a better sense, from their perspective, of geographic equity. That's sort of the question that I hear them asking. Is that a fair summary, Mark?

DR. MARK MILLER: Yes, I think that's a large part of it. I suppose there's also just the question of whether 100 percent is the reference point.

MR. HACKBARTH: From our vantage point we said that ought to be the goal over time. Congress hasn't ever officially embraced that, but clearly with MIPPA they've expressed an interest in trying to get some savings out of the program. And what's held them back is the geographic issue.

So in defining the scope of the project, Jay, the first set of questions is different approaches for dealing with the geographic issue. And then sort of a second wave

of issues came up around risk selection and related to that how the industry uses excess dollars and the like. As you know, you can imagine sort of a tiered response, picking up with Peter's question, where we try to get an early response on the geographic issue, although I'm aware of how complicated even that can be, how many different possibilities there are. But we could say we're going to focus on that as installment one. If we could get it done before March 2010, that would be great. But do so with an eye towards also taking on some of these other issues in successive volumes, if you will, of this report.

So let me just throw that out for discussion.

And Bob is first in the queue.

DR. REISCHAUER: Thank you, Mr. Chairman. I was going to talk about Nancy's point which actually relates also to Arnie's. You were sort of asking what happens to the MA payments that are in excess of the plans' cost of providing A and B benefits. The law says there are only three permissible uses of it: extra benefits, rebates of premiums, or give it back to CMS.

MR. BERTKO: Provider payments.

DR. REISCHAUER: Provider payments, yes.

And their data is all going to report that they do those or they're in violation of the law. And their Medicare medical loss ratios are all going to reflect those same numbers.

So I'm just wondering whether the interest you have in this topic is really better directed to the IG's office rather than to the MedPAC staff. Because in finding something like this, what we would be doing is finding that they're breaking the fundamental law. And I think they're probably better at hiding it than we are at finding it. I'm sure there is some shifting of overhead costs and things like that that go on in some induced inefficiencies in these programs that use up some of these resources. But I'm not sure that we should spend a lot of effort really in this area.

And then there's sort of the second point which you sounded like a member of Congress, I mean you had sympathy for well, what if all of these extra benefits went to the benefit of low income participants in these programs? And what we have said historically on the Commission is why should low income beneficiaries in MA plans get help that those in fee-for-service don't get, if you want an equitable

system? Or maybe it should all be rechanneled into low income subsidies for everybody.

DR. KANE: Can I respond?

For the first part, which is that they're supposed to say X and so they're going to say X -- well, as someone who looks at multiple data around -- what people tell Medicare in their formal reporting isn't necessarily what they tell shareholders or other parties. So sometimes it's interesting to look at others sources of data beyond what they're reporting to Medicare to see what you think might also be going on. So I'm open here. I was hoping the NAICs would be more useful and maybe they would be if we knew how to ask more specifically and analyze in a different way. I'm not sure. I think it's hard to do.

Maybe we should be looking at the shareholder reports on EDGAR on the SEC's filings and seeing what they say. In other words, looking at some of the traditional ways these industries report about their own performance might be a useful exercise. And I think that's the level I was really at.

The second issue that we've already told Congress what to do with low-income beneficiaries is fine, and I

agree with what we've told them. And I guess I'm just trying to get back to well, is that even a true claim? And so yes, I agree why should they be subsidized this way? But I'm just wondering is it even a valid claim that that's where all the excess is going, is taking care of low-income beneficiaries?

DR. MARK MILLER: I just want to make one clarification, and I'm sure you know this but just to make sure that the rollout more broadly.

They're required by law to do certain things, as you guys ticked off. But remember, each of those things are fully loaded. I know you guys know. I just want to make sure everybody knows. Administrative, overhead, and profit margins go into providing each one of those benefits.

And I think that's some of what -- if I understood what you were saying -- Arnie is talking about with the medical loss ratio. And I know you know all of that. I just want to make sure everybody does.

DR. SCANLON: I was motivated to look at this whole issue of risk adjustment in part because I share Bob's concerns about the other sources of data. So the idea of having an estimate of what these individuals might have cost

in traditional Medicare is an indicator about value to me because it's not dependent upon these data that by law have to show certain things.

DR. MILSTEIN: My point is probably just as easily handled off-line with Bob and Mark.

DR. CHERNEW: It actually turns out that we have a proposal that I think is soon to be funded to look at this issue by looking at how the plans behaved when payment rates changed. I think the important thing is even if you knew in some accounting sense where the money was going -- if you could somehow say this is the part that was over 100, this is how it's going -- that doesn't mean if you cut back payments you would know how they would change in response.

So for the real point, which is what should you do based on this, you don't know how they're going to respond. And the essence of the work that we've proposed to do is to look to see in the past as payment rates have changed over time how plans have changed their behavior. And that you can measure more easily, at least in some crude ways, because you can see that the premiums were and you can see what the benefits offered are.

So I think if you understand the plan response

that's a little different than trying to figure out whether the money in some esoteric way is spent on the right thing or the wrong thing. I think what we really care about more is if we change payment one way or another what do the plans do?

And it's hard to tell what that would be, even if you could, in an accounting way, figure out what their medical loss ratio was. Because if you paid them less, that doesn't mean their medical loss ratio is going to change. They could change care in a whole bunch of ways and keep the same medical loss ratio.

DR. MARK MILLER: This conversation should go on. To the extent that has been looked at -- and Carlos, I'm thinking you're one of the people who have looked at this in the past. I mean, one of the things we know is that the extra benefits and the coverage of cost sharing gets scaled back and plans drop out.

So I think in some ways empirically some of the things -- depending on how the rates change -- is known. And then the problem that you have is okay, is that okay? Or how many plans do we want? How many extra benefits? I think we kind of know, in some ways, what their immediate

reactions are.

DR. CHERNEW: I think that literature is kind of sketchy but I agree there's some literature.

MR. HACKBARTH: I think this is an important point in that it defines sort of the moorings of this work. What are we trying to accomplish through this program? Are we trying to maximize plan participation, additional benefits for Medicare beneficiaries? That leads you to one sort of policy.

Are we trying to, on the other hand, maybe a different goal is to try to create incentives for the most efficient plans, and that would lead you to a different direction.

MedPAC is not neutral on this question. We have a long-standing position that we think the private plans should be welcome into Medicare. They should be used as a way to import efficiency into the programs by engaging plans that can do things that traditional Medicare finds it difficult to do.

It should not be a vehicle for trying to provide additional benefits to low income beneficiaries or anybody else because there are more efficient lower cost ways that

that goal can be accomplished.

So rather than opening up all sorts of new issues I'd say let's stick with our definition of what the program goal ought to be and then answer the specific question are there other ways that we might geographically adjust payments other than 100 percent of the county level that achieve the goal of rewarding efficiency, importing efficiency into the program.

DR. CROSSON: I would add one other point there, and that is that I thought and have thought for a long time that one of the main goals was something called care coordination. These plans are called coordinated care plans for a purpose.

So it seems to me if we're going to think about the relationship of the payment, our recommendations around payment, to the fundamental idea underlying Medicare Advantage we have think -- as was mentioned earlier -- about some of the clinical aspects of what the purpose of these is and what the relationship then is to how we recommend a payment system.

DR. CHERNEW: I agree in general with the notion of understanding what the purpose of the program is and I

accept the general MedPAC position. But I think the key thing for the report, relative to the original point that was raised is, if we were to make a payment recommendation, whatever that is, the relevant piece of information at least I would like to know is what the response would be for the plans. So I'm less interested in rewarding efficiency or not rewarding efficiency or doing any of these other things which I think matter as much as, at least for starters, understanding how plans would respond if we were to do something.

So I would like to make the system more efficient, higher quality, less money as opposed to have some other goal. And to do that, regardless of what we think the goals are, understanding how the plans will respond is the crucial parameter. To see if it meets whatever goals there are, we need to know what it's going to do to see if it meets those.

DR. DEAN: I had a question that relates to the whole risk adjustment issue. As some of you know, there's a special needs plan in South Dakota that was devoted to cardiovascular disease that just announced that they're closing down after about a year or a year-and-a-half of operation. I talked to the medical director of that plan

and said what's the deal, what's the problem? His explanation, and I'm sure it's not the only thing, but he said that the subsidy that they get from CMS is a risk-adjusted payment, I understand, based on their enrollment.

And he says that they were not able to get enough information from the providers, from the physicians, in terms of the information that came in on the claim forms listed two or three diagnoses -- I'm wondering if this makes sense -- where he says we know that many of those patients have five or six diagnoses and would qualify for a much richer subsidy but they simply weren't able to get the information.

Like I said, I wonder, is that a legitimate concern or is that something that's going to be a problem?

MS. PODULKA: We've heard the same concern from a number of SNPs who have spoken with us over the past year and a number of the organizations that represent them. It's something that we're definitely tracking on. It's definitely a concern. I'm not sure what the response is.

Basically it comes down to, if I understand it correctly, the physicians who participate in the plan's network aren't coding all of these diagnoses. But in part

that's the relationship between the plan and the physicians and I'm not sure where we or Medicare fit into that.

DR. DEAN: He said that the requirement is only that they are required to report up to three, or something like that.

DR. HARRISON: I think what happened was let's say you need to have congestive heart failure. Well, it turns out that somebody would present themselves and say they have congestive heart failure. But when they would look back in the records to do the risk adjustment, they didn't have congestive heart failure. And so sometimes there might be a lag of a year and sometimes there might be codes that have fallen off that it wasn't coded. And so I think that was part of their problem.

Now of course, when you're comparing the fee-for-service, this thing would go on the fee-for-service, too. It just doesn't have the same payment implications.

MR. HACKBARTH: We are just about at the end of our allotted time and I've got four people on my list: John, Bob, Jack, and Karen. So if we could keep the comments brief.

MR. BERTKO: Just quickly to address Mike, Nancy,

and maybe Bob on this. There was a natural experiment with what happens when you compress rates from the BBA. So from 2000 to 2003 if you wanted to look back and see what happens, you could. I don't think much knew is going to be learned about it. So I would go back to the intent I think that Scott described at the beginning for where we should aim most of the work on the study.

DR. REISCHAUER: Two things. I was actually going to talk about natural experiment, too. And it relates to what Tom brought up when we're thinking about risk adjustment and how good the existing system is relative to maybe some others. There are plans that disappear from counties and the folks in them go back into fee-for-service. And developing a database which would be year one/year two of these individuals and then seeing how from their year two experience you would rate them versus how CMS did in year one might be some kind of test.

The second point I was going to say is Glenn and I at least won't be here for this -- free at last -- this report. But having spent eight or nine years worrying about this issue, and I know I disagree with Glenn on some of this. But if we start out with a payment system that paid

no more than fee-for-service would in the nation as a whole but we allowed geographic variation what would govern that variation? I have argued in the past that Medicare has monopsony power and its ability to dictate prices is not shared by Medicare Advantage plans.

The question is could you create an index of Medicare payments versus what market payments are in each area, paid by larger insurers, and use that ratio to vary the fee-for-service? I see Bill saying no, so Glenn, you have one person on your side. Across the nation the weighted average would come out to be fee-for-service but it would reflect local market conditions.

This is sort of one of the arguments that individuals representing rural districts would have, which is there's only one hospital in the area and they can charge these private plans whatever it wants.

So that's my contribution to the 2010 report.

MR. EBELER: I go back, in some ways, to Jay's original comments, sort of reinforce that. I would certainly support this idea of looking at this as a broad project rather than a narrow how do we tweak it. It seems to me it's a great opportunity. We have flagged a number of

underlying analytic questions or steps that need to build into part of that.

The one we might want to think about linking is the other study here which is the comparison of quality within MA as well as quality outside of MA. Again, if you really think broad scope and long-term here, and you intersect our general principle about payment for quality, you would want to at least think about those two studies at the same time because they may feed your future payment rates as you go forward.

DR. BORMAN: Listening to what Tom brought up and some of the other discussion this leads me to comment that I would share Bill's and other people's concerns about being very careful about the risk adjustment, particularly for entities that have robust IT capability in health care reporting. The number of diagnoses is pretty easy to manipulate and to increase very rapidly. And I would have some significant concern on relying on those kinds of things.

There's a great ability here to do a fair amount of code creep. Just because if somebody has a problem-based list, that list carries forward to every visit, every

treatment or whatever, whether or not that treatment or visit anything to do with one or five of those things on that list. And so I think we need to be very careful. I would support being very careful about the risk adjustment.

MR. HACKBARTH: That will have to be it for today. I think we have outlined a lot of potential directions, important directions this might take. I would be happy to see it get bigger rather than keep it small, especially since I won't be here to have to do the work.

I think a question that we ought to come back to, and I would ask Mark and the staff to think about, is whether we might want to consider a phased strategy, an earlier narrow response on the geographic question asked with the subsequent installments plan on going into risk adjustment and some other issues.

So that's a question to think about and the next time we can take up this topic when we talk about the work plan we can try to resolve that issue.

DR. REISCHAUER: Just a possibility, I was sort of surprised when this report was due because it wouldn't surprise me at all if the Congress got into this issue before then. So I think we should be prepared to be asked

anyway for information on this or options on this before then.

MR. HACKBARTH: And I think informally there have already been some expressions of interest, could you get this done sooner than the statutory due date. We need to think a little bit about our plan on this one.

Thank you all, good job.

Next is the MIPPA update on ESRD.

MS. RAY: Good afternoon. MIPPA substantially changes Medicare's payment system for outpatient dialysis services. During this session, I'll summarize the changes and answer any questions you might have.

Just a couple of sentences first, before I start this slide, on Medicare's ESRD program. End-stage renal disease is a disease-specific entitlement. Medicare benefits are available to people with ESRD who are under age 65. Individuals who qualify for Medicare on the basis of ESRD get all the same benefits as those who qualify on the basis of age or disability. Most ESRD beneficiaries are on dialysis.

Currently Medicare uses a two-part payment structure to pay for dialysis services. Dialysis facilities

receive a prospective payment, called the composite rate, for each dialysis treatment they furnish. In addition, facilities receive separate payment for certain injectable drugs, like epo, vitamin D, and iron. These drugs were not available when the composite rate was first implemented in 1983. Spending and use of these drugs have increased significantly during the past 20 years. In 2006 drug payments accounted for about one-third of a facility's total Medicare payments.

The Commission and others, including GAO, have raised concerns about this two-part payment method. Facilities have stronger incentives to control the cost of services included in the payment bundle compared with services that fall outside of it -- specifically injectable drugs that are separately billable. Separately billable drugs have historically been profitable for most facilities.

The Commission has a long-standing recommendation for the Congress to broaden the payment bundle and include commonly furnished services that Medicare currently excludes. We recommended that when creating this expanded payment bundle the Congress account for factors that affect providers' costs, like patient case-mix. We also

recommended that the Congress implement pay-for-performance for facilities and physicians who treat dialysis patients. As you'll see, MIPPA is consistent with the Commission's recommendations.

First, I'd like to mention two refinements that MIPPA makes to the current payment method. It updates the composite rate by 1 percent in 2009 and 1 percent in 2010. The 2009 update is consistent with MedPAC's recommendation in our March 2008 report.

Beginning in 2009, MIPPA mandates a site-neutral composite rate. Hospital-based facilities were paid $4 more on average than freestanding facilities. MIPPA's change is also consistent with the Commission's recommendation which we made back in 2005.

MIPPA makes three changes to modernize the current payment method. Consistent with the Commission's recommendation, MIPPA broadens the prospective payment rate by bundling the composite rate services with separately billable services, including injectable drugs. The broader payment bundle will start in 2011.

Second, MIPPA links payment to quality, and this is also consistent with the Commission's recommendation.

P4P will begin in 2012.

Third, MIPPA creates a statutory annual update to the prospective payment rate beginning in 2012. MIPPA requires that the Secretary update the payment rate by the ESRD market basket minus 1 percentage point. Under current law, the Secretary does not have this mandate. Since the implementation of the composite rate in 1983, the Congress has changed the rate when it has decided that such a change is needed to ensure the adequacy of Medicare's payment rate. There have been gaps when the Congress did not update the composite rate. Specifically, there was not an update between 1996 to 1999, 2002 to 2004, and in 2008.

The broader payment bundle will include services in the composite rate as of 2010, separately billable injectable drugs and their oral equivalents, lab tests furnished for the treatment of ESRD that are not in the composite rate.

The Secretary also has the discretion to include other services that are furnished to beneficiaries for the treatment of ESRD. One candidate may be oral nutritional supplements. Last year, the Commission discussed the potential benefit of this service. Another possible

candidate the Secretary could consider are Part D drugs that are used to treat ESRD-related comorbidities. Including ESRD drugs paid for under Part D might help ensure that beneficiaries receive appropriate care, it may improve patients' compliance with their drug regimen, and it may also ensure that providers do not substitute Part D drugs for drugs covered under the broader dialysis bundle.

There will be a four-year phase-in of the broader payment bundle beginning in 2011. Facilities have the option to opt out of the phase-in and be paid completely in full under the broader payment bundle beginning in 2011.

MIPPA sets the payment rate at 98 percent of the estimated total payments if MIPPA had not implemented a broader payment bundle.

Finally, the Secretary has the discretion in setting the unit of payment. Currently, facilities receive a payment for each treatment they furnish. Other options include paying for dialysis on a weekly or monthly basis.

MIPPA includes several adjustments to the broader payment rate. The first three you see here are mandatory and the last three are discretionary. It requires that the Secretary adjust for patient case-mix, which can include

comorbidities, patient weight, age, rate, ethnicity and other appropriate factors. It also requires the Secretary to adjust payments for high-cost patients and for low-volume facilities that incur high costs.

The Secretary has the option to adjust for geographic factors, for facilities that treat pediatric patients, and for facilities located in rural areas. There is a table in your briefing materials that compare adjustments under the new broader bundle to the current method and I'd be happy to answer any questions you might have.

The pay for performance program will begin in 2012. You will see that much about the program is consistent with the Commission's recommendation.

The Secretary must develop measures assessing each facilities' anemia management and dialysis adequacy and, to the extent possible, indicators of patient satisfaction, iron management, bone mineral metabolism, and vascular access. MIPPA requires that the Secretary develop a performance standard that is based on levels of achievement and improvement using the selected quality measures.

The law permits the Secretary to reduce the

bundled payment rate by a maximum of 2 percent for facilities that do not achieve or make progress toward the performance standard. Facilities achieving the lowest total performance scores will receive the largest reduction in pain. The individual and total performance scores will be publicly available online and posted at each facility. And the Secretary is also required to establish a process for updating the measures over time.

Finally, I'd like to discuss with you two other changes MIPPA makes related to kidney disease. First, the law establishes a five-year pilot project in at least three states to increase the awareness of chronic kidney disease. This will begin in 2009.

The second change, beginning in 2010 the new law covers up to six educational sessions for beneficiaries with severe kidney disease but who are not yet on dialysis. This is called Stage IV chronic kidney disease. The sessions well instruct beneficiaries about managing their comorbidities for the purpose of delaying the need for dialysis, ways to prevent kidney related complications, the different ESRD treatment options including in-center and home dialysis and kidney transplantation, and the different

options available for vascular access.

That concludes my presentation and I would be happy to answer your questions.

MR. HACKBARTH: Thank you, Nancy.

DR. CASTELLANOS: Nancy, it was a good report and I'm glad to see we made a lot of progress. One of the questions I had last year was where does the physician fit into the bundle? And is his or her cost covered under the facility fee?

Now in the real world what happens is that the physician at the dialysis center is in charge of the dialysis as it's occurring. And I think Karen, I don't mean to put words, but I think your comment was when you were on the CPT Editorial Committee you thought it was all bundled and that was the intent. But we never really got a good answer on that.

The real problem here is that these people are sick, not just from dialysis problems but from other comorbidities. It's very, very difficult for these patients to come into the doctor's office is to be treated, concomitantly for another non-dialysis related disease process. And we were hoping that this would be allowed that

the doctor could see that patient at the time of dialysis, not just for a dialysis-related problem but for his general medical care. We were hoping we were going to get a determination on that. Do you have any follow up on that?

MS. RAY: The physician gets paid based on the Part B fee schedule, the physician managing the dialysis patient gets a monthly capitated payment. And that payment, like it's called, covers a month of care generally and it covers the physician's outpatient care of the dialysis patient. It is, in part, based on the number of times that the physician -- often a nephrologist -- sees the patient, whether it's once, twice, three times or four times a month.

I just want to be clear about this, Medicare pays the physician directly. It does not go through a dialysis facility. The facility is not paying the physician. Medicare is paying the physician.

DR. CASTELLANOS: Let me just clarified this: he gets paid just to manage the dialysis. How about for the other non-dialysis disease processes?

MS. RAY: I can't speak for all nephrologists. I think the extent to which a nephrologist cares for other conditions, that's going to vary from physician to

physician. I would have to see in the literature if there has been any survey work done on that. There's nothing that I can recall that has been. I think that's going to vary from physician to physician.

DR. CASTELLANOS: Thank you.

MR. EBELER: Thank you, Nancy. If you could just elaborate on two aspects of the pay-for-performance system. As I understand it, it's not a withhold. It's a reduction of up to 2 percent if you don't hit the quality standards? And the second is that the anchor for the quality measures sound like a pretty low anchor. It's the lesser of where you were on quality or what the national average is?

MS. RAY: The answer to your first question is yes, that's how I interpret the law. And again, we will see how -- CMS is going to have to presumably write a reg to implement this and we will see how they implement it. But yes, that is my interpretation.

Your second question is for the first year of the program the law explicitly requires that the Secretary implement P4P for dialysis adequacy and anemia. And yes, you are correct, it's based on the performance, the lesser of the facility's performance between 2007 and 2009 or the

national average, yes.

DR. MARK MILLER: Did you say that's just for the first year? In subsequent years that standard changes?

MS. RAY: Yes.

DR. MARK MILLER: Because I hadn't caught that.

DR. BORMAN: Just two items. The first would be in those educational sessions about Stage IV chronic kidney disease. Was there any mention of -- specifically you mentioned talking about access options and different types of dialysis options if they came to that. I think one of the pieces here -- and it has something of a quality piece to it -- is are people being appropriately evaluated as transplantation candidates at a suitably early point in the course of their disease? Because certainly there are patients who, rather than spending some prolonged time on dialysis prior to receiving a transplant, would be better served by moving fairly quickly to transplantation and obviate a pretty big expense and also a period of time that perhaps will increase their complications as a transplant recipient. If you're sicker having sat on dialysis for a while before you get your transplant the odds that you're going to have complications go up.

So I think, in terms of making this the most part proactive positive thing for patients that we can, that there might be some value to thinking of this more broadly in terms of all the options and thinking about transplantation as an option.

And then my second comment would be trying to link this to some other things that we're talking about. It strikes me that some of these centers are another opportunity for examining physician financial relationships. We've sort of focused our ideas on ASCs, specialty hospitals, and some of those kinds of things. I would just suggest that a lot of these have been in place for a long period of time. There's probably a fair amount of information out there and we might want to broaden our thinking on physician financial relationships to use this as an example of a place that we could also do some investigation.

DR. REISCHAUER: A clarification and then two observations. The clarification is on page 10 of the summary report you gave us it says payment for six sessions will be paid for under a physician's fee schedule, however only rural providers will be paid?

MS. RAY: Let me clarify that. What the law specifically says is that physicians and certain nonphysician practitioners are eligible and providers of services located in rural areas. That's what the law says.

DR. REISCHAUER: What does it mean? I mean, is an urban physician not a provider?

We'll move on to my second point.

DR. MARK MILLER: We talked about this. The payments go only to the rural providers?

MS. RAY: I think the CMS lawyers are going to have to look at this provision. The way it is written is that it says that a qualified person is a physician or certain nonphysician practitioners and provider of services located in rural areas.

DR. MARK MILLER: Just to be direct, when we ran across this, too, we had the same reaction. There may be some lack of clarity about it, but first read was kind of oh, this seems to go just one way. Is that fair?

MS. RAY: Yes.

DR. CROSSON: I may be wrong but what I just heard was physicians and certain nonphysician providers and providers in rural areas, meaning who don't meet the

criteria of the first set could still receive payment. That's how I interpreted it.

DR. REISCHAUER: People who are illegally providing medical services in rural areas are allowed to get paid?

DR. CROSSON: There may be some sorts of physicians --

DR. REISCHAUER: I just thought I had read it wrong. I can live with the ambiguity.

DR. MARK MILLER: For the same reason that there's $1 dollar in the --

DR. REISCHAUER: I know why that's there.

I agree with whichever Commissioner said -- Jack -- that the up to 2 percent reduction is too small an incentive to expect much behavioral response for pay for performance. And I think we should maybe say that at some point.

The goal of the session was to see whether we have any concerns about what's taken place. And the answer is I do have concerns about all of these adjustments that the Secretary will or can make. And it strikes me that some of them are redundant and others might be dangerous. There is

a low volume which has to take place and it's a pretty big incentive. It can't be less than 10 percent. I presume what we're talking about is adjustment, it's always up in this program. It's not an adjustment down.

And then there's a geographic adjustment which may take place and a rural adjustment which may take place. I guess I am concerned that we might have all three and they might be stacked one on top of each other. And we might, in the sense of having a low volume adjustment, be encouraging inefficient sized operations.

I was wondering whether there was any discussion at all of low volume, yes, but only if you're at least 50 miles from another one, as opposed to having a low volume provider every other block in New York City, and whether we should raise some of these concerns before the Secretary has to sit down and really think through exactly what he or she might end up doing.

MR. GEORGE MILLER: Along those lines that Bob brought up, I was thinking of it in a different way but he outlined it perfectly, at least for my question. That is as we look at this do we have a way to determine if access is particularly addressed if there are some variations or if

there's -- as the Secretary makes adjustments, how do we impact access? Is there a way to measure that and make a determination? If adverse is adversely affected, then what happens at that point?

DR. MARK MILLER: Your point is to be sure that as we go through the process of commenting on adjustments and how they go forward with implementing the program, be sure that part of our comments are driven by assuring access?

MR. GEORGE MILLER: Correct.

DR. MARK MILLER: Got it. No problem.

And actually, we pretty typically try and keep quality, payment, access, and equity for the provider in mind as a standard thing, but it's well worth repeating here.

MR. HACKBARTH: Others?

So a number of issues and potential concerns have been raised. What we would be doing is using the March report chapter on the update as a vehicle for discussing some of those issues?

DR. MARK MILLER: I think there's two things and I was thinking about this as we were going along here, Nancy. If there are issues that we want to raise in the March

report, and then obviously in the comment process when the Secretary starts to say this is how I'm planning to proceed on this, I'm going to do these adjustments. That's another vehicle for us to go. Is that what you were thinking?

MS. RAY: Yes.

MR. HACKBARTH: Thank you, Nancy.

Next is the MIPPA provisions on DME.

MR. GLASS: Good afternoon. Today I will give you and update on DME competitive bidding and the changes to that program brought about by MIPPA. I will briefly walk through how the competitive bidding program came about, how the first round of competition which was briefly operational in July of this year turned out, and how MIPPA delayed and modified the program.

As a brief reminder, Medicare spending last year on durable medical equipment, prosthetics, orthotics and supplies -- which we will call DME - was $8.6 billion. There's several relevant characteristics of the industry. First, it is a very unconsolidated industry. It has over 115,000 suppliers, over 90 percent of whom billed Medicare for less than $300,000.

Second, there have been some persistent reports

that the fee schedule prices are too high. For example, in recent testimony the CMS Administrator pointed out that Medicare prices are often several hundred percent higher than Internet prices for the same items. Because many items are commodities with little service element to them, this could be evidence of inaccurate pricing.

A troubling characteristic is that in a recent report the HHS OIG found an error rate of 29 percent in a sample of claims. This translates to about $2.7 billion of improper payments. The errors in that report could range from not having the right medical documentation all the way to supplying equipment that no one ordered or wanted, in other words, fraud.

Fraud has been a persistent problem for DME and CMS has launched targeted actions in areas such as Miami and Los Angeles which have a history of high incidence of fraud.

Against this background, competitive bidding for DME has been proposed as a way to get more realistic pricing and to eliminate marginal suppliers prone to fraud and abuse.

The Balanced Budget Act of 1997 called for a demonstration of competitive bidding for DME. The

demonstration took place in Polk County, Florida and San Antonio, Texas from 1999 to 2002. Prices for the competed items dropped by 17 to 22 percent with no significant quality or access problems. In 2003, prior to the final evaluation report, MedPAC recommended expansion of competitive bidding for DME into the Medicare program, given the results of final evaluation were favorable. As it turned out, they were.

In the Medicare Modernization Act of 2003 or MMA, the Congress required that Medicare phase-in competitive bidding for DME as part of the program. Round one would incorporate 10 metropolitan statistical areas and round two an additional 70, with others to follow. It also gave the Secretary the authority to change the fee schedule prices in other areas in light of the prices coming out of the competitive bidding. Round one started in July but was stopped by MIPPA. Round two never got underway, although the MSAs for it were chosen.

Looking at round one results: over 6,000 bids were submitted in the 10 MSAs for the nine categories of DME that were competed. Categories include, for example, hospital beds and oxygen equipment.

About half the bids were disqualified for reasons such as missing documentation or lack of accreditation. I will get into that in more detail in a minute. The remaining bids were analyzed and arrayed from lowest to highest. The capacity of each bidder was noted and when sufficient capacity plus a cushion was met, the median bid of those winning bidders was made the price in the MSA. Higher bidders were then excluded. As a result, not all bidders were awarded contracts. 1,345 contracts were signed with 325 different suppliers.

Suppliers without a contract were not eligible for Medicare DME payments in the competitive bidding areas. There was an exception for grandfathering. In oxygen, for example, an incumbent supplier could choose continue to provide oxygen for the people they had been doing it for but they couldn't accept any new clients.

There was a single payment rate for each item in an MSA and all winning bidders are paid that price. CMS estimated that those payment rates resulted in 26 percent savings compared to fee schedule prices. And the prices were locked in for three years. Savings varied by category and MSA. For example, prices for mail order diabetic

supplies dropped by an average of 43 percent. None of the resulting prices were higher than the fee schedule. The detailed results by MSA and category are in tables one and two of your paper.

The contracts went into effect July 1st 2008 and CMS sent out notices to beneficiaries and referral agents such as physicians and discharge planners telling them which suppliers were under contract.

The industry expressed great concern about the competitive bidding program. It estimated that there were 4,500 suppliers in the 10 MSAs of which only 325 were awarded contracts. The number of losers greatly outweighed the number of winners and the industry contended the access would suffer. Many suppliers simply didn't bid at all and of those who bid, some were disqualified for lack of financial documentation or failure to be accredited and some submitted bids that were too high to win. It was expected that there would be fewer suppliers at the end of the process but the final number may have seemed a bit jarring.

The industry also contended that the lower prices might lead to lower quality products being offered to beneficiaries and that eventually even the winners would

suffer financially. There were also concerns about the implementation of the program. There were reports of long delays loading data into the automated system of data being lost or garbled. Many bidders were disqualified for financial stability because of missing documents or not meeting standards, yet some bidders insist they had supplied the documents and didn't know what the standards were.

There were also doubts raised about the calculation of capacity, particularly for bidders with no facilities in the area.

The final concern was winning bidders with no current operations in an area or with no experience with a particular category of items. For example, a winning oxygen bidder who had not previously supplied oxygen.

There were other perspectives, however. CMS estimated significant savings for the Medicare program and therefore for beneficiaries who use DME. Those beneficiaries have to pay a 20 percent coinsurance on DME items.

CMS also stated there were more safeguards than the current program has. Bidders had to be accredited, although all suppliers will have to be accredited by the end

of September 2009. There would be monitoring of quality and the financial stability rules would help week out marginal suppliers. Currently it is very easy to qualify to be a DME supplier, as GAO recently demonstrated by setting up two fictitious storefront operations. Taken together, those safeguards and the bidding process itself would help reduce the opportunity for fraud and abuse.

The winning bidders also had a perspective. They had been able to successfully work through the process and were willing to supply DME under terms of their contracts for the specified prices for three years. They felt that any problems could be rectified without delaying the program.

In the middle of July the Congress passed MIPPA. It terminated the contracts that had been awarded in round one and had just taken effect at the beginning of the month. It delayed the competitive bidding program as shown on the slide. This is essentially an 18 or 24 month delay. But it kept the same MSAs except for San Juan, which will no longer be in the competitive bidding program. It also removed one of the categories, negative pressure wound therapy items.

To cover the cost of delaying the program, the fee

schedule amounts for the competed items will be reduced by 9.5 percent in 2009 nationwide. The cut is less than the 26 percent savings began it is nationwide, not just in a limited number of MSAs. Nevertheless, it is a significant cut. In a hearing of the House Ways and Means Health Subcommittee, when questioned as to whether the industry would accept price cuts to get rid of competitive bidding, the industry representative answered yes.

The legislation also has a number of other changes to address concerns and to improve implementation, as shown on the next slide.

The changes include OIG verification of pivotal bid amounts and single payment amounts, timely feedback to provide on missing financial documentation, and accreditation of subcontractors and disclosures of plans to use subcontractors. It also excludes certain complex power wheelchairs group three or higher from competition and off-the-shelf orthotics that a physician or hospital would normally supply to patients as part of a professional service.

One interesting change is requiring the Secretary to use the regulatory rule and comment procedure to use

information from competitive bidding in setting the fee schedule rates in other areas. Before the Secretary had more latitude to do it as he saw fit. And it requires DME suppliers to stock multiple types of diabetic test strips and an OIG study to determine which ones. You have a more complete list in the paper of other changes.

I would be happy to answer any questions that I can and I look forward to hearing your views.

DR. SCANLON: I am not sure where to be on this topic. In reading the chapter, it kind of reads like he said/she said to a great extent. And so where one comes down is uncertain.

At GAO I was there when we were pushing for this idea because the problem of setting prices for DME over the years has been incredibly difficult to resolve. There have been other attempts to try and bring prices, Medicare prices, in line with what you can get at the drugstore when you walk in and pay cash. And yet we've never succeeded.

There is a huge issue here with respect to implementation. And during the demonstration there was a great effort devoted to the implementation and the oversight of the implementation. And for CMS to pull that off on a

national scale or even on a 10 MSA scale is a whole another question. So being reassured by a process of accreditation is potentially risky because you can have an accreditation standard but whether or not people adhere and continue to adhere, that's another issue.

The other thing which I have a big concern about which I don't believe it's been resolved is the whole question which is that Medicare does not know what DME it buys. You can tell me if this is wrong but products are put -- similar products are lumped into a single code and anything that qualifies under that code is paid the same. We had an example where there was a 1,700 percent variation in the retail prices of the items under a single code. Medicare was paying right in the middle. So depending on which item you supplied you either lost about 60 percent or you made about 1,000 percent.

So it's this question of with that kind of a situation and you competitively bid this, what do you expect to get? I can cut the price 50 percent and still make 400 percent. Or is that going to be the kind of situation where there's going to be continuing competition and we're going to get prices down to the right level? Or were there really

legitimate quality differences among those items and we really should be recognizing them?

Medicare needs to move to a better understanding of what it's buying. And part of that is just to know what it gets in terms of the products it purchases today. And it doesn't, because everything has been lumped under these single codes.

MS. BEHROOZI: Bob, you referred earlier to the monopsony power of Medicare as a purchaser and I think it's really a lock-in on DME, at least from the perspective of a private payer.

When it comes to labs and when it comes to imaging we have been able to be good purchasers and negotiate with groups that provide those services and do considerably better than the Medicare fee schedule. But when it comes to DME, it's a lock. It's the Medicare fee schedule or nothing.

I don't mean to be too provocative but it's right here in the paper that the industry representatives said that they'd be willing to come up with $6 billion to get rid of the bidding. So there's something that doesn't have anything to do with appropriate pricing going on here and I

think that it's kind of right out on the face of it. It's a real shame that the effort to introduce at least some of the good parts of the market while protecting access and predicting quality didn't go forward and the whole health care system is suffering for it, all the payers and certainly beneficiaries are suffering from it.

DR. KANE: I guess one comment I have is that a political strategy of going from 4,500 suppliers to 325 is guaranteed to be a failure. So I think maybe there are other ways to do this. For instance, could you use bidding to set the price rather than set the -- and I guess one question is how much were higher volume expectations bringing down those prices or not?

And then the next thought that came to mind in that regard was where in the distribution chain are the bidders coming from? Because you can have manufacturers, wholesalers and retailers. I guess are there economies of scale somewhere in that chain or not? And that's all related to do we need to restrict it to 325 or just set a price based on bidding, on competition, and leave it there so you're not disappointing 4,200 angry suppliers.

The other question I have is what role -- this is

the kind of -- can you just go to drugstore.com and order some of this? If so, there's a price right there. I don't want to advertise any one retail drug store over another but there are online prices. To what extent did they inform this process? Or are we just out there once again kind of hoping that these bidders will be real? To what extent are these bids being checked up against what you can get on drugstore.com?

MR. EBELER: A comment and a question. My comment sort of builds on Mitra's and your explanation of sort of the difference between the 26 percent and the 9.5 percent was helpful in terms of technical budget neutrality. It certainly suggests that there is several percentage points of payment on the table that one could look at, recognizing some of that may be volume. But there is still a pretty wide gap there.

My question is could you say a little more about what we know about the timing of the rollout of the updated process? You've got a little bit in here, but do we know anymore beyond this about when and how this is going to roll out?

MR. GLASS: It says the competition has to occur

for round one in 2009. It doesn't say when the results of that competition have to be put into the prices. In other words, if you did it right away in 2009, could you put the contracts in place by the end of 2009 possibly? Or the beginning of 2010?

So the beginning of 2010 would be -- putting the contracts in place by January 2010 would represent an 18 month delay. But if they can't do it that rapidly, then maybe it could be up to two years. And CMS has not said when they're going to start around 1.2, as they're calling it.

DR. MARK MILLER: I guess since we're kind of talking among ourselves up here, I wouldn't think that -- I think CMS is leaning forward to get back on track. But I don't think realistically they could have payments driven off of bids faster than say 2010.

MR. GLASS: Everyone seems to be talking about 18 to 24 month delay or something like that.

DR. MARK MILLER: Glenn's off-line comment was does the legislation require an 18-month delay?

MR. GLASS: It requires the competition occur for round one in 2009. That's all it requires. It doesn't say

when --

DR. MARK MILLER: It doesn't say 18 months.

MR. GLASS: It doesn't say that.

DR. MARK MILLER: I'm sorry, I interrupted you.

MR. EBELER: That's okay.

DR. CHERNEW: I just wanted to respond to Nancy. The thing about the bidding is you have to give people an incentive to bid low. So it's hard to set up a bidding system where you use the bidding to set prices if the people who bid high don't in some way get penalized for bidding high. So you need some bid design mechanism there. You might not have to punish them completely but you need some mechanism for giving people an incentive to bid low one way or another.

The question I was going to ask before Nancy's comment was it strikes me there's two somewhat separate issues. One of them is it strikes me that people understood that the payment schedule was too high or there was a feeling that the payment schedule was too high. Competitive bidding is but one way of dealing with that that has pros and cons. It strikes me that the pro is over time if you have that system it maintains its ability to work and maybe

it helps you fight fraud, although I can envision other ways of dealing with fraud apart from if having -- if that was your problem, you might find a different way of dealing with it.

And of course the bidding process, as was pointed out, has a number of problems in it in terms of potentially the stability of the market and who's in and things like this. And over time it might not always work as well as it did initially. So I think it's worth some thought about how to design either a better bidding system, if you think one needs a better bidding system, or just a better way of setting prices that may or may not rely on the bidding.

My inclination is part of that should involve the consumer of these services to shop a little more than we might enable them to shop in the 20 percent co-pay portion might not give people enough incentive to make the decisions on their own. But again, I haven't thought through how to design that system yet.

DR. REISCHAUER: It has always troubled me that Medicare bundles together sort of new procedures in hospitals or DME into these categories and has one price. I was wondering if we should enter that fray.

In the world of computerization having 5,000 items is not difficult. When Giant buys soup from Campbell, it doesn't pay one price for all soup. It pays Campbell differently for onion soup versus mushroom soup. Why Medicare can't enter that world, particularly in this area, I just can't understand. Because it isn't like these problems are often substitutable at all that are in the same category. They're similar in some respects but a brace for an arm or a brace for a leg, and you can't take one and put it on the other.

DR. BORMAN: First, I would support Mitra's comment that certainly, unless I'm missing something here, there's something fairly bald-faced in this that deserves address. And however we can get there is to the benefit of presumably our customers and the beneficiaries.

One thing I would ask is particularly as I look at a piece that was carved out of this, the negative wound pressure treatment devices, there certainly is room in here for comparative effectiveness to inform some of this conversation. There are certainly seemingly many more patients receiving that. Yet at least in my personal experiences it seems like there's very few people with open

wounds anymore who aren't getting one of these devices. And yet it appears that there were some wounds that healed before the advent of these devices. So it's certainly does raise some questions.

Another area that seems to me -- and Tom could probably speak better to -- is that there seem to be an ex-potential increasing number of people with diagnosed sleep disorders and on various oxygen and CPAP therapies, and things than seem to be warranted by guidelines and/or efficacy.

So just trying to weave some of our themes together, that if we need to re-examine this other than in a pure competitive bidding way, that perhaps some of the higher ticket items could be informed through the comparative effectiveness discussion and sort of move it away from the criticisms that were made in this particular process.

MR. HACKBARTH: Based on the comments, it seems like there are a number of different paths we might go down. One, of course, is just be silent and not take this up, not invest resources in it.

A second would be to reiterate our prior support

for the idea of competitive bidding, although I think that since it's been several years since MedPAC has looked at this I think that would entail our doing a pretty detailed review of the process and potential issues and how the process is run, and a fairly significant investment of time and effort.

A third possibility is to say well, the notion of competitive bidding is attractive for the reason that Mike mentioned, because it creates an ongoing dynamic that will tend to hold down payments over time. But there might be other bidding models different than the one used here that may be better, may provoke less political resistance, whatever.

And then the fourth path is to say well, maybe competitive that isn't the best approach at all. There are other ways to get equal or at least comparable savings that don't involve the process of competitive bidding.

I have heard some interest in each of those three paths, not much in favor of silence. So let's do a quick second round. Any reaction on which of these paths we ought to be focusing our effort on? And please keep your comment short because we are a little tight on time.

MR. GEORGE MILLER: Thank you, Mr. Chairman. I would echo and support what Mitra said concerning the fact that the industry spoke very loud and clear they would want to do away with it. As a result I think we should speak out, particularly if we're looking at the entire system of saving dollars. I'm not sure of the methodology but certainly we should speak very clearly that affording working savings with some type of methodology for choosing that is something this Commission should speak forcibly for.

DR. SCANLON: I think we should look at the issue of competitive bidding and seeing how we could make it work. And maybe an alternative model of competitive bidding is the right approach. Maybe there is this sort of unidentified other model out there besides competitive bidding.

In terms of both Mike and Nancy's comment about the retail prices, there were efforts to collect retail prices but the problem is that in a government program like this the standard for when you can change the price was so high that we never could get the retail prices to be used. There was a process called inherent reasonableness. I think over a period of I don't know how many years one price managed to be changed out of all the items that were there.

So the issue is if there's another method besides competitive bidding where the suppliers tell us something that they're willing to accept, I don't know what it is. But if it's out there that would be great, if it eliminated some of the difficulties we're going to have with competitive bidding. Because we're going to have difficulties with competitive bidding. It's not going to be a cakewalk.

I would echo Bob's comment. It would fulfill GAO's wish. We were making this recommendation over and over again, which is this is a world of computerization. People are putting universal product codes on their products already. And you're making them go and change those to HCPC codes in order to get paid. The Defense Department even uses the universal product code. So why can't CMS use it?

The response was always well, we'll have to set prices for every universal product code. No, you don't. You can start with the HCPC codes that you've got, have a mapping from the universal product codes to HCPC codes. And over time understand what you bought and refine your definition of products.

It's not something that should be so difficult to

overcome. And it would help the providers, as well because they're just needlessly having to create separate codes now.

DR. CROSSON: I guess to me the consideration in terms of whether we spend time on this is whether we actually have a customer for our work and whether CMS is, in fact, looking for options or is set on this course, which is to replicate the current idea and do it a couple of years later and the like.

I was attracted by Mike's idea that there may be a different way to do this. It seems like compared to some of the things that we deal with the idea of setting a benchmark price in this area at least intuitively shouldn't be that hard, if you can look on the Internet and find out what it costs. It's a lot easier to do than some of the other benchmark pricing processes that we deal with. And then if you could design sort of a benefit sharing relationship between the beneficiary and Medicare in terms of the beneficiary choosing the best value, you'd have a market-based system that might make sense.

Now I listened to Bill and he was explaining that that's not that easy. But to me if there is a customer for this and if there are some concepts maybe in the first round

set of analysis and discussion that have some viability, then I would be in favor of it. If in fact this course is set, CMS pretty much wants to do what they want to do or they feel that they've been directed to do something, then it may not be the highest priority.

MR. HACKBARTH: The question of what CMS's intent is, I think is complicated by the fact that there is an election on the horizon. Clearly the idea of using competition as a tool was a high priority for this administration and for the Republicans when they controlled the Congress. Whether it will continue to be a priority, I don't know. Certainly the election could influence that.

To me what makes me want to take this on in some fashion -- I don't know what the solution is -- is George's point that when there is such a seemingly egregious problem between what Medicare is paying hand and the generally available prices to just turn and walk away from it is troubling to me.

DR. CHERNEW: I was just going to respond to say that in some sense this is a bit of a sentinel issue independent of what we think is going to happen in DME per se, because this reflects a whole series of aspects of

payment and payment system and the way the system works.

And so I think that we need to address this issue not just in how we think DME should be paid, which is important, but how we think the process can be used. If we can't make competitive bidding or something like competitive bidding work for DME, that carves out a whole set of other approaches that just have to be off-limits where it's going to be harder. And that might be the lesson learned.

So for that reason I think we need to take it on. I do think it's actually worth some resources to understand the aspects of the merits of the arguments pro or con and to think about different ways of dealing with this. Certainly one of the ways that historically people have tried to deal with problems like this have been to contract out to other organizations. So you, Medicare, aren't setting the price for this particular product code but there's some other organization that is supplying a broad set of things that has an incentive that if they can get better prices from suppliers. So you could think of other ways to spread the risk or spread the cost of this high price, some of which could be the beneficiary, some of which could be some other organization. But someone should gather that rents from

being able to get a better price on this.

And we could think through that, and I think it's worth it not because it's so important for DME but I think it's worth it because I think the theme behind this transcends just DME. And DME has some properties that might make it -- this is going to come up for prescription drugs too, I think.

DR. DEAN: Just a question. First of all, I totally agree. My experience in listening to my patients is there is huge abuse in this area and a lot of things get supplied that never even get requested and so forth. So it definitely needs to be addressed.

Are there protections in the current program or the proposed approaches to make sure that we don't go overboard in the other direction? For instance, there are some of these services that are needed on a fairly urgent basis, especially oxygen. And right now, even though I live in a very isolated area, we have easy access to that.

I wonder, are there access provisions in the proposed or existing --

MR. GLASS: In the demonstration they found that access was not hurt at all or was not hurt significantly.

DR. DEAN: In the demonstration I don't think any of those were carried out in any rural areas was it?

MR. GLASS: No, this is only in MSAs.

DR. DEAN: That's what I thought.

MR. GLASS: And CMS was proposing to monitor access as time went on and bring in more people on contract if, in fact, any access problems arose.

MR. HACKBARTH: Quick comment, Bruce?

DR. STUART: Very quick. Do we know how the VA and DOD pay for DME?

MR. GLASS: We did look somewhat at how VA paid for oxygen and I'm trying to remember the answer to that. I can get back to you on it. I think it may have varied by which VA district you were in.

DR. STUART: It just might provide some useful context for this.

MR. HACKBARTH: So here's where I think we are. George and Mike have laid out important reasons not just to walk away from this. At the same time, I think we're very much open as to what the best approach is to pursue. So I think the task for you, Mark and David, is to help us structure a discussion next time we take this up about what

path or paths we wish to explore further.

DR. MARK MILLER: I've been thinking about this as it's been going along and we'll come back to you. I think what I'll have is two plans, a kind of light resources/heavy resources.

MR. HACKBARTH: Thank you, David.

Next up is public reporting of physician financial relationships, a topic that we discussed in our last cycle and there was quite a bit of interest expressed by commissioners in the topic and potentially moving towards recommendations on this issue.

So Ariel, when you're ready, you can go ahead.

MR. WINTER: Good afternoon. As Glenn said, I'll be discussing public reporting of physicians' financial relationships with drug and device manufacturers, hospitals, and ASCs.

Before I start I want to first thank Hannah Neprash and Jeff Stensland for their contributions to this work.

We discussed this topic at our March and April meetings, which led to a chapter in the June report. The chapter expressed the Commission's interest in public

reporting system. And our goal for the March report is to pick up where we left off and to move toward recommendations on this issue.

For today's presentation, I will start with physicians' financial relationships with drug and device manufacturers. We will review key findings from the June report and then outline a proposed framework for a public reporting system and highlight some key questions.

I will also discuss options for public reporting of physicians' financial relationships with hospitals and ambulatory surgical centers. We expect today's session to lead to draft recommendations, which we would present at a future meeting.

I'm going to start by summarizing some key points from the June report. Please bear with me if this seems very familiar to you. The first point is that financial relationships between physicians and drug and device manufacturers are pervasive. Here are some examples on the slide, which were also in the June report. A physician survey found that most physicians have interactions with drug manufacturers. According to a recent study, drug companies spent $7 billion on physician detailing, which

refers to visits from sales representatives to physicians, and provided free samples worth $18 billion in 2005.

The Association of American Medical Colleges has observed that "medical schools...have become increasingly dependent on industry support of their core education missions." In addition, device companies have financial ties to physicians related to product development, education, training, and research.

Relationships between physicians and manufactures have both benefits and risk. Physicians play and important role in developing new drugs and devices by running clinical trials and providing expert advice. In addition, marketing efforts directed at physicians may lead to greater use of beneficial treatments. But physician industry ties may also undermine physicians' independence and objectivity.

According to studies in this area, industry interactions are associated with more rapid prescribing of newer, more expensive drugs and requests to add drugs to hospital formularies. In addition, there's evidence that clinical research funded by manufactures is not always objective and publicly available.

The private sector and government have made

efforts in recent years to curb inappropriate relationships between physicians and manufacturers. Industry and physician groups have developed voluntary guidelines for these relationships. For example, the PhRMA guidelines limit gifts to physicians to those of an educational nature that are worth less than $100. The Office of Inspector General has issued guidance to help manufacturers comply with the anti-kickback law which prohibits companies from making payments to induce or reward the referral of items reimbursed by Federal health programs. But there's no mechanism to measure and enforce compliance with these guidelines.

There is also evidence that some inappropriate practices may still occur. For example, a recent physician survey found that some physicians were still receiving tickets to cultural and sporting events from drug manufacturers, which is a violation of industry and physician guidelines. Several academic medical centers and medical groups have adopted strict policies to limit physician interactions with the industry. For example, Stanford's Medical Center bans sales representatives from patient care areas and no longer accepts industry funding

for specific CME programs.

Five states and the District of Columbia require drug manufacturers to report payments they make to physicians and other health care providers but only one of these laws -- that of Massachusetts, which was just enacted -- also covers device companies. Most of these laws have significant weaknesses. The data collected are often incomplete and not easily accessible. For example, Minnesota is the only state to currently make public the names of physicians who receive payments but this information is not yet available in a searchable database. In addition, payment categories are vaguely defined which makes it difficult to analyze the data.

And option we discussed in the June report is to have the Federal government collect national data on physician industry relationships. Among the potential benefits of public reporting are that it could discourage inappropriate arrangements. The press and researchers could use the data to shed light on physician industry relationships and potential conflicts of interest. And payers and plans could use the data to examine whether physicians' practice patterns are influenced by their

relationships with the industry.

We also describe some concerns about a national database on physician industry relationships. There would be compliance costs for manufacturers. There would also be administrative costs for the government to implement and enforce the reporting law. Public reporting might discourage beneficial arrangements between physicians and industry. And public reporting would not eliminate conflicts of interest. However, it would help identify the prevalence of various arrangements and could lead to clearer and stronger ethics policies.

In our June report, we indicated that we would further explore key design questions for a public reporting system. How comprehensive should the system be? What size and types of relationships should be reported? And should a Federal law preempt state laws? In the next several slides, we propose a framework for a reporting system organized around these three questions. I'm also going to touch on a couple of other key design issues. At the end of the presentation we will seek your input on the approach we have laid out.

First, we'll explore how comprehensive the

reporting system should be. The first question is which types of manufacturers should be included? In our framework, we propose including manufactures of drugs, devices, and supplies and companies of all sizes, large and small, in order to achieve a level playing field.

The second question is whether payments to recipients other than physicians should be included? In our framework we propose including academic medical centers because they receive significant financial support for research and education from manufacturers. We also suggest including continuing medical education organizations because commercial support accounted for half of total CME revenue in 2006, $1.2 billion. We also propose including patient advocacy groups and physician membership organizations because they may receive grants from manufacturers for research and education. For example, Eli Lilly has begun public reporting its contributions to these groups on its website.

One of the key questions is whether companies should be allowed to withhold information that they deem to be proprietary? There's a trade-off between allowing manufacturers to protect sensitive information about product

development and the public's legitimate interest in learning about the industry's financial relationships.

The Vermont disclosure law permits companies to decimate information as "trade secrets" that is not publicly disclosed but this policy resulted in 72 percent of payments being withheld from disclosure in 2006 and 2007. One option for navigating this issue is to allow companies to delay reporting of payments to physicians that are related to the development of new products such as consulting agreements and the funding of clinical trials.

This delay could be tied to a point at which the development effort becomes publicly known. Clinical trials of drugs and devices become public when manufacturers register them on a website maintained by NIH. Under a law passed in 2007, companies are required to register phase II and phase III trials.

For other payments related to new product development such as consulting agreements, reporting could be linked to FDA approval of the product. Because the product may be under development for several years, you may want to consider setting a time limit such as two years, after which payments would have to be reported regardless of

FDA approval. In other words, reporting could be delayed until the earlier of FDA approval or a set number of years.

The next set of questions relate to the size and types of payment that should be reported. State laws have different thresholds for payments that must be reported to the state, ranging from $25 to $100. We propose that the lower end of this range be the threshold for reporting under a Federal system two reasons: first, this would enable collection of data on smaller gifts and meals. Second, two of the three states with higher thresholds, thresholds higher than $25, also have a ban on some types of payments which we're not proposing for a Federal law.

In addition, we would need to decide which types of payments or transfers of value should be reported. Our proposed framework includes a comprehensive list of payments and relationships, ranging from relatively common to less frequent interactions. They are listed on the slide here. Many of these categories are included in at least some existing state laws.

An important question here is whether companies should have to report free samples provided to physicians. On the one hand, this would increase compliance costs for

manufacturers. On the other hand, reporting of samples would provide a more complete picture of industry relationships with physicians. According to a survey conducted in 2003 and 2004, 78 percent of physicians received free drug samples in the last year. As we mentioned earlier, drug companies provided free samples worth $18 billion in 2005.

The third important design question is whether a Federal law should preempt state laws. The argument in favor of preemption is that it would reduce compliance costs for manufacturers because they would only have to comply by with one uniform Federal law rather than multiple state laws. In addition, a single source of information should reduce confusion among users.

An argument against preemption is based on respect for state autonomy and the potential for the Federal government to learn from state laws. A potential compromise would be to allow states to collect information that is not collected under a Federal law. In other words, a Federal law would a minimum floor. For example, if the Federal excluded reporting of free samples, state laws could require such reporting. But if states passed their own laws under

partial preemption, companies would have to comply with multiple requirements, thereby increasing their compliance costs.

Another significant design question is how to make the data easily accessible to the public. This is a relevant question given the difficulties of accessing data collected under state laws. First, it would be important to create an online database that is easy to search and download. Second, the payment category should be clearly defined and standardized so that information is consistently reported. And third, the database should allow users to search for payments by type, amount, physician, and manufacturer.

Finally, we consider some implementation issues. First, which agency should administer a reporting system? The Congress could choose to delegate responsibility to the Secretary and allow him or her to choose an agency. Possibilities include the FDA, because it regulates drugs and devices, or CMS because it pays for a significant number of these products. Both agencies, however, have severe funding and staffing constraints. A third option could be OIG because it has responsibility for investigating

financial relationships that may violate the anti-kickback statute.

Second, the administrative costs of implementing a reporting system are unclear. According to Minnesota, the cost of collecting the information from the industry and posting it on a website is minimal. But Minnesota's program does not yet have a searchable electronic database, which might increase the costs.

Further, we lack data on costs incurred by states to monitor and enforce compliance with the system. We may want to consider asking Congress to provide sufficient resources to the Secretary to administer a reporting law.

Now we'll turn our attention to reporting of physicians' relationships with hospitals and ASCs. The number of physician-owned specialty hospitals more than tripled from 2000 to 2008, from 46 to roughly 175. There were also an unknown number of general hospitals with some physician ownership. The number of Medicare certified ASCs, most of which have at least some physician ownership, grew by over 60 percent from 2000 to 2007, to almost 5,000 facilities. There has also been an increase in joint venture facilities owned by physicians and hospitals such as

imaging centers and cardiac catheterization labs.

The Commission has previously express concern that some of these types of relationships may be designed to increase volume of services without improving quality and coordination of care. Evidence from the studies of physician-owned hospitals suggest that physician ownership can affect the volume of services in a market.

Currently, it is difficult for payers and researchers to obtain information about these financial relationships. We said in the June report that collecting this information and making it available to the public would help payers and researchers examine how these financial ties might influence patient referrals, quality of care, and the cost of care.

Here we summarize the current rules on hospital disclosure of financial relationships with physicians. First, hospitals enrolling in Medicare must report individuals -- including physicians -- who own 5 percent or more of the hospital but these data are not publicly available.

CMS also requires hospitals to inform Medicare patients if they are physician owned but this information is

not provided to CMS or other payers or researchers.

Finally, CMS will be collecting detailed data on financial relationships from a sample of up to 500 hospitals in a survey called the Disclosure of Financial Relationships Report. Hospitals will be required to report information on physician ownership and other financial relationships, including the value of compensation arrangements.

Here we describe two options for CMS to collect data on physician/hospital relationships and to make it public available. Option one is to require all hospitals to provide information on all physician owners to CMS, which would post this information on a public website. Because CMS already collects data on individuals who own 5 percent or more of the hospital, the additional reporting burden for this option should be minimal.

Option two, which is more extensive, is to create a public database of information on other financial relationships between physicians and hospitals such as leases and joint ventures. Because of the need to balance transparency with limiting the administrative burden on hospitals, you would probably want to select only certain arrangements for reporting. Before deciding which

relationships to include, it may be prudent to wait for a review of the information that CMS will collect through the DFRR, which may shed light on the prevalence of various arrangements.

Here we describe the current rules on ASC disclosure of physician ownership. Just like hospitals, ASCs enrolling in Medicare must report individuals who own 5 percent or more of the ASC but these data are not publicly available. CMS has proposed requiring all ASCs to disclose physician ownership to Medicare patients but this information would not be provided to CMS. And finally, physician-owned ASCs that comply with an anti-kickback safe harbor must disclose their ownership to patients but not to CMS.

An option here would be to require that all ASCs report all physician owners to CMS, which would post this information on its website. Because CMS already collects data on physicians and other individuals who own 5 percent or more of an ASC, the additional reporting burden should be minimal.

So to conclude, we are seeking your guidance to help shape draft recommendations based on today's

presentation. Specifically, the proposed framework for public reporting of physician relationships with drug and device manufacturers and options for public reporting of physician relationships with hospitals and ASCs.

I'd be happy to answer any questions you might have about the presentation.

MR. HACKBARTH: Thank you. Let's just go down the row here.

DR. CHERNEW: I just have a quick clarification question about the 5 percent ownership in hospitals or ASCs. It was written as if an individual owns 5 percent. But I could envision certain types of administrative entities that could mask -- I don't own it. I own some part of some other practice or something, and that other practice entity owns some portion of it.

So I could see a scenario where you could get around those types of issues, and where actually you might feel like you had a strong financial incentive to do something but it didn't show up in entity and sort of complicated other arrangements that could get around those types of rules.

I was wondering if that came up and if you have

any thoughts on that issue?

MR. WINTER: That is a good point. I believe the enrollment form requests just the names of individuals. It might also request entities that own 5 percent or more, but I'd have to check that. It does require reporting of information about partners and things like that, so that might come. I will take another look at the form and see what it says but you do raise a good point about the broader issue, if you just require reporting of individual physicians will you then be missing out on other financial interests.

DR. CHERNEW: So I guess if there were 21 physicians that owned something evenly, if every single physician would own less than 5 percent, but it could still be very significant portion of that physician's -- because the thing would just be bigger.

MR. WINTER: Right now that would not show up. That would not be reported to CMS.

DR. CASTELLANOS: First of all, I think it's a good presentation and I think it's very apt to be -- we need to talk about this now.

I'm fully in favor of public disclosure. I think

we have two issues here. One is the relationship and one is financial interest. I think as far as the relationships, as far as that goes, we just need to be very consistent. We need a level playing field and we need to be comprehensive. I would hope that by -- what I'm saying by consistent is a lot of the medical specialty societies -- and I know the AMA has already gone on record on some of their recommendations. I would hope that when we make some recommendations that we're all together in the same field, at least on some of the issues or the small issues.

As far as financial interests, I'm for total transparency. I don't think it can work any other way. Both with the ASC, both at the specialty hospitals, joint ventures, employment contracts and the independent diagnostic treatment centers. I think we need full disclosure and transparency. It's not going to work any other way.

DR. CROSSON: I think I agree with Ron on that and I continue support this set of initiatives. There's a lot of things in here. I can't comment on all of the questions. I would comment on a couple. I do like the approach to dealing with the issue of the proprietary information

loophole. I think that's very well thought out and I would support that. It would seem to work very well.

One area I think that's the most complicated for me is the samples area. As we've dealt with various issues impacting drug costs and the practice of medicine that has been the most difficult one. The use of samples clearly has the intention and the effect of increasing the use of newer higher cost agents rather than older equally effective agents.

On the other hand, it's also helpful financially to beneficiaries and to non-Medicare patients. And in some certain cases it's helpful to certain physicians in the practice of medicine. For example, when we began looking at this issue some years ago we had a lot of complaints from our dermatologists who use tiny little tubes. And there are so many variations in the response of individuals to various dermatologic agents that it's easier, and in fact cost effective, to test little tiny amounts of multiple agents until you find out which one works. And the sampling process is one way of doing that.

Now eventually, we decided to dispense with that and actually, in our own organization, manufacture tiny

little tubes of stuff but I can't recommend that to everybody.

Having said all that, I would to come down I think again on the side of disclosure. One of the issues is the question of how much of a cost burden this would cause. When I asked folks in California, they well, none at all because California already requires the reporting of this information by -- I hope this is correct -- by the pharmaceutical companies with respect to the provision of samples. So one thing might be to find out if it's possible, whether that's accurate. I think it is. And in how many states that actually already is the case. So much additional burden would this be on the pharmaceutical companies?

In the end, probably the value of doing this would be longer term and that would be to help understand what the impact of the provision of samples is on Medicare costs and also increasingly now, with the doughnut hole, on the out-of-pocket costs to beneficiaries. We might learn something from this.

MR. WINTER: If I could just answer the question about which states require reporting of samples, of the five

states plus D.C., all of them except Massachusetts, I believe, specifically exclude samples from public reporting. Massachusetts' law, which was just enacted, is quite broad. There are no explicit exclusions. It says any fee, payments, or economic benefit provided to a physician must be reported. That remains to be seen how that's interpreted when the law is implemented, whether that is understood to include samples or not. So information on samples is not currently being reported by any state.

And our information is that California does not have a reporting law. I will double check on that but what we found is that they do require manufacturers to set I think a limit on aggregate payments to physicians in a single year. I'm looking at Hannah for confirmation and she's nodding her head, which is good.

DR. CROSSON: I'm sorry then, perhaps I was misinformed.

MR. WINTER: We will double check. That was just our understanding.

MR. GEORGE MILLER: Thank you, Mr. Chairman. I also want to echo that I think this is a very good report and I fully appreciate all of the work that went into the

report. I would just like to echo what was said earlier about the financial interest statement in this report. I think it's very important that we are totally and completely transparent, and that goes across the board in every area with full disclosure.

I also want to talk a little bit about the notion of a level playing field because, especially on the specialty hospital side, at least from what I read and what I know personally and anecdotally that the reason specialty hospitals come in existence particularly is because they deal with certain DRGs that pay better. You rarely see a group of physicians or others get together and start emergency rooms, as an example, to meet a need. It is very, very specific.

So I think full disclosure in some regards. I'm not sure if this goes far enough, but certainly full disclosure. And I would even suggest we make a recommendation that is any financial interest, not 5 percent but any financial interest.

Many of the ASCs and the surgical specialty hospitals have non-compete clauses in their agreements which means that they don't want someone to go out and then build

another facility close by and move that business. That's why they have non-compete. So again I'm very supportive of this report.

DR. MARK MILLER: Let me say something really quickly, since this has come up twice on the 5 percent. The 5 percent -- and Ariel, just make sure I'm right here -- anybody with 5 percent ownership, and I think it's predominantly individual, but 5 percent ownership in either hospital or ASC has to report that to CMS now. That information is not public.

Our point is as long as you're in there getting 5 percent, why don't you get any ownership -- and Mike has made a good point about individual versus others -- and make it public. So we're asking you to think about going below the 5 percent, not accepting it. And you're agreeing.

DR. SCANLON: I'd echo the support for this very strongly. I think we need incredible transparency here although I'm about now, in some ways, to contradict that by saying I worry a little bit about having a threshold that is too low and that we get too much information and the important information is lost. $25, I can't even fill my Prius anymore for $25.

So I would be interested in a threshold that is something of a cumulative payment for a period of time, a quarter or a year, and something more like $100. Because I don't want to have a ton of $25 payments and not see what the important ones are in that.

The second point is a question more, and that is sort of the issue of the ability of the Federal government to preempt state law in this area. We do have that thing called the Constitution, which leaves certain powers within the province of the states. And so the question is in this area would the Federal government actually be in a position to do that? Or would it have to be done with the carrot and stick approach which we use a lot, which is to say if you don't do it we're going to do X or Y? Or if you do do it, we will do X or Y.

We have ERISA, seems to be a clear preemption, but the circumstances of that may not apply in this case. So there's a question of we shouldn't go forward unless we know we have a reasonable legal basis for it.

DR. KANE: I'm a little concerned about the complexity of what's going to become the reporting requirement. I'm very supportive of the general idea and I

think the devil will be in the details. I'm just thinking about when you start looking down into who owns what, the whole opportunity to create shell organizations -- there's just going to be an enormous -- for those who really want to be deceptive -- and we've seen that happen before -- it's going to be really hard to figure who really owns that hospital if they have six different shell organizations which represent 100 different people.

So one of the things that came to mind is what kind of audit capability are we going to recommend here? Because if someone is honest, that we'll be fine. But the people who you most want to catch, like the guy at Harvard/Mass General, the psychotropic king for children, he just didn't tell the truth to Harvard or to Mass General.

And so I think you will get a lot of honest people out here and then the ones that you really want to catch, I'm not sure how you will catch them unless you come up with a way to audit that. And that really adds just an enormous amount of cost. So we need to think about either the audit capability or an enormous penalty if you do get caught not complying. And I think we need to talk about that somewhere and how we would deal with it.

The other piece is, being someone who deals with CME a lot in my own school, we are required at this point to disclose -- to get CME credits, you've got to disclose where you were born and who your mother is practically. So in fact, the CME organizations are trying to do disclosure, and that's actually part of being accredited to be CME.

I'm just thinking now our CME organization gets put in a public dataset for receiving money from Pfizer, who hands out money pretty regularly for public health issues.

Is the point there that you want Pfizer to stop supporting the public health CME? Or that you want people to -- I guess I'm saying where are you going with that? I guess we need to think more about what the goal is. I'm happy to dump Pfizer but then I don't know what that means financially or programmatically.

So if the goal is to ensure that physicians aren't being unduly influenced, knowing what goes to CME isn't going to do it for you I don't think. And some of these intermediate organizations, because you can't link it down to a physician and say that physician is changing their behavior because Pfizer supports the School of Public Health. It's just a harder linkage to make because there's

an intermediary organization there.

So if you really want to just say where are the financials where the physicians are being financially influenced, then I wouldn't broaden the reporting requirements to every intermediate organization that gets the money because you can't link it back down to the individual doctor very easily. So I'm just thinking of the complexity of this and how to maybe look for this to possibly simplify it for that value added that you might get out of it.

And it always does have to be offset by what you're going to discourage because I can tell you already that if people are worried about what it looks like to have Pfizer giving my school money and it's going to be public, they would probably say forget it, we don't want to do that. And there are some potential downsides to that.

I don't know, I think we need to disclosure but we need to think very carefully what's the goal and how do we narrow the weapon to hit the target rather than everybody who's ever received any money from a pharmaceutical company.

And then think about how do we audit that or penalize that the noncompliant or you'll get garbage

in/garbage out and you won't catch the people that you really want to.

MR. WINTER: Glenn, can I just give one point of information in response to Nancy's comments about the CME disclosure?

I mentioned Eli Lilly is putting on its website payments or grants to physician organizations, patient advocacy organizations. It also includes medical education grants under the context of CME. And 12 additional device and drug manufacturers said in a letter to Senator Grassley that they intended to do a similar type of disclosure on their own websites. So it wouldn't be one central database but on their own websites disclosing medical education grants.

DR. KANE: That's okay. I'm just saying if we said that this should be a Federal law that you do that, you're sort of implying that there is something bad going on there. And I guess there's a difference between that and Eli Lilly voluntarily doing that.

And I will say I know our organization is starting to sort of shy away from wanting to take anything. And is that what you want? We need to think about what we're

encouraging, as opposed to what we want to hit right on the nail head.

MR. BUTLER: I wasn't here when we did the report last year but I sense a lot of energy around this topic for sure, not just because it's important but I sense a legislative schedule, too, that if we're going to weigh in we probably would want to weigh in sooner rather than later on this one, from everything I understand.

The first comment, I'll try to stick with our ground rules. You've asked us so many questions to comment on so I'll try not to do it all.

Conflict of interest sometimes can be viewed two ways. One is there are a lot of good things that are going on, as Nancy said. But they ought to be disclosed. In fact, they're excellent things but they need to be disclosed so everybody's aware of them. The first is having conflict of interest in disclosures because you really don't think it's a good idea and you're trying to get rid of it or discourage it. And so I think we ought to think about some of these things in that light as we begin to categorize.

Even when you talk about the thresholds, $25, are we trying to just mask or get around a decision around say

drug samples or something like that rather than just coming out and saying is that a good idea or not? We ought to declare on some of the categories perhaps more directly rather than trying to finesse it through a dollar threshold.

Frankly, if you had it at zero, you might even relieve administrative burdens and do away with it altogether if that's what you want to do. So that's just a general comment.

We've got two different categories here, one is the drug and device relationships with physicians and then the second is the hospital/physician relationships. They're really quite different. They have some themes to them that are the same, though.

I would be definitely in favor of the Federal versus the state to the extent that you can do it. I would be in favor of going beyond individual physicians to physician organizations and academic medical centers. I guess I would caution a little bit on the reporting side, being at an academic medical center. Sometimes what a device company may categorize in their books as a certain item could be categorized as something quite different in our book. So how do define those things is not -- what one

person calls a research grant somebody else may call something else. So there are some definitional things to work through that I think are important if it's going to be publicly disclosed.

On the hospital side, too, I think that we need to be broader than just the option one, which is -- you posed two options. We need to be broader. It does give me a bit of a headache to think about reporting everything under the sun. Administratively that would be difficult and probably inappropriate. I don't know that you need to know the rent that physicians pay in physician office buildings. That's subject to other fair market test as it is now, so you don't have to disclose those things as I wouldn't think. Nevertheless, it ought to be broader than is proposed under option one.

Here I think there's a principle that's important though, and that is I think it should be used more for the screenings of the patterns of behavior in order that we can develop better policies as opposed to a database that can go after specific compliance issues where I gotcha on this particular physician or something. So I think it's more of a filter or a screening to determine where we ought to

direct our attention versus the database where we're going to find the bad actors. I think that should be done in a different way.

MS. BEHROOZI: To quote Mark, "I'm really excited." The ball is really rolling here.

MR. EBELER: You said that too enthusiastically.

MS. BEHROOZI: I'm sorry, I tried.

I think you're right that time is of the essence because so much is happening around this now. Because the more evidence that comes out -- no, the more data that comes out, rather, the more you can link it to evidence of -- not in all cases by any means. But in cases where it ought not to happen that there is improper influence of prescribing patterns or treatment patterns or whatever.

Existing, as I do, in an environment where we are required to pretty much report everything, we just are used to it. You just report everything. You take that side of your general ledger or whatever, all the payments out, and you report them everywhere you're supposed to report them and let other people do with them what they may. And unfortunately, given some people's feelings about the labor movement, they don't do very nice things with it but we've

been living with that for a long time. And it has created some good things for the labor movement.

So whether it's something that might be characterized frankly by the industry -- I'm sorry, I'm violating the rule and responding. So there's so many points.

Just in terms of broad reporting, there may be cases in which the industry or the recipients would say this is a good thing. We appreciate that Pfizer is supporting the School of Public Health. Pfizer wants to advertise that it's supporting the School of Public Health. But it's done in a very random individual sort of spun way rather than all of it being accessible in one place, not only reported by publicly accessible. And I think it's a very important part of all of the recommendations, that all of the information be publicly accessible and in an easy format. It's not that hard to do anymore on the Internet. Definitely, in terms of the trade secrets exemption that can swallow the rule, that clearly seems the wrong way to go.

In terms of clinical trials -- I don't know, this might be a dumb suggestion -- not only in terms of timing but is it worth it to just report the fact that a company is

paying somebody to do a clinical trial without identifying the substance of the trial, at least up to that point where the substance of it needs to be reported elsewhere. Because then that gives other people an incentive to say hey, hasn't two past? Or shouldn't it be in phase II by now, to seek the underlying information about it.

On the question, though, of samples. Having said kind of the same things I've been saying before, supporting the broadest kind of disclosure, in terms of the value of the information for drug companies to report every sample they give to every individual doc, if we're concerned about the influence on prescribing patterns, it's a different kind of influence than giving somebody, for example, baseball tickets or paying them a third as much again as their salary to make them feel good about a particular drug company or look at that drug company through a certain lens.

Jay, I think you said it that patients also like the idea of free samples. If you list all the docs getting free samples from certain drug companies, that might drive business their way because want to go there to get those free samples.

It's not quite -- it seems to me, in the same

nature as the other kinds of influence. And I wonder what information would be of the most value. Maybe reporting that geographically or something like that. It's almost more like direct to consumer advertising where maybe a market is influenced. Although if people have looked at it and found that it's useful to report it on a physician level basis I'm certainly not against it. But I just wonder if it's worth thinking about whether it's different.

DR. REISCHAUER: I think this work is moving forward very well and I agree with lots of the comments, as will be obvious. I'm for broad inclusiveness in this, in general. I wonder if we need something about journals, newsletters, et cetera, that food group.

I'm not that much in favor of letting them withhold information that's deemed by them to be proprietary. That strikes me as a loophole which you could drive an aircraft carrier through. And better to be nonspecific about what the purpose of the grant was then to not disclose it for a few years. So I would come out there.

I'm with Bill on the threshold. I would be for an annual amount and it would be fairly high, $100, $200 even. And I would make sure it was indexed because these things

have a way of getting to be totally irrelevant after a few years.

But I think we demean lots of professions to think that they're going to be influenced by a hamburger and a free pen.

I wasn't clear, are we making the receiver and the giver both provide the information?

MR. WINTER: Just the provider, just the manufacturer in the case of the drug and device manufacturers.

DR. REISCHAUER: With respect to the free samples, the world is changing now and more people are under formularies. And the importance of this -- and there's more of the PDP calling back and saying I'd like to substitute this for that. And so I think some of the concern about this, which I think was serious and very legitimate a decade ago, is less serious now. And we should weigh that because there are advantages, as others pointed out, to not having to report the free samples.

With respect to preempting state law, Bill I think is right. But I also wouldn't worry tremendously about this because my guess is the states will get out of this business

if there is an adequate Federal law and there will be a lot of pressure from provider groups and from giver groups to say look, the Federal law is enough. So I wouldn't waste a lot of time worrying about which way we came out on that one.

DR. MILSTEIN: I also agree with this being a useful area of policy development and there have already been a number of comments on what are some of the key planning variables that you want to take into account. I agree with most of the comments. A couple of others that I would like to throw into the mix, not because I know in advance that they are feasible but just because I think it would be valuable to have staff look into the feasibility of it and give us some feedback, would be opportunities to increase the specificity of what's disclosed.

What I refer to as -- for some of these categories it might be more informative not only to disclose that certain financial interests are at stake, but that relative to peers in the same community there's disproportionate use of a facility in which one has a financial interest. I think that might be a little bit more specific to what it is that we are trying to capture and induce provider reflection

on.

And then the second variable that I think would be -- at least I would value some staff feedback on feasibility -- is the variable of salience of what is disclosed to beneficiaries for whom these services are being ordered. For example, I think if I were a Medicare beneficiary about to have a nonemergency hip replacement I would like to know without having to go to the Internet if I was not Internet savvy as to whether or not the proposed artificial joint that was being prescribed for me was one in which the surgeon had a financial beneficial interest in. So that would be another dimension in terms of recommendation. If you could explore the feasibility of it I think I would at least find it very valuable.

DR. BORMAN: This is really nice work and I think it really has crystallized the questions. I may wander down a slightly different path than many of your all's commentaries I think, however. First, let me say on a personal basis, I think total transparency, complete disclosure, how can we be against that? I think maybe we need to look at this -- and Nancy brought up a little bit, what's our goal and where are we trying to get to?

Frankly, I think the biggest thing that can come out of this is affecting people at the margin. There's three groups of folks here. There's people who aren't creating issues in the way that they do this. Whatever conflicts or potential conflicts they have, they're managing them appropriately. And that's the kind of professionalism that we hope would be 100 percent and that we're all saddened to say may not be 100 percent.

For that group of people, we want to make this not difficult to them. We don't want to make life harder for them. And I think that's really important here because we can get wrapped around the axle on a lot of details here. I think we want to keep in mind that there's a large volume of people here that are behaving appropriately and the first thing we want to do is do no harm.

There's a group of people who are doing very bad things. Hopefully, a very small group, but a group of folks who are doing very bad things. They are very creative people. The six shell corporations, I'm not sure I could have articulated but they're very bad people. And I'm not sure that we can come up with a sequence of recommendations or things that clearly will capture all those people. We

may need to expose them to the light of day best that we can and then figure out what to do about them.

Then there's people in the margin that maybe are skating on some thin ice, that maybe are doing some things that maybe they haven't totally thought through and that when forced to or when somebody reports here's this relationship, the sum total of that will cause them to stop back. Just the sheer publicity that has surrounded this in both professional and lay press may, in fact, be modifying some behavior. And that's probably where this process can have some impact.

But I would worry very much about our ability to hurt the great majority of people and companies and things that are doing good. The suggestion or the example that Nancy offered about CME sponsorship. I personally encounter in a number of organizations in which I'm involved the increasing difficulty of getting support for good reasons. The bureaucracy to get through at a given company to get $1,000 to support residents getting a text, a trip to a simulation center, or whatever, has become quite incredible. And to some degree we are penalizing -- we are hurting some things that maybe we'd like to support.

So I would just ask that let's try and make this not too complicated and at least foster the ability of the good to continue.

DR. DEAN: I think Karen probably characterized it extremely well. Obviously, I totally support the direction or the activity. But I think your characterization of it is important. And we want not to lose sight of why are we concerned about this in the first place, and that there is some bad behavior out there. But hopefully it's limited to a relatively small proportion of the profession and we need to get to that rather than making it difficult for everybody.

With that in mind, I think that argues for raising the amount or the value of the relationship that we're going to try and look at. So I agree with Bill and whoever else has said it, that the $25 level I think is way low.

Secondly, the samples issue is a complicated one but my inclination would be not to include samples at this time for a whole lot of different reasons, even though there are lots of concerns about that. But for the most part, physicians don't benefit from the availability of samples. In fact, it may complicate our lives for some of us. So I

would tend to leave that out.

But it's a concern. There's a very interesting article I've got in front of me that just came out in the Annals of Internal Medicine that demonstrates the extent to which some of these companies will go. This is an article about how one manufacturer set up, ran, and completed a full clinical trial of a new drug that was timed to be released -- - the clinical trial was designed to be released at the same time the drug was released. And instead of involving just a few researchers that would have been far and away the most efficient and effective way to run the trial, they involved several hundred community physicians and labeled them as investigators. The whole purpose of the thing was to introduce them to this new drug. The purpose was totally withheld from the participants all the way around and only came out in a subsequent lawsuit.

And even to go farther, the physician that ended up as the lead author of the paper that appeared in the Annals of Internal Medicine -- which is a highly respected journal -- did not even participate in the trial and didn't know anything about it until after it had been completed. The company had written the paper and he was asked if he

would like to have his name put on it, which he did -- which I think is highly questionable.

In any case, it's incredible how far these efforts and how extensive some of these efforts of promotion are. So anyway, whatever that's worth.

MR. EBELER: Ariel, in the paper you mentioned some research that looks at the impact of some of these relationships. And I think Karen has raised a good point. There is different relationships here. You don't want to affect the vast majority of folks who are doing the well-intended thing.

But my understanding of the research over time is that the relationships that do occur, the provision of samples and everything else, does trigger at the margin changes in behavior. Different prescribing practices, lower use of generics and things like that.

MR. WINTER: Right, that's an accurate summary of the research. These were studies that were been done in 1980s and 1990s so there's not been a lot of stuff done since then. But there's a pretty comprehensive literature review published in 2000 which found that interactions with the industries associated with more rapid prescribing of

newer drugs, less prescribing of generics, and those sorts of things.

MR. EBELER: There's no implication of that of sort of a bad actor. It's just over the course of time people change -- at the margin change their behavior.

MR. WINTER: [Nodding affirmatively].

MR. HACKBARTH: Let me make a few quick comments on the discussion to this point. Almost all commissioners have spoken and clearly there is enthusiasm for taking up this issue.

There are so many questions here that were laid out in the presentation. We sort of jumped around, as Peter pointed out. Different people have taken up different questions. So it's a little bit difficult to make too much of that piece of it. I do hear a theme, at least among some commissioners -- and I share this so I'm highlighting it -- about carefully weighing the risks and benefits of this. I, too, think transparency is a good thing. But even good things can have unintended consequences. And so I think as we go through the individual issues and subsequent conversations, we do need to take due care that we structure things so that we try to minimize, at least, unintended

consequences.

I expect the next step here is to sort of systematically march through the issues that you laid out in your overview presentation and we'll do that at the next meeting. I'm not prepared, at least, to try to summarize where we are on any of those at this point in time.

I have for people who wanted to make a second comment and then we will be out of time. And I'd ask those four to please keep it brief because we're already about five minutes over. I have Mike, Jay, Ron and Mitra.

DR. CHERNEW: I would just encourage some thought to thinking about which activities should be disclosed by whom. So in some cases, like ownership of a hospital or something like that, it strikes me that that should be disclosed by the physician. And the threshold should be -- maybe it's just the warm glow of us filling out these sheets. It should be a threshold based on is it significant in terms of your income, not significant in terms of the percent ownership of some facility that you have.

Whereas other things, the trial story, for example. That strikes me that you could have never expected the individual physicians to deal with. They didn't know

one way or another. So that has to fall in a different organization.

So I just think there needs to be some nuances to the different activities that are going on and what organization or individual needs to disclose them and what makes sense to them.

DR. CROSSON: Just to return for a brief moment to the sampling question, because I reflected, Ariel, after your comment about what, in fact, I had heard. And I believe I misspoke when I said I thought that California required reporting. I think what I was actually told was that the pharmaceutical companies were required to account for the provision of drugs, including samples, when they were provided to physicians.

So it might be -- in assessing the impact it might be useful if you can to check on that also, whether that is either an internal issue for the companies or, in some cases, a state requirement, accounting and not reporting. Because obviously if the accounting is going on then the reporting becomes much simpler.

DR. CASTELLANOS: Again, when it comes to time limits I don't think we can drill done on anything

significant. I think we'll all have the opportunities later on to drill down.

Just three things, and really what Tom and Karen has said, you don't want to throw the baby out with the bathwater. And Karen's point about doing no harm is really important.

The only other question, and maybe it's throwing something into the mix that we don't want to do, but last year when we discussed this we talked about direct to consumer advertising. I noticed there was an absence of this. Is this something we don't want to deal with with this topic? I know we dealt with it last year with this topic.

DR. MARK MILLER: There was no intent to leave it out. We are trying to structure kind of a transparency policy here on the physician ownership and then the drugs and devices. And we just hadn't kind of got our arms around -- you know, this is kind of a divide it into. So we haven't said that DTC is off the table. But we felt like we could kind of head towards recommendations on disclosure policies here in sort of a coherent way and DTC is coming up later.

MS. BEHROOZI: I guess it's in response to a number of people who have talked about not throwing the baby out with the bath water or doing harm. It's not all about gotcha. It's not all about pointing out the bad people doing the bad things or even some people in the middle who might not realize they're doing bad things. One of the purposes -- I was actually trying to find it in the slides -- is just for researchers to examine the impact of payments. Maybe it's something that explains a lot of this geographic variation that we're looking at and leads MedPAC or any other agency to come up with policy recommendations that aren't about saying these physicians are doing bad things or these medical schools or whatever are doing bad things.

But there's restrictions on advertising for whatever, alcohol and things like that, for those reasons. Maybe there are other policy things that we would do in connection with influence that we see through these patterns of payments.

I think that selectivity in deciding what needs to be reported, the more selectivity not only makes it more burdensome and confusing and eludable, but also enhances the notion that these are the bad things. These are the shady

things. And the more you make it across the board, the less it is about targeting anyone as a bad actor and makes it easier to comply with.

MR. HACKBARTH: All right, thank you. We look forward to more on this.

Our last session for today, or at least before the public comment period, is on beneficiary-centered assignment. This is under the Part D low-income subsidy. We have a guest, a familiar guest. Welcome, Jack.

DR. SOKOLOVSKY: Before I introduce somebody who needs no introduction, let me just set the context for this work. As I'm sure most of you know, when the Medicare drug benefit was implemented in 2006 Medicaid beneficiaries who were dually eligible for Medicaid and Medicare switched getting their drug benefits from Medicaid to Medicare. And those beneficiaries who did not choose a plan of their own were randomly assigned to plans that met a low income threshold in each region.

In subsequent years, many beneficiaries have been reassigned to plans when the plans that they were already in, when the premiums in that plan no longer fell at or below that regional threshold.

In earlier years, and I believe it was Nancy who first started this line of research, she suggested that maybe randomly assigning people on the basis of their premium was perhaps not the best way to go for the beneficiary and also for the government. And so in our first attempt at looking at this, we looked at the feasibility of assigning beneficiaries to plans that best covered the drugs that they were already taking so that although they would be reassigned, the disruption would be less. And we also looked to see whether, in fact, it made any difference.

We found that it was feasible, that some states were doing it. And we also found that on a drug by drug basis there was a considerable range of costs for particular drugs. And so many of you said well, but these beneficiaries don't take one drug. What happens when you look at the whole regimen of drugs that they're taking? Does this disparity continue? Or is it kind of washed out, one drug is cheaper in one plan but another drug is cheaper in another plan?

So our team of researchers from Georgetown University and NORC at the University of Chicago have looked

at this issue and Jack is going to present the results here.

DR. HOADLEY: Thank you, Joan. I'm glad to be back here again to talk about this issue.

Joan has mentioned the basic situation that this is in, which is what I've got on the first slide here. I just really will make two points on this. One is that in the very first year of the benefit there were certain reasons why CMS particularly was interested in doing random assignment. They wanted to avoid steering beneficiaries into any particular plan. And they also thought that random assignment would have some value in stabilizing the market because all of the qualifying plans would be guaranteed a certain share of beneficiaries in that first year.

The other point I want to make is that it sort of feels like if you don't know all of the specifics about how this goes on, why is this an issue on an ongoing basis? There are not that many new beneficiaries in any given year. But as John mentioned, as plans come and go from meeting the threshold for qualifying for the assignment of low-income beneficiaries and beneficiaries not having to pay a premium, there can be quite a few beneficiaries who need to go into a new plan in order to maintain that status. In fact, 2

million, roughly, had to be reassigned for 2008. So this does become an ongoing issue and there are new rules going into effect for next year that further change how this is done.

As Joan mentioned, our previous report did look at this, was a limited look looking at one drug at a time. In the process of that, we defined this concept of beneficiary-centered assignment as any kind of method of trying to assign beneficiaries to a plan that provides, in some sense, a good match with the current drugs they use. I will talk about a couple of specific ways of implementing that in a minute.

Our previous study did show that it appeared that you could design a system of beneficiary assignment to reduce the out-of-pocket costs that beneficiaries pay, potentially to reduce the need they have to use drugs or for their current drugs anyway to be off formulary or to have utilization management requirements. We thought possibly you could design beneficiary-centered assignment to at least avoid adding Federal program cost if not potentially to save.

So as Joan said, we wanted to go forward and try

and talk about this in a broader way instead of looking at one drug at a time, to really look at what a real person would look like. So our key questions were do the results change when considering larger portfolios of drugs? Do the results change when considering all of the costs, premiums, deductibles, and copays? Previously we just looked at the co-pays for particular drugs. What benefit of beneficiary assignment might work best when you take into account both beneficiary and government costs? How do the costs for both the beneficiary and the government compare to what we're doing now under random assignment?

And finally, what would happen if you allowed beneficiaries to be assigned to enhanced plans? I will talk more about that near the end, but basically the kinds of plans that have some benefits beyond the basic benefit.

I won't say much here about the methodology. I can respond to questions on it. But basically we looked at five regions. We're looking at 2008 plan structures and specific cost of those plans in 2008. We created 10 sample beneficiaries using 2004 MCBS data. Our idea was we wanted some people with some complexity. So in the end we wanted people who qualified for the low-income subsidy and we ended

up with all 10 of our sample folks using at least four drugs. So it's important to emphasize they're not representative because obviously there are a lot of beneficiaries who don't use that many drugs. But the whole point was to show what happens when you have more complicated patients.

The first answer really is that yes, plan assignment does matter. If you look here at our 10 beneficiaries and you look at Jason down on the bottom, for him it doesn't matter that much. His out-of-pocket costs are only $3 different whether he's in any of the 12 plans in the New York region. The government's costs are equivalently not very different. There's $130 or so difference.

But for most of the other beneficiaries the differences are more extreme. The two I've highlighted in red -- although it looks orange up there -- show you really the most extreme variation. So for Betty, her costs can vary from just under $200 to over $3,000 out of pocket cost depending on which plan she's assigned to. And again assuming she continues to use her current drugs.

Ellen, similarly even worse, $160 to over $6,000

in costs. You can look at the government side of this, you see similar contrast for what the government is picking up, depending on the cost.

What drives these differences? The major factor is what drugs are off formulary for a particular plan. So as soon as the drug goes off formulary -- again for the moment assuming the person continues to take that drug -- they then are responsible for the entire cost of paying for that drug. The government does not pick up the cost of an off-formulary drug. So basically the government does better when there are more drugs off formulary for a particular plan assignment and the beneficiary does worse.

What can the beneficiary do? Of course, there are options. They can substitute a different drug with the help with their physician. In many cases that may totally appropriate. In some cases, that may not be clinically appropriate.

They can request an exception. That's not always an easy step. We've heard in focus groups that it doesn't happen very often and neither physicians nor beneficiaries tend to like to do that.

They can pay the full cost out of pocket with no

government subsidy if they can afford to do so.

They can simply skip taking the drug with whatever consequences. For some drugs that may be minor. For some it may be serious.

Or they can take advantage of their options that other beneficiaries don't have of switching plans, even in the middle of the year.

I would also note that plan premiums really weren't what's driving the difference. It really is the cost of the drugs and the off-formulary drugs. Premiums are a small factor but not a very significant one.

So our goal in looking at some different ways to implement beneficiary assignment is to see if we can reduce the beneficiaries' cost, as well as the hassle that they face if they have current drugs that are not on formulary and they need to either consider switches or exceptions while trying to keep the government's costs as low as possible. So we devised three rules by which we can to beneficiary assignment.

The first one is the simplest, find the plan that has the lowest cost for the beneficiary under the LIS rule. That's basically what the beneficiary would be doing if they

used the plan finder and picked a plan using the plan finder.

But as you will see, there are some reasons why these may not turn out to be the best ways to do it. So we tried a couple of alternatives. Rule two simply tries to minimize the number of drugs that are off formulary since that is the biggest driving factor in figuring out where plans become more expensive.

Rule three then is trying to minimize the total cost paid by the beneficiary or paid on behalf of the beneficiary, regardless of whether it's a beneficiary cost or a cost that the government is picking up for it. This is really like the plan that the beneficiary, if they weren't subsidized, would be picking using the plan fighter. We thought maybe that was the cheapest overall and perhaps that would be the best balance of minimizing costs for beneficiary and for government.

So what happens? Here we picked one of our beneficiaries, and this is Ellen who -- as you remember from the other graph -- was one of the more expensive ones. She uses a lot of different drugs. I think she uses about eight or nine drugs total. You can see that like the first

example, her costs can vary quite a bit from a little over $1,000 to over $6,000 across these nine plans.

We sort of used the median total beneficiary cost as our way of replicating a random selection. So randomly she gets put in plan G. But that means her costs were $3,000, the government's costs were $3,500. And you can see there that there are some potentially better choices for both her and the government, thought of together.

But as you also see there, it's kind of hard to figure out if you just looked at this and said what's the best balance to put her in, it's not obvious.

You will see here that under the three different rules we get three different assignments for Ellen. Rule one, which puts her in plan D, puts her in the plan that has her very lowest costs but you could increase her costs just a little bit under rule three by about $60 and lower the government's costs by about, $6. Is that a trade-off we would be willing to take as a policy option? Under rule two, which has the fewest drugs off formulary in this case, it doesn't seem to do very well because it adds $1,100 to her costs while essentially not changing the government costs.

Of course, this is one person's example and everyone looks different. But you can see from this the complexity of trying to balance off different aspects of government and beneficiary costs.

So here we take our 10 beneficiaries in our five regions and simply average across them. Again, I want to emphasize this is not intended to be representative or what this would look like in the scoring, because if you were scoring this you would have to look at the real distribution of beneficiaries and lots of other things like that.

But what this does illustrate at least is the potential for how you can improve things. So on the left hand is the random assignment -- again we used a proxy of median spending. In this case, because we wanted to actually put somebody in a real plan rather than use some kind of calculation here. But all of the rules, one, two and three, did better for the beneficiary than the random assignment by quite a bit. It was almost $700 cost for the beneficiary in the random assignment on average across our 10 beneficiaries in five regions. But between $200 under rules one and two and then as much as $400 under rule three.

So the beneficiary does better with each of these

rules but does the best, by definition, under the plan that minimizes beneficiary cost. Rule two tends to add about $41 on average for the beneficiary in order to obtain $150 savings for the government. Is it a good trade off to make? Are we willing to add a bit of extra cost to the beneficiary to make the government's costs come down? That's a policy option.

Rule three does bring the government's cost down further but starts to put the beneficiary's increased costs up to the point that it's going to be a little bit more noticeable. It goes up almost $200 from rule one. So in my mind, at least, that's a harder option to take but again it's another potential trade-off.

So what happens if you were to allow this additional option of enhanced plans? Again, remember that an enhanced plan is one that starts from the basic benefit and adds something to it, whether it's gap coverage, what it's taking away the deductible, whether it's lowering the copays but something that adds some value. And so any beneficiary who is making the choice for themselves without being a subsidized beneficiary may pick an enhanced plan because for their particular situation the extra premium is

worth it to acquire the extra value.

So we wanted to see if that could be true. And we restricted this because again part of the whole system of low-income benchmarks is to give plans some incentive to keep their premiums low. So we said we're only going to pick enhanced plans that have their premium for the basic portion of their benefit below the benchmark. But we would allow the government to buy the enhanced plan, paying the extra premium, if it turned out that that created some savings for both the beneficiary and the government.

On this averaging across again our 10 beneficiaries in five regions, it seems to do that. So under rule one, if you add in the enhanced plans, you get about a $50 or $60 savings for the beneficiary and a bit of savings -- about $30 or $40 just for the government. But both entities create some savings.

Under rule two it's similar, about $30 savings for the beneficiary and a little over $100 savings on average for the government. Again, this would have to be tested with a wider range and a real scoring but it does suggest at least the possibility that allowing the government to buy into some of the enhanced plans, getting that extra enhanced

value that those plans come with could end up saving both the beneficiary and the government some money.

So concluding this, we do see that beneficiaries seem to gain access to some or all of their currently used drugs with less hassle and lower cost using beneficiary assignment as opposed to what they're getting through random assignment where they've got the possibility of ending up in a plan that's good for them but they have the possibility of ending up in a plan that's really very much a poor risk for them. The government might experience at most a small cost increase compared to random assignment. Again, that needs to be further tested in a full scoring sense.

We also took note, in comparing the regions, although I didn't present this detail, that in the regions with fewer qualifying plans you often had a bigger swing. And so there was the potential for even more value there. And as benchmarks and potentially a shrinking of the market, this could be a more common situation. So at least the data suggest that despite possibly a little bit of extra government cost beneficiaries assignment could become a rational approach to improve access and reduce cost and that uncertainty for low-income beneficiaries.

And then what we'd need to know from here to further understand this, there are certain things we can't get by just doing these kind of simulations off of sample beneficiaries. And eventually, as drug claims really are available to folks, and possibly with some other data, we would like to be able to answer questions such as what do beneficiaries really do when they hit an off-formulary drug? Do they, in fact, switch to a different drug? Do they request exceptions? Do they pay out of pocket? Are any low-income folks really paying those extra costs out of pocket? We certainly think some non-low-income people do with people with limited resources may not. Do they stop taking the drug? There's certainly some reason to suspect that that may be happening. And how often do they, in fact, switch plans? Are they already assigning themselves to a more suitable plan on their own without the help of an assignment program?

With that, I'll take any questions.

DR. STUART: I have a question and an observation and a comment. Let me start with the observation first. This market in which plans are competing with each other based upon what they can offer to beneficiaries is driven,

in large part, by the assumption of formulary compliance. And by that I mean if the plan is going to get the best price from the drug company for having their particular product on the formulary, they are only going to be able to do that if they can, in some way, enforce utilization of that drug.

Now enforce is not a legal term here, it's an economic term. So I think you want to think about how the market works when you think about the implications for the research that you're involved in here.

Now the second thing, and this is an observation as well, it seems clear for this population that switching to a covered drug, if they stay in that particular plan, is more than likely to be the action that's taken here, particularly when you're dealing with the numbers of the magnitude that you're looking at here. People who are on LIS are not going to be paying $6,000, so they really are forced to switch and to stay on the formulary drug, as long as they are the ones that have to pay it, which is my third point.

And I don't how this works. I know that Medicaid and State Pharmacy Assistance Programs under certain

circumstances can cover drugs that are not covered under the Part D plans, and I'm not sure how this actually works in practice now. But to the extent that a low income beneficiary who was Medicaid eligible lived in a state that would provide some kind of wraparound coverage then it might be Medicaid or the state assistance program that actually is the one that was bearing the economic burden if the individual doesn't switch to a covered product.

DR. HOADLEY: My understanding is in the case of Medicaid few states are picking up off-formulary drugs as part of their Medicaid. They may be picking up some of the excluded drugs, the benzodiazepine barbiturates, that Part D simply doesn't cover at all although they will start in a few years.

The State Pharmacy Assistance Programs, however, in some cases -- and of course, they only exist in a subset of states -- some of them would be helping to pick up off-formulary drugs. So certainly that's an additional complexity that's going on in those kinds of things.

I think your general point about where the incentives are when they're off-formulary it seems like you're probably right, and most people are getting

themselves switched or doing without. Embedded within this is also some cost differences having to do with high-tier and low-tier drugs where the low-income person gets no financial difference. They're paying the same, for any branded drug, paying the same copay and the government is picking up the difference. So that's a part of it, although it's the off-formulary drugs that our data suggest is really what's driving these kinds of larger differences.

DR. CHERNEW: That was really fascinating and an area close to my heart. I had a few loose questions that may end up being research things.

The first one is I have mixed feelings about this based on whether I think the formulary restrictions are good or bad. I spend a lot of time awake at night worrying that the person is not going to take the medication and won't switch and it will be a medication that's really important. And I really would like it to be the case that if there was a medication that was really inefficient, that you could get the person to switch to the much more efficient medication and it's very hard to tell which is true.

So understanding something about the clinical nuance of what types of drugs these are and what the likely

outcomes would be is fundamental to understanding whether this is good or bad because I wouldn't want to get into a situation where we were assigning people to drugs that allowed them to continue inefficient and perhaps harmful drug consuming behaviors. But I also wouldn't want to assign them to a plan which because of its structure discouraged them from taking clinically appropriate potentially life-saving medications. And those two things both might be going on here and that matters a lot.

The second point I want to make relates to this enhanced plan thing. When the beneficiary and the government benefits I think what has to happen there loosely is the plan pays more. And so I think that's sort of inducing some sort of adverse selection. So I can't imagine that if you had that deliberative assignment of people that were taking drugs that the plan was covering well and you put them into certain plans that that wouldn't induce a change in what the plans did. And so I think this is in the spirit of what Bruce said, but I don't think you can take sort of the plan response.

Some of the this I think takes what the plan did is set and then says that conditional on what the plan did

how do we put people around? But I think if you started moving people around with different conditions systematically based on where the drugs were, you would see the plans themselves changing their premium or their coverage or something. And I think that would matter.

All of that said, I do think that as you go forward some deliberative thought as to how one might do this would likely get us a better outcome than random assignment but it's not completely clear to me yet how.

DR. HOADLEY: Two quick comments on that. One on the second point, yes, it definitely does create a kind of adverse selection. But of course, the plan finder for everybody who is picking plans is fundamentally doing that. And we've seen that with the very rapid rise and fall of the enhanced plans that provided full gap coverage. It was selected into them exactly the people that needed them and they were more expensive and plans stopped doing that.

On the first question, we've tried to think about could you go in and make adjustments to the assignment based on more substitutable drugs, trying to optimize. But the idea that you could do this in some kind of systematic way for beneficiaries in an open season kind of framework is

kind of mind-boggling, that you could somehow put in clinical factors.

But we did see certainly, and there's examples in the full report, underneath some of the cases where you see okay, in one case it's a PPI and most clinicians would agree that substituting amongst different PPIs is quite readily doable. In other cases, the drugs in question were drugs where it wasn't so clear that a substitution could easily be done. So you can certainly see the instances of those kinds of cases. But sort of figuring out on a policy basis what to do with that, that's the hard part.

DR. REISCHAUER: All economists think alike. Bruce made one of the points and Mike made the other. I'll just put a footnote on his second point, which is what's best for the beneficiary is worse for the plan. And if plans set their premiums based on a certain amount of irrational behavior that everybody isn't using plan finder, what you might get is a situation where Jack assigns everybody to the best plan for the beneficiary, the plan then loses money in that year, has to jack up its premiums the next year, which puts it above the benchmark, which means you then have a whole bunch of people you have to

assign in the following year. So you're sort of maximizing turmoil while minimizing yearly costs for the beneficiary.

DR. HOADLEY: I think that could very well turn out to be a scenario.

MR. HACKBARTH: I think the other implication of this is GAO only needs to appoint one economist to the Commission.

[Laughter.]

MR. BUTLER: We're going to talk about the Part D work plan tomorrow, so I'll try to limit it to this discussion. But of all of the things we've talked about today, I think the number and mix of drugs an elderly takes has as much to do with the costs of health care ultimately as almost anything that is occurring, both positively and negatively.

And so when I look at this and I look at the impact of that drug costs, per se, to the individual or to the government it is a very interesting exercise. But the compliance to the appropriate mix and range of drugs, if taken or not taken, I bet you the cost or cost savings associated with that probably would trump these numbers wildly, is my guess. I'm not an economist.

So my point would be your question is related to the compliance and what happens in the behavior of the beneficiaries in their use of the drugs is probably the more important research question then simply are we going to get them into the cheapest best options in the short run.

DR. MILSTEIN: This is very useful, but whenever I see an analysis in which the economic unit is anything less than total cost of care, I'm concerned. And so I wondered, are there any state Medicaid programs that in their supplement to Medicare capture the Medicare claims experience in enough detail such that it would be possible to assess the impact of these patients who were involuntarily switched on a broader range of outcome variables than drug spending? For example, total cost of care to both Medicare and the Medicaid program, and some clinical parameters we might reasonably be concerned about such as higher rates of ER use or hospital admission associated with patients who were involuntarily reassigned.

I think it's extremely useful but not that easy to interpret in terms of policy recommendations.

DR. HOADLEY: I think that's an excellent point. And it's probably not so much was states might have the

data, because the states are really only facing the marginal cost of the other services is really fundamentally a Medicare question. And the opportunity once we see merged Part D claims with Parts A and B claims will be to be able to look at there adverse consequences? Are there new hospitalizations? Are there reduced costs because of --

DR. MILSTEIN: I'm sorry, but do we really have to wait? For example, if there's even one or two state Medicaid plans that do capture reasonable Medicare claims detail in their wraparound of Medicare, could we not mine that database for starters? And I know that for example I was a junior collaborator on some research in South Carolina Medicaid. I can't answer whether or not drug coverage was captured, but we got quite good detail on what Medicare covered as a primary for dual eligibles from the Medicaid data system in South Carolina.

DR. HOADLEY: The problem continues to be that even the state can't look at what the drug use on the Part D side is until these claims work their way out. So they're not able to see what drugs people are taking right now under Part D.

DR. MILSTEIN: But when they wrap around a Part D

plan --

DR. HOADLEY: Most states aren't doing a wraparound for Part D. Even those that are, some of the SPAPs, the State Pharmacy Assistance Programs, may be able to see some of that for a subset of patients and that may be one possibility, yes.

DR. CHERNEW: Arnie, I'm sorry to interrupt but we're actually working with a long-term care pharmacy to do this for -- some subsidy patients are in nursing homes. And for the ones in nursing homes you can get the drug part from the long-term care pharmacy. And then you can get the utilization data separately. You don't get all of the other data that's not coming from the long-term care pharmacy but you can understand the answers to the health outcomes and the hospitalization type things if you imputed a price. And so we're dealing with the randomization in that project.

DR. CASTELLANOS: I'd love to give a real world experience on what happens and I think Tom, you may want to do it and Karen, you may want to ask that.

Do they request exceptions? Yes, the patient does and the physician does. I look at this as an unfunded mandate because I'm obligated morally to try to help the

patient. I can't tell you how much work that is for the physician office and for myself and how may times I call 1-800-busy and never be able to speak to somebody.

But it's a hassle, as Jack said. And it would be nice if we could somehow smooth that exception process.

Quite honestly, if they're astute and healthy and intelligent they look to switch plans. Most of the time they do. But if they live in Southwest Florida where I live they don't have that ability. They don't have family, support. They have very few people to go to. So what do they do? They stop taking the drug. It's not fair but that's what happens. This is my real-world experience.

MR. HACKBARTH: Any other initial comments?

So what I've heard is sort of a series of questions. At first glance this seems to make eminent good sense. But then there's sort of what are the second order effects? How is beneficiary behavior affected? How us ultimately the total cost of care affected? How is plan behavior affected? And all of those seem like reasonable questions that you'd want to address before you start down this path.

Any reactions to that, Jack? And how many of

these questions can we tackle short-term as opposed to long-term?

DR. HOADLEY: I think that's the challenge, is trying to sort through. I think some of the simple things that we ought to be able to get a handle on, the claims data, should start to become available within a couple of months. Some simple questions are how many of these low-income beneficiaries are, in fact, changing away from the randomly assigned plan each year? Is it 1 percent? Is it 20 percent? We actually don't know that. Some of the real basic bits of information, if it is more like 20 percent then maybe the ones who are the worst mismatches are getting that corrected. If it's a much smaller number, maybe that's not happening.

Now that by itself won't tell us are the right people switching, what are the kinds of circumstances. But there are definitely some good questions to ask. My personal view would be try to begin to move toward some of this and you can further fine-tune through some of the implications over time. Maybe in some cases what we can't kind of look at here is if people are in a plan year one, year two, they've reached a certain equilibrium with that

plan. They've gotten themselves switched over eventually to the right drugs maybe for that plan's formulary -- this goes to what Bruce and Michael were talking about and Bob. They've made some adjustments, the economics has played out. It may have taken a while to get there. Eventually they got with their doctor to get either the exception or make a switch.

And then, of course, that plan suddenly becomes ineligible. Are there ways potentially to let the person stay in that plan even though that plan is no longer benchmarked? That raises some other questions. I think there are some different kind of things you can think about. But we are asking people potentially to really -- they've made the moves, they've gotten adjusted to one plan. And all of a sudden because of the way the rules work, they're going to be switched and they've got to, at the very least, go through all of that disruption.

DR. STUART: I'll keep this short. This study is based on the presumption that the formulary is a given and the people are kind of moving around, and how you can move them around so that they fit their formulary right.

The other way that you might look at it is to say

is the formulary right? Current CMS policy is that there is a safe harbor if the CMS rules regarding the formulary development are followed.

Now that's also something that I think we should take a look at, and maybe we can talk about that tomorrow, because there really are two parts of this. First of all, there really is a clinical issue associated with whether drug A or Drug B should be on that formulary, depending upon whether certain individuals would respond better to one or respond better to the other. If there's good clinical evidence that that's true, then maybe the current policy of allowing the plan to make a decision to have just one of those on the formulary is bad public policy.

The second way that one can get around this is through this exceptions procedure. The way it is now my understanding is that the plans have quite a bit of flexibility in terms of how they handle this. There are clearly some CMS rules in terms of they do it but it's pretty easy to make it hard to get an exception. So that would be the other way around, is instead of trying to switch the beneficiary from one plan to another is to just make that exceptions procedure work better if, in fact, the

switch shouldn't be made.

DR. CHERNEW: I was just going to give a number. There is -- I think it's a Health Affairs study by someone named Newman in 2007 that suggested that 11 percent of non-institutionalized dual eligibles switched in 2006 to give -- so roughly 10 percent of the people. And the institutionalized people have further protections because if their drugs are off-formulary someone else has to eat the cost. If you're in a nursing home --

DR. HOADLEY: If it's not in the formulary, no. If there's a copay involved, they don't pay any copay. But if it's non-formulary -- most likely what will happen is the institution will get involved and they will either get the exception or get the drug changed. But it's not that somebody picks up the bill for the existing drug. That person in the institution has more leverage, has more allies as it were.

MR. HACKBARTH: Any last comments?

Thank you, Jack. Good to see you again.

And finally we will have a brief public comment period.

Okay, we are done for today. We reconvene at 9:00

a.m. tomorrow. We do start with our expert panel so we will want to get started on time.

[Whereupon, at 5:07 p.m., the meeting was recessed, to reconvene at 9:00 a.m. on Friday, September 5, 2008.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, September 5, 2008
9:03 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, J.D., Chair
JACK C. EBELER, M.P.A., Vice Chair
MITRA BEHROOZI, J.D.
JOHN M. BERTKO, F.S.A., M.A.A.A.
KAREN R. BORMAN, M.D.
PETER W. BUTLER, M.H.S.A
RONALD D. CASTELLANOS, M.D.
MICHAEL CHERNEW, Ph.D.
FRANCIS J. CROSSON, M.D.
THOMAS M. DEAN, M.D.
NANCY M. KANE, D.B.A.
GEORGE N. MILLER, JR., M.H.S.A.
ARNOLD MILSTEIN, M.D., M.P.H.
ROBERT D. REISCHAUER, Ph.D.
WILLIAM J. SCANLON, Ph.D.
BRUCE STUART, Ph.D.

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P R O C E E D I N G S

MR. HACKBARTH: Good morning everyone. We have two sessions today. The first one is an expert panel on imaging services and then the second is on Part D.

Ariel, will you introduce our guests?

DR. WINTER: Yes, thank you. Good morning.

Before we introduce this morning's expert panel on imaging, I would like to briefly review the Commission's work on this topic and recent legislation.

First, we recognize the impressive technological progress in imaging, which has increased its importance for diagnosis and treatment and expanded the availability of imaging in freestanding centers and physician offices. While imaging can lead to improved detection and treatments, the rapid growth of imaging services within Medicare, geographic differences in imaging use, and variations on the quality of providers have all raised concerns about whether imaging is sometimes used inappropriately.

Over the last several years, the Commission has focused on improving both the quality and payment accuracy for imaging services and I'll summarize this work over the next few slides.

In our March 2005 report we recommended that Medicare set quality standards for all providers who bill the program for performing and interpreting diagnostic imaging studies. In the MIPPA legislation the Congress mandated accreditation for all providers who perform advanced imaging. There are still no standards, however, for physicians who interpret the studies.

We also said that CMS should improve Medicare's coding edits to reduce unbundling of imaging services and reduce the technical component payment for multiple imaging services performed on contiguous body parts. The technical component payment covers the cost of the equipment, non-physician staff, and overhead. In 2006 CMS adopted the second of these recommendations and it did so in a budget way, that is there savings were redistributed to other physician services.

Finally, we made two recommendations to modify the physician self-referral law, also known as the Stark Law. I won't spend time describing these but they are referenced on the side and I would be happy to take questions on them later.

We also spent time looking at how imaging services

are paid under the physician fee schedule and found that payments for certain services may be inaccurate. We determined that MRI and CT services may be overvalued because CMS may be overstating the per service cost of imaging equipment. We also found that CMS's method of adjusting for geographic differences in input prices may overpay for imaging services in the areas of high input costs and under pay in areas with low input costs.

The Deficit Reduction Act of 2005 had two provisions that reduced payment for many imaging services beginning in 2007. In the first provision, Congress mandated that savings from the multiple imaging procedure payment reduction be returned to the Trust Fund. As I mentioned a few minutes ago, when CMS adopted this policy for 2006 the savings were redistributed among other physician services in a budget neutral way.

In the second provision the physician fee schedule rate for the technical component rates may not exceed the hospital outpatient rate for the same service. In other words, the outpatient rate acts as a cap on the physician fee schedule rate. For example, the 2008 fee schedule rate for MRI of the lumbar spine would have been $488. But

because this is higher than outpatient rate of $344, the fee schedule rate is reduced to the outpatient rate.

CBO estimated that these provisions would save about $500 million in 2007. We estimate that this would be about 5 percent of imaging spending on that year.

Now we'll switch gears and look at growth in the use of imaging services relative to other physician services. We're looking here at cumulative growth in the volume and intensity of services per beneficiary from 2000 through 2006. Over this time period the use of imaging, as indicated by the red line, increased almost twice as fast as all physician services, as shown by the purple dotted line in the middle. Imaging grew by 10 percent per year on average between 2000 and 2005. This growth slowed to 6.2 percent between 2005 and 2006, as you can see from the bend in the red line, but this is still much higher than the 3.6 percent increase in all physician services in that year.

We're looking for your guidance today in developing our future policy agenda on imaging issues. We've invited three experts to discuss their recent research on key issues related to imaging use.

The first speaker will be Lawrence Casalino, an

Associate Professor in the Department of Health Studies at the University of Chicago. He will present the results of a report that examined the literature on physician self-referral.

Next up will be Laurence Baker, Professor of Health Research and Policy at Stanford University School of Medicine. He will discuss his recent work on both physician self-referral and geographic variations in imaging use.

The third speaker will be Bruce Steinwald who is Director of the Health Care Team at GAO who will talk about a recent GAO report on trends in Medicare spending on imaging, the use of imaging in physician's offices, and private sector approaches to managing imaging services.

There are detailed bios on each speaker in your binder. After we hear from our three guests, there will be an opportunity for your discussion and questions.

DR. CASALINO: It's a privilege to be here and I'm looking forward to the discussion. I will go very quickly through the first few slides.

I think the reason that I'm here is that the Robert Wood Johnson Foundation has commissioned a series of so-called synthesis reports and I was asked to do one about

a year ago on physician self-referral and physician-owned specialty facilities. This included specialty hospitals and ASCs, but also diagnostic imaging. The report is available online. That's the website. I do want to thank Sarah Goodell, who worked on behalf of the Foundation with me on this project. It's a lot better for her help.

I won't belabor this. You're all familiar with it and Ariel just mentioned it. Payments under the Medicare fee schedule have really almost doubled between 2000 and 2006. As Ariel said, this is the fastest growing service provided by physicians and the fastest growth has been in advanced imaging like MRI, and CT nuclear medicine.

One question is how much of this growth is due to physician self-referral? No one knows for sure but the answer is probably a lot of it. If you consider radiologists not to be self-referring physicians but other physicians -- when a cardiologist receives a payment for doing an imaging study self-referral probably is involved. Then you can interpret these figures.

So radiologists' share of Medicare payments for imaging has been steadily going down and that of other physicians -- especially cardiologists and orthopedists has

been going up. You see currently down to 43 percent for radiologists and it's up to 25 percent for cardiologists. Over a four-year period that's about a 10 percent increase for the cardiologists and about a 9 percent decrease for the radiologists. Orthopedists and cardiologists performing huge amounts more imaging now than they did a little more than a decade ago, 33 times more for orthopedists.

This is a study that just give came out done by Jean Mitchell, who's done a lot of good work in this area, looking at patients of a large PPO in California. This is just a sample of the data in the paper. You can see that the increase in outpatient MRIs for these patients, a lot of it is coming from self-referring physicians, 155 percent increase over a four-year period. Also increasing in hospital outpatient departments when radiologists were collecting the imaging fee but quite a bit less than self-referring physicians. And then there are the IDTFs, independent diagnostic testing facilities. I'll have a few more comments to make about them at the end, but they also increased the amount of MRIs they were providing substantially.

This is also a fairly recent article, not exactly

from an unbiased source, but interesting Medicare data. You can see again, these are the top three specialties that provided the most outpatient MRI scanning outside of radiology. You can see a huge increase for orthopedists and neurologists.

I have primary care physicians highlighted here because I'm not aware of any data on this but it's not likely that very many primary care physicians have MRI scanners in their offices. So if you look at these 58,000 procedures that primary care physicians were paid for doing an MRI scan in 2005 you have to think that these are from some forms of leasing or per click arrangements, the kind of things that some people are quite suspicious of.

There is, as you know, a proliferation of arrangements, leasing per click under arrangements between hospitals and physicians, and then a variety of arrangements that I really don't know of any data on -- in fact there's very little data on any of this -- between IDTFs and physicians, ways to get physicians money for working with IDTFs, let's say. Whether this is payment for referrals is obviously a controversial question.

So how much of this increase in imaging is

inappropriate? Nobody knows for sure and there's different ways of defining what's appropriate. The way that health policy analysts would like to define appropriate is in compliance with guidelines, if there are any. For a physician in the office or a patient -- and I was in this position for 20 years -- appropriate may be if it has some chance of doing the patient benefit, very little chance of doing them harm, and the patient wants it it's hard for me to tell this patient in front of me you can't have this. I think most physicians in practice would still argue that that's the definition of appropriate. That obviously has very different implications for how much imaging is going to be done.

So we do know, in terms of how much is inappropriate, that there's a lot of interregional variation so someone's probably doing too much. We know that there are some tests -- there's way too much imaging done too early for lower back pain, for example. There are lots of studies, old and now some new, that show that self-referring physicians do order a lot more images. Both cross-sectionally and longitudinally there have been studies where suddenly physicians get a chance to get paid for imaging and

they start ordering more.

Health plans state that -- and a little bit of this has been published -- that when they institute various procedures that make it harder for physicians to order imaging or get paid for in the rates go down. Again, I know from experience it doesn't really take you at any time to order an image and very little to interpret it whereas it does take you time to see patients. So if you feel squeezed for income, it's quite an easy way to increase it by just ordering more imaging. And you don't have to be a raving cynic or a bad person to do this. It can just be on the margin, it can be quasi-unconscious probably. But it's a very easy way. You can order images without limit. You can't see patients or do surgeries without limit.

Effects on quality, very little data available. There's a little data to suggest -- and I believe this is probably true -- that both on the technical and on the interpretive side, the professional side, that in general in primary care offices the imaging probably isn't done as well. There is one study that showed that -- a small study but for chest and extremity films the primary care physicians' interpretation of films that were done in their

offices was validated by radiologists about 90 percent of the time. But then when they had other radiologists look at the films and also had the actual clinical diagnosis of the patient, what happened, they actually saw that a little bit over a third of the time but there's a disagreement between the radiologist's reading and the primary care doc's reading, the primary care doc was right. And these were usually fractures of the extremities -- and I had this in my office -- when you know there may be a problem if there's a subtle fracture, you may be more likely to pick it up than the radiologist. I'll come back to that in a moment.

There's no data on this that I'm aware of but it's plausible to me, at least, that when specialists -- say when an orthopedist is interpreting an MRI of a knee -- my guess is that they're probably pretty good at it because they do a lot of it. So there may be less of a quality problem there, if you think there is a problem, then there is in primary care offices where as primary care physicians we just don't do that much of any one kind of imaging, most primary care physicians.

There's a recent OIG study of IDTFs that showed almost all of them not complying with Medicare requirements.

You could argue that some of the things that the OIG dinged them for were kind of picky, but a lot of weren't. 13 percent of the procedures were performed by unlicensed technicians, for example.

Just one other side thing on quality, this is a New England Journal article quite recently, estimated that 2 percent of cancers -- fairly soon estimated that about 2 percent of cancers in the United States will be a attributable to CT scans. That doesn't mean the CT scans were inappropriate but it's something to think about.

It's a different question to talk about whether an imaging procedure is appropriate and whether it's performed in an appropriate setting or whether it should be done by self-referral and I think it's important to distinguish those.

There has been talk of Medicare doing prior authorizations. I'm going to just end with some quick editorializing here. I actually just wrote another report on what I think Medicare ought to do to be a value-based purchaser. And I initially put this in but then I took it out for some of the reasons that you can imagine.

I don't necessarily disagree with this as a

recommendation. I would say that thought should be given at least to not making it a blanket requirement for all physicians but just -- I know MedPAC is doing some work to try to profile who the high-cost imagers are. And if they could be identified, those should be the ones who should get prior authorization. It would be much more cost effective to do it just for them than for everybody and there would be probably less political backlash. Because again, I can tell you from experience, if you think that you're an efficient physician and you have to go through this and it's costing you time and money, and it just seems like a useless hassle you really hate it but you actually know some guys in your community who you wouldn't mind seeing it done to.

[Laughter.]

DR. CASALINO: I think that's really true. Now that doesn't mean you won't get backlash from organized medicine and various specialty societies.

Should one size fit all in terms of self-referral on imaging? I don't think so. At a minimum you can have these kind of categories. In primary care physician offices -- I'm saying small or medium as opposed to bit multispecialty groups. A bit multispecialty group can have

great equipment and have radiologists and probably not have so much of a problem in terms of quality. You still have the self-referral incentive to worry about.

But I think in a small office on balance the quality technically and interpretive isn't going to be as good. But that doesn't mean that the net quality won't be better. So again, if you have an 80-year-old woman with congestive heart failure, who may have pneumonia and the nearest place to get an x-ray is five miles away and it's hard to get her in and out of a car and you really want to know if she has pneumonia then, doing that x-ray in your office -- or you want to know if someone has a fracture that you can take care of -- doing that film in your office offers, I think, a lot of not just convenience but potentially quality benefits because you can do things right there, you know what's going on, patients love it.

I think if standards were promulgated for primary care offices so that we could feel fairly confident that the technical and professional sides were being done well, I personally think it's a pretty good thing. You still have the self-referral incentive. How do you deal with that? Maybe with the prior authorization policy that we just

talked about.

Specialty offices, I would say basically the same thing.

Lease and per click arrangements, I think it's important to understand that the benefit that I just rushed through of having things done in the physicians' office is not true for lease and per click arrangements. I don't see really any potential benefit of any kind to anybody from those, except from the referring physician and the place that's doing the films. And I wouldn't be sorry to see those go.

And just to finish up these, to me at least -- and I haven't been able to find anybody who says differently -- IDTFs are mysterious. It's very hard to tell how many there are. No one knows really who owns them. They mostly do imaging. About 85 percent of what they do is imaging. They've increased their share of advanced imaging up to about one-quarter of all that gets done from 3 percent in 1995.

The OIG did a report a few years ago that -- it's kind of buried in there but if you do the math you can see that they found that about a third of the imaging was

unnecessary or hadn't even been ordered by any physician as far as they could tell in some cases.

So I think that why should we have IDTFs? First of all, I would say more needs to be known about these and it would be a great subject for a study by MedPAC or GAO or whomever, including just who owns them and who refers to them if one could figure that out.

Why should they exist? Only if they provide some kind of quality or efficiency or convenience advantage. And maybe they do, in some places. Frankly, I don't have an opinion about that. I just don't have any idea and I'm not sure anyone knows enough to have an opinion.

I think that the steps Medicare has taken recently to ban that kind of leasing arrangements that IDTFs have with physicians can help eliminate some of the less desirable self-referral incentives but I do think more should be known about these.

With that, I will pass things on.

DR. BAKER: Good morning. It is a pleasure and a privilege to be here to share some results of work that I've been involved in over the last couple of years, mostly in the last year, related to various aspects of imaging

diffusion and imaging ownership by physicians, looking at mainly the effects on utilization and spending.

I've brought pieces actually of three or four different projects and I will try to summarize what the results from some of those are and would be happy to take questions or talk about more specific aspects of them at a later point in time.

The first question that I have some results to share with you on has to do with the effects of expanding imaging availability on the use of imaging. So as we put more MRI scanners in, as we put more CT scanners in around the country, what effect does that have on utilization and ultimately on Medicare spending?

There has certainly been a lot of diffusion, a lot of increase in the number of units available. These are estimates that we have made of the number of CT scanners and the number of MRI scanners in the country based on some industry data. 5,300 approximately CT scanners in the U.S. in 1995, up to 8,300 by 2004, so plus 3,000 CT scanners over a 10-year period. 2,400 MRI scanners up to 5,800, so about doubling the number of MRI scanners over a 10-year period. A fairly dramatic growth given the kind of parameters you

usually see in medical technology change over time.

This has gone along, of course, with increases in utilization. This is data on the number of CT scans in blue and MRI scans in red/maroon for Medicare fee-for-service beneficiaries. So we've more than tripled or just about tripled since 1995 the number of CT scans and MRI scans that are being done. We're at about 600 coming up on 600 scans per 1,000 -- 600 CT scans per 1,000 beneficiaries per year now and almost 200 MRI scans per 1,000 Medicare beneficiaries per year. So dramatic growth.

Is there a relationship between the availability of scanners and utilization? There certainly is. This is a plot from just a basic analysis we did that used 318 metropolitan statistical areas, so 318 dots up there. On the x-axis, the horizontal axis, is the change in the total number of MRI units in that metropolitan statistical area between 1994 and 2005. You see quite a lot of geographic variation. Some places added 100 scanners. A lot of places were adding 25 to 50. And there were some places that didn't add very many at all, and so there's quite a bit of change there.

On the vertical axis is change in the total number

of MRI claims in the Medicare fee-for-service population and you also see quite a bit of geographic variation there. The two are quite closely related. So the plot follows a nice upward sloping pattern. We fit the regression line there. And if you look at that regression line long enough you will conclude that every additional scanner added is related to or associated with about 800 additional MRI procedures for the Medicare population.

I could show you the same figure for CT scanners. It would show the same pattern but the coefficient would be even bigger. Every additional CT scanner is worth about 2,500 additional CT procedures for the Medicare population.

This, of course, ends up affecting spending. In one analysis we did a couple of years ago we looked at changes in the outpatient MRI scanner availability in different MSAs and came to the conclusion there that each additional outpatient MRI scanner would drive up Medicare imaging spending in the average MSA by about 2 percent.

Now 2 percent is a vague number so I did a back of the envelope calculation in real dollars. Just using some general estimates of the average cost to Medicare of an MRI scan, if you put an outpatient scanner in it generates 800

additional procedures. Without trying to be too precise about it, a rough estimate is that that will cost about $500,000.

So if you were to take the 5,000 scanners that we have now and add maybe 100 scanners, it would end up about $50 million in additional Medicare spending on imaging, based on just an extrapolation, a back of the envelope calculation from the kinds of numbers we've been putting in.

Of course, the policy questions are not just about spending. They are about the value that you get from spending. It's certainly an important point that needs to be considered in any kind of discussion. There are certainly benefits -- I say probably on the slide and I should say certainly -- some benefits from expanding imaging utilization.

We've been involved in one study that looks at the use of CT for carotid angiography. So if you have a problem with your carotid arteries it can be diagnosed with CTs these days instead of using a catheter-based more invasive diagnostic test. The use of CT reduces side effects risks and it looks like this is a useful thing in that increased use of CT for carotid angiography is associated with

expanded availability of CT scanners and the kinds of things that we just talked about. So putting more of these pieces of equipment in does look like it generates benefits in this one case, and I'm sure in others as well.

But as we were just talking about with Professor Casalino, and has been noted in quite a number of places, there are also reasons for concern that expanding the availability of the pieces of imaging equipment will also be associated with less clearly beneficial utilization. And back pain is one good example that's up on the slide.

So just to quickly summarize that line of research, we certainly find lots of evidence that expanding availability is associated with expanding utilization and expanding spending. Perhaps that is not a shocker. It would, in some sense, be surprising if expanding availability was not associated with expanding utilization and spending.

So why, in some sense, bring it up? I bring it up because I think it's a crucial point for consideration of how one might think about managing expanding spending and utilization on imaging. If we're going to talk about ways to manage, ways to influence, ways to improve the efficiency

of the imaging sector in the U.S. health care system we have to do that in the context of a world in which we've greatly expanded the availability and which continued expansion of the availability will put continued pressure on to utilize the machines and utilize the equipment that we've put out there. The effects, just the associated effects that go with expanding availability are very important drivers of utilization independent it seems of the kinds of things that we've tried to do in the past few years to slow down utilization. Just availability is an important driver.

We've also been engaged in some research and now, turning to the second piece of the talk, we've also been engaged in research on physician ownership of imaging equipment and the use of imaging, looking at some of the issues that are associated with physicians who acquire or lease MRI equipment.

As we were just talking about -- I can do this slide quite quickly. As we were just talking about there's been a dramatic increase in this over time. I have up there the share of physicians observed to be billing Medicare for technical components and global fees associated with MRI and broken into orthopedists and neurologists, the two

specialties that do this the most often. You can see on the left, in the blue, the share of orthopedists who look like they've acquired or leased an MRI machine over the years -- 1999 on the left to 2005 -- go up quite a bit. It's about a quarter of physicians by 2005. For neurologists, similarly an upward sloping line. Only about 10 or 11 percent but still a dramatic increase over the last seven or eight years. So quite a bit of change in what looked like physician ownership or leasing arrangements in these two specialties.

These, of course, are not the only specialties and ownership and leasing arrangements are not the only arrangements under which these kinds of equipment is -- well, looks like it might be acquired or create some financial incentive. So there's certainly been a lot of change in this area.

Our question is what effect does acquiring MRI have on the use of MRI? We come at that -- this is kind of a techie slide. Let me just summarize.

We come at that by trying to find episodes of care -- for patients who see an orthopedist or see a neurologist, we find what look like index visits, so new visits,

outpatient visits, and we try to track forward then from those visits whether they get an MRI within seven days. We've also done other takes on how they get an MRI.

We classify each episode according to whether the first physician, the orthopedist or neurologist, that the visit looked like they had acquired MRI by the time of that index visit. So if you have already billed Medicare for a technical component and it looks like you've acquired MRI at the time of that visit, we will call you a visit to a physician who looks like they have acquired MRI. If you haven't ever billed for a technical component, we'll say no and do the analysis on that basis.

This is the tip of an iceberg really. We've done lots of other things to try and characterize and think about but I'll stick to that definition for the results that I'm going to show you today.

So this is just a graph of the share of visits that are made to orthopedists or, on the bottom, neurologists that look like acquired MRI. You see those going up over time, hitting about 25 percent in 2005 for orthopedist visits. So about a quarter of the orthopedist visits in Medicare are made to an orthopedist who looks like

they have some acquisition ownership or leasing arrangement with MRI equipment and about 10 or 11 percent of the neurologist visits by Medicare fee-for-service patients are made to neurologists who look what they've acquired or have some arrangement with MRI equipment.

Doing a simple analysis, we can break all of those visits into two groups: bright green visits which are made to physicians who don't have MRI and dark green visits that are made to physicians who do have MRI. We can graph and I graph on this figure the share of those visits that have MRI by any provider within seven days. If you visited a neurologist with no MRI equipment, about 9 percent of those visits will have an MRI done by someone in the next seven days. 14.5 percent of the visits to physicians who own MRI equipment will have an MRI done within the next seven days.

For orthopedists, the effect is a little bit smaller, the numbers are a little smaller, 4.7 percent and 7.5 percent so an increase of about 2.8 percent there that are associated with visits that are to a provider who owns the equipment.

This result is like results that have been put out by other folks over quite a long period of time that suggest

that financial self-interest that ownership arrangements are associated with increases in use. But there have been criticisms that have been made of these kinds of analyses. One of them is that the providers who are most interested in doing MRI will be the ones who buy the MRI anyway, and so it's very hard to know the causal effect of owning MRI in these kinds of cross-sectional studies. So we wanted to fix that in our work. So we went on and did some additional analysis.

This is, in some sense, the next step which is to take the same physicians now before and after they look like they acquire a piece of equipment and redo the analysis so that we adjust, in some sense, for the characteristics of physicians for the preferences that they might have about using MRI equipment or referring MRI scans.

Here you see essentially the same result survives but the effect is a little bit smaller, the magnitude of the relationship is a little bit smaller. So in the light blue visits that are made to neurologists who will acquire but before they acquire and the darker blue visits made to neurologists who acquire after they acquire. You see there about a 3 percentage point increase in the probability of

getting an MRI if you go to a neurologist after they acquired compared to before. For orthopedists it's about 2.7 percent more likely to get an MRI.

Also, this is an advance, a methodological advance in some sense but it's also not entirely satisfactory because there are general trends toward more utilization over time and there may be other variations across the patient groups associated with different physicians. So to do the full blown analysis we needed to run some regression that would adjust for time trends and adjust for other characteristics. You can see some description on the slide of the kinds of things we adjusted for. There are demographics, there are the diagnosis codes of the patients, spending by the patients, comorbidities, years and month of the visit to try and adjust for a bunch of things. We do this -- for those of you interested in the techie aspect of the analysis, we do this using a fixed effect model which controls for physician fix effects and other time trends.

The result then is on this slide which unfortunately isn't in a pretty colored graph. It's a very academically looking slide. You can see for orthopedist visits on the left, the cross-sectional result, that initial

result, was plus 2.8 percent in the probability of getting an MRI if you went to a provider who looked like they had acquired MRI. When we did the pre/post that changed to plus 2.7 percent for the orthopedist visits. When we do the full-blown analysis it's plus 1.5 percent so it's a reduction in the effect but still a positive and statistically significant effect.

You see the same thing for neurologist visits, the cross-sectional results which parallels a lot of the earlier literature and then two attempts to do more precise or more refined analysis where we get to about a 2.2 percent increase.

So that's the details, in some sense, of the results. What are the main points of the results? We guess, after quite a bit of work to try and control for and adjust for as many things as possible, the result that acquiring MRI certainly does change physician practice patterns. If you go from before you have a relationship or before you look like you've acquired or leased a piece of equipment to afterwards you will see changes in the number of referrals, changes in the ways that the equipment is used.

The effects are statistically significant although they are smaller than some of the other effects that have been found in previous work. They are still relatively large though. If you do this on a percentage basis it's about a 25 percent increase in the probability of getting a scan after a provider acquires a piece of imaging equipment.

The back of the envelope calculation in these samples, if you were to increase the share of visits to providers owning MRI by 10 percentage points, which would be a reasonably large increase but not out of the ballpark given what we've seen over the last few years, you would get about 4,000 more MRI procedures from orthopedists and about 2,500 more from neurologists.

We've done some work on the effects on Medicare spending. The question there is if you look before and after someone acquires MRI at the average cost that their patients incur, the average Medicare spending their patients incur over 30 days following the visit what happens to spending? If you just thought about, say in the case of orthopedists a 1.5 percent increase in the probability of getting MRI and that MRI costs you something like $600 --

which is an average that we calculated vaguely, is a little over $600 in our data that Medicare spends on an outpatient MRI procedure -- then you would see $10 or so, roughly speaking now and not trying to be overly precise but a ballpark figure, $10 or so increase in average cost. We see about plus $16 in spending for these patients which says that there's more going on, that MRI is associated with other things that the providers are doing, as well. So you see a $16 increase there and about a $60 increase for neurologists' patients, much larger than would be associated with the cost of just the MRI themselves. So there's an effect on costs that includes the MRI but also probably includes other things.

These numbers don't include what looks like it will be a small offset in outpatient spending. So outpatient Medicare spending will decline, the dollars, the numbers I just showed you were physician spending.

So if you do a back of the envelope calculation on that data, if you increase the share of visits to providers owning MRI by 10 percentage points, you'd get about $4.4 million in additional spending from orthopedists, about $6.8 million in the neurologists. Big numbers although not

necessarily as big as the effects from capacity. If you were just to increase the number of MRI scanners in the first bit of work by 100 scanners you would get maybe $50 million in additional spending. Here, pretty large increases in the share of physicians who are owning the equipment generate four or five, maybe a little bit more depending on how you slice the numbers. But not 50 million.

So how do we conclude? Expanding imaging availability is an important driver of utilization and spending. Expanding provider ownership is also a driver of utilization in spending. The big question, of course, is are we better or worse off expanding utilization of these procedures can be beneficial to patients? There are certainly lots of cases in which that appears to be the situation but it's not clear that they always are or that as we expand further we will continue to make inroads into the most useful places. And so it's certainly important to consider the benefits and the potential for less beneficial utilization, a set of considerations on which I don't have data to present to you today.

What our policy response is, I actually will not spend a lot of time on this since Professor Casalino and the

next speaker also is going to speak about this. But it may be that limiting options for physician financial self-interest may be a useful set of approaches. Prior authorization may be a way to better channel and improve efficiency. Standards, accreditation and credentialing and maybe other capacity management would be ways to think about how many of these things are out there chasing Medicare dollars and generating some pressure for expanding utilization.

With that, I will conclude.

MR. STEINWALD: While Ariel is setting up, Mark, I brought my laser pointer. I'm not going to use it. I think there's a good chance I would blind Arnie Milstein. I know he's a lawyer in addition to a doctor, so I'm going to leave it on the table.

[Laughter.]

DR. MARK MILLER: For your information. this is a long-standing point of contention between Bruce and I, the laser pointer thing, that GAO gets them and MedPAC doesn't.

[Laughter.]

MR. STEINWALD: Hey, it's your tax dollars at work.

I'm here to report, as Ariel said, on a recently published study. That's the title of the study and its code number. It's readily available on the GAO website if anybody would like to download it.

The study was requested, it's a bipartisan request from Senators Rockefeller, who chairs the Subcommittee on Health of the Senate Finance Committee, and Senator Gordon Smith, who is the ranking member of Senate Aging.

In their request to us they emphasized two things. One is some concern about the payment changes effected or about to be effected by the Deficit Reduction Act that Ariel referred to. They also referred to MedPAC's work and asked us to build on MedPAC's work to provide them even more information on imaging trends and spending and to help them consider what Congress might do to address the issues related to imaging.

As you know, they did at least partially address some issues in the recently enacted MIPPA, Medicare Improvements for Providers and Payers Act -- oh patients, yes of course. Sorry.

[Laughter.]

MR. STEINWALD: Three research objectives, I won't

go over them here. To look at the trends through 2006, look at the relationship between spending growth and the migration of services to doctor's offices and then what practices have private organizations used to try to manage imaging and spending in benefits.

I won't go into detailed scope and methodology. The important things there are we split imaging services into advanced and standard imaging, as you have done in much of your analysis, and also made the distinction between the technical component and the professional component. The technical component, as you know, is the test itself. The professional component is the interpretation of the test.

We did a whole bunch of interviews, as well. This is not a random sample. We sought private plans that were active in managing imaging benefits. We interviewed radiology benefit manager companies. We interviewed CMS and its contractors and several stakeholder organizations, including several medical specialty societies and two organizations listed there that are not necessarily happy with our work.

Our findings: rather than just read the slide I'll go to the next one that shows it graphically. Basically

over the 2000 and 2006 period, that's the increase in standard imaging, x-rays, mammograms and other standard imaging advanced at a more rapid pace. In our data advanced spending overtook standard in about 2004. Even though there are far more standard imaging procedures, obviously advanced are much more expensive and therefore now contribute more to spending than the standard imaging does. The total basically over that six-year period doubled from about $7 billion to about $14 billion.

I emphasize that this is just Medicare Part D. In terms of total imaging spending, including the rest of Medicare and private sector I've seen estimates as high as $100 billion or so for total imaging spending.

Almost all of that spending increase has been due to volume of tests and the complexity moving from more rapid growth in advanced imaging. There are other reasons for the increase. Over that time period the number of fee-for-service Medicare beneficiaries increased and we were only looking at fee-for-service Medicare. That is not true for 2007. There is actually a decrease as more beneficiaries moved into Medicare Advantage plans. But over this period there was an increase.

There are also these separately billed ancillary items that aren't subject to RVUs. They are the radiopharmaceuticals and other products that are necessary often to provide in conjunction with advanced imaging. And they're not trivial. So they contributed some to the increase. And then over that period there is a small net increase in the conversion factor, which was the least of the contributors to spending growth.

Our second finding relates to the association between the growth in spending and the migration of services to physicians' offices and IDTFs.

Graphically that's the pie chart for 2000, about $7 billion. And even then the highest proportion was physicians' offices. But moving to 2006, you can see the migration out of hospital settings into doctors' offices and into IDTFs.

We also observed that in many specialties -- this is consistent with Larry and Laurence -- I can't call them both Larry I was told -- consist with their findings that in many specialties more and more revenue is being obtained through imaging as opposed to therapeutic services. Cardiology kind of stands out. Cardiologists get more than

one-third of their Medicare revenue from imaging services and other specialties are less pronounced but this trend is similar.

And then finally, the geographic variation that we've all referred to. There's not much of a pattern here. The lowest is Upper New England and then moving into the other areas of the country it's hard to discern a distinct pattern geographically that distinguishes high and low.

Finally in the highest category we get to Florida, of course, and its partner in crime, Nevada. I don't have an explanation for Nevada. But suffice it to say there's still a substantial variability in imaging spending per beneficiary across the U.S.

So having examined some Medicare data, we then sought to determine what is the private sector doing to manage imaging spending, knowing that trends are similar there. Again, I won't read the slide but the bottom line is that they were doing lots of things so the plans that we talked to. Most predominantly, they were using prior authorization to manage the imaging benefit in addition to credentialing and prior notification and the other things that you all have already talked about. Of those that used

prior authorization, the vast majority used radiology benefit manager firms to implement their prior authorization program.

CMS, for its part, uses a retrospective approach. Now CMS has identified imaging as -- I think they call it a vulnerable area or an area that produces vulnerability to excess Medicare spending. It has directed its contractors to give special emphasis to looking at imaging claims. However, it is, in essence, post-payment claims review, what some people call pay and chase. They pay the claims and then try and figure out which are the claims that they shouldn't have paid and then try to get the money back if they can.

So all of this led us to the following recommendation: the combination -- by the way, we framed our study in terms of Medicare's fiscal sustainability over the longer term. I'd like to point out at this time that I am now Medicare eligible. I'm still a Federal employee but I'm hoping that one day if I need an MRI there's going to be some money there to pay for it.

So within the context of needing to get control of Medicare spending and observing the rapid growth in Medicare

Part B and in particular imaging and in particular advanced imaging services combined with the migration to doctors' offices where there's less oversight of appropriateness of care and the substantial geographic variability, all combined led us to the recommendation to CMS to address the rapid growth they should consider more front end approaches to managing the imaging benefit. That could include prior authorization and privileging but not necessarily limited to those techniques.

CMS's response to our recommendation, which is published in our report, and you're welcome to read it, if I had to characterize it using one word I would say they were skeptical. They didn't disagree but they said well, you know, Medicare is really not like the private sector and if we were to implement something like what the private sector is doing there are other concerns that we would have to address like they emphasized, for example, proprietary systems don't work very well in a public program. They emphasized that there's an appeals process that could overturn decisions. And so they expressed those concerns.

Our response to those concerns was we didn't deny that they were legitimate concerns but we did say that we

don't think that post-payment claims review is going to get the job done in a benefit that's growing as rapidly as this one and that some front-end approach, it seems to us, to be appropriate. The concerns that they put forward need to be addressed but it seemed to us that they could be. And we're anxious to see, of course, whether CMS does decide to do a more front-end approach to managing the imaging benefit.

MR. HACKBARTH: Thank you, lots of material for discussion. I suspect we'll have lots of questions and comments. We've got, I think, 40 minutes left for discussion.

Could I just see the hands of people who want to get in the queue? Why don't we just go around and give everybody a chance.

Before we do that I'm going to take the prerogative of asking the first question. Maybe we ought to give Ron the second opportunity --

MR. EBELER: Your hand wasn't up.

MR. HACKBARTH: I've got the microphone though. Maybe we ought to give Ron the second chance to respond to the partner in crime allegation.

Here's my question. Jack and I were talking about

this before the meeting, before we get to policy approaches, I want to focus on the evidence that we've got a problem. Clearly, there is evidence of rapid growth, evidence that ownership is associated with still more growth. Ultimately, the question we want to ask, though, is whether cost per episode is increasing. We've often heard that well yes, more is happening in the physicians' office but that's a substitute for things that might have happened previously in the outpatient department. Or yes, more is happening in the physician office but that allows for more accurate diagnosis and treatment, which means that maybe more costly treatment is avoided. It seems to me the way you get at those issues is look at the effect on cost per case while trying to control for quality.

I'd like to ask the panel if you're aware of research that approaches it that way? And what the findings are?

MR. STEINWALD: I'll start. I believe you had your own estimate and ours was consistent of the amount of the growth in Part B that's simply substituting for another setting. I think the evidence is that it continues to grow in the other settings, even though there's some

substitution. I think your estimate was around 25 percent and ours was similar. So there is a bit of that.

But on the other side of that issue is how much of this additional growth is associated with additional spending for therapeutic services? So when we look at just imaging by itself I think it's important to recognize yes, there's a substitution effect. Yes, there's earlier diagnosis and treatment, at least in some cases. But there is also evidence of kind of a multiplier effect of more imaging, detecting more conditions, more false positives that need to be followed up, more conditions that maybe don't have a lot of clinical importance but still yield more therapy.

So when we see these imaging spending trends, I think we're probably just looking in part of their effect on spending.

DR. BAKER: Let me make a couple of comments. The first question you asked was whether there are offsets, whether we expand spending in physician offices say and also reduce spending in outpatient settings or other kinds of spending.

Some of the work that we've done does start to get

at that. It's a little bit preliminary are so it's ever so slightly dangerous for me to start talking about it as if it's fully done. But I'll say that the work that we've done so far suggests that there are increases -- for the orthopedists and neurologists that we like to study -- there are increases in the physician spending that are associated with acquiring the equipment. They are likely to be partly offset by reductions in outpatient spending. But the offsets in outpatient spending that we measure are much smaller than the increases in the physician spending that we see.

So I don't have a number to put on that at the moment but I suspect that the end result when we get to the final report on this research is going to be that there are net increases between physician and outpatient spending.

The place that it gets a little fuzzier is when I throw say hospital spending or other high ticket items in which makes the results fuzzy and it's hard to tell then with statistical precision what's going on. So we may not reach a conclusion that we will have total spending including hospitalization with statistical precision.

But in the question of physician office and

outpatient trade-offs it's going to be positive, I think.

You know, there are a bunch of questions that you head toward the become very interesting. And those are the effects of additional imaging utilization on other services and other kinds of spending. So for a carotid artery patient where we might increase utilization and may be more likely to do a CT scan, there are certainly possibilities for offsetting expensive side effects or other kinds of things that go on.

For other cases, for a back pain patient we may actually do more imaging and that may lead to more surgery for the patients. And so there's, I think, scenarios to be created on both sides. My guess is that in the end it's going to vary a lot by type of patient and by specific circumstance.

So I don't know that we have -- in our work we start to have some of these for particular cases where we started to do some analysis but ultimately I think it's going to require quite a bit of analysis to get a number of different conditions with different clinical scenarios considered so that one can start to see the range of possibilities that are out there. And I don't think we're

there yet. We'll start to be there over the next several months, I think, in our research group with a couple. But ultimately it's going to require more than that.

DR. CASALINO: I would just add three things quickly. One is that it may be in some cases that there could be increased spending for the episode but still it would be increased quality. It's not necessarily increased spending for the episode and you don't get any benefit for it. That won't always be the case.

I think the most important thing I would add is that, as you know, this will really probably -- when this is studied, as Laurence just implied, it will vary a lot, I think, what the findings will be by type of episode. So if you're doing an imaging study that has a decent chance of detecting a treatable cancer early, that can increase quality and might actually save some money. Or if you could find carotid or coronary artery disease earlier than you otherwise would, that could actually save some money.

If you're doing imaging of low back pain or of someone with an injured knee and you're getting MRIs, that's probably not -- I find it -- I can't really think about how that is likely to save money on an episode. And it's

probably not going to improve quality most of the either, especially for the back.

But then again, from the patient's point of view, and therefore from the physician's there are more subtle quality increases that Medicare might not want to pay for but that is very important to patients. So if someone has severe acute low back pain they actually want to know if they have a herniated disk or not because that does help a little bit -- although not that much -- with them knowing what to expect over the coming weeks or months. It's not going to make any difference in the end, really, to how things turn out that they know or not but they want to know.

Similarly lots of people, when they hurt their knee, they actually don't want to wait two months to find out if they have -- what kind of tear they have of their medial collateral ligament. They actually would like to know right away. Again, Medicare may not want to pay for that but from a patient point of view it's desirable.

So you can see the kinds of imaging of the low back or the knee, for example, those kind of episodes, I expect that the imaging will just increase the cost of care for the episode with quality increases that are more the

subtle kind of thing that I just mentioned than anything that one can really define as a treatment benefit.

DR. CASTELLANOS: First of all, thank you for coming. We really appreciated this.

I don't think there's any question that we all recognize there's a problem. I think we can beat that into the ground but we all recognize that. The question is how do we deal with the problem? This is what we want your help from.

I have a couple of questions for each of you and if you mind if I go over that. Larry, I thought it was a good presentation. One of the things that bothered me a little bit about your talk was that 2 percent chance of cancer. That's the New England Journal article that was written by the group in Colombia. And it was really extrapolated from the Hiroshima data. This is totally estimated over the next 20 to 40 years. The reason I ask you to comment on it is because we shouldn't use that to prevent people from getting CAT scans when it's appropriate. I think the authors in that article say that.

I think if the lay public hear that 2 percent it kind of raises a flag. And I think it should be a

discussion between the physician and the patient. And quite honestly every medical specialty is looking at that issue of overexposure to x-ray. So I think it's a point to bring up but it shouldn't be a red flag.

Larry, I thought your point was good about utilization. We've already started some breaks with the DRA, which started in 2005 but wasn't implemented until 2007. Nobody mentioned the results of that. I think the data for 2007 is out and it shows that there's been a significant decrease. It's cut down the rate from 2005 to 2006 by over 50 percent. So policy has helped but I think we need more than just policy.

I think appropriateness is the word, and I've heard that. Bob Reischauer last year mentioned something very smart and very astute. It's not the site of service where you get the study done but it's the appropriateness. It is just as appropriate to have that study done in my office -- and Bruce, I'm one of the criminals from Florida. I have a CAT scan machine but I can tell you the benefits of it -- is there a financial benefit to me? Yes. I'm not going to say there isn't. But there's a significant benefit to the patient: convenience, early diagnosis, coordination

of care, safety. And in my office it's a savings to the Medicare program as opposed to getting it done at the hospital or somewhere like that.

So there are some benefits so you don't want to throw the baby out with the bathwater. So I think appropriateness is...

Larry, the other comment you all made, and especially with the GAO study, is how can we front end stopping this? It may be necessary to do that. I'm not saying it's not. We were fortunate last year to have a panel of experts on imaging. I don't really recall everything that was said but I went back to get the data and I looked. There was a gentleman from Minnesota who was a primary care physician. I know because I went up to talk to him afterwards.

Instead of having preauthorization, which seems to be maybe a stumbling block, he mentioned prenotification. I don't remember his statistics but in his printout thing that he gave out he said prior notification had a significant impact without any denial required.

That wasn't mentioned, about prenotification. I really would like any information you have on that. Maybe

that would -- certainly from the physician community it would be much easier, it would be less of a hassle and less work. And I don't think any physician wants to do that but I think if we need to do something that may be a little bit more appropriate.

Again, thank you for coming. We really appreciate your talk.

MR. HACKBARTH: Thanks, Ron.

Before the panel answers, I'm a little worried about the time. We've got a half hour and I think almost everybody had a question to ask. I would ask the panel to really try to be brief in responses and probably we'll have to limit ourselves as commissioners to one question. So choose your best one while you're waiting your turn.

Go ahead.

DR. CASALINO: I can respond very quickly.

First of all, basically agree with what the thrust you're saying is. The most important thing for me that you said is don't throw the baby out with the bathwater. If you give me a policy choice of everyone is going to have prior authorization or we're not going to let physicians do imaging in their offices, I'd say great, let's go for the

prior authorization. I think it would be a mistake to ban all in-office imaging. I do think there should be standards.

Prior notification, I don't know how good the data is. I've had conflicting stories. But it's certainly something that could and should be considered probably.

DR. BAKER: It may be a brief comment to agree again with the notion of appropriateness and making sure we do the work to get the quality effects considered well.

The one thing that I would just note, you asked about the DRA effects and the changes over time. I think those will be studied for varies reasons that I don't want to bore you with. We don't have the newest data yet. But as soon as my group gets them we will work on it and I'm sure others would do that, too. So I presume we will know within a fairly short period of time what happened with those.

MR. STEINWALD: GAO is going to come out with a report within a month on the effects of the DRA and some of the information is already out from CMS.

Ron, I'm sorry about the Florida remark. The point there is how variable spending per beneficiary is.

And as in other context we look at that variability and we say well, then it can't all be appropriate if people are getting a certain level of services and with all the evidence indicating quality and outcome roughly equivalent in the lower spending areas than in the high, we use that information as indirect evidence of a concern for excess utilization.

DR. DEAN: I will follow up on Ron's question. The whole issue of preauthorization -- I'm a primary care physician. But you sort of responded to that.

But if we're going to get to the appropriateness level that we'd like to have, which we assume we're not there yet, it depends on the development of criteria and guidelines and so forth. And I wonder what your opinions are in terms of how well developed those are? No guideline is perfect and there's always exceptions. And in this area I think there's probably a lot of exceptions. I don't know. I'm just curious in looking at this how well developed are the guidelines in the criteria? And are they useful enough to move us forward in terms of deciding appropriateness?

DR. CASALINO: I don't feel that I am familiar enough with the guidelines in each area of imaging to make a

useful comment about that. But you know as well as I do that when you're actually out there in the field -- and especially for the more vague kind of problems, not when you know someone has -- they just have a TIA yesterday. You can do guidelines for that. But it's pretty easy for physicians and patients to think the guidelines don't apply to the situation.

But I don't have a good answer to your question.

DR. BAKER: I don't have a great answer in the sense that we have not ever tried to survey the literature. Plus I'm an economist. So when I read guidelines I read them with a very different viewpoint than a physician.

We have, in some cases, been able to go and, as an economist not necessary training in all the details, we have been able to go, in several cases, to the literature and find things that look clear enough to me to do analysis on. Back pain is one example. But we've never done a systematic study to know if we're there for all the different conditions that are out there.

MR. STEINWALD: The specialty societies are working on it. I can't tell you how far they've gone. But if you go to their websites, the American College of

Radiology and Cardiology, you'll see at least some evidence that they're investing in the development of guidelines.

MS. BEHROOZI: My comment and question is about imaging so I guess maybe it's mostly directed to you, Bruce. I was surprised that a minority, I guess, of the plans that you talked with have privileging in place while virtually all of them had prior authorization. In our plan, which serves a few hundred thousand health care workers, we recently instituted both prior authorization and privileging -- and part of the reason that we did them together was because prior authorization, while we talk about it in here as a useful tool to manage inappropriate utilization, out there it's called denial of care.

So when we were messaging to our members and getting them to accept this new regime, the theme was the right procedure at the right time from the right provider. And privileging really is, for us it was lower hanging fruit administratively. It's not that only radiologists can perform imaging procedures. But by specialty there certain groups of codes that we will pay for. It might be outer extremity fractures in a primary care physicians' office, that could be included given the evidence.

And especially in light of how privileging addresses more directly it seems some of those quality assistance and some of the issues about the arrangements like the per click and leasing deals, I wonder if you have any impression of why it's not utilized more or why you wouldn't emphasize it more in a recommendation to CMS?

MR. STEINWALD: I don't have anything bad to say about privileging. And let me emphasize that our survey of the private plans wasn't a random survey, and so you shouldn't take the proportions of plans that use any technique as representing a national proportion.

As certainly many of them do use privileging and maybe that's a trend that will go forward. But all we did was observe that of those that are really attempting to manage the benefit, the vast majority of them are using prior authorization, sometimes in conjunction with privileging as your plan does. And many of them though also are using instead prior notification. Profiling is another technique. So there is a range of techniques at play but in the groups that we talked to the one that is clearly the most prevalent is prior auth.

MR. BUTLER: Okay, I'm pretty passionate about

this particular subject not just because of the cost issue but because of some of the patient care issues. I would start by saying that it's easy to jump to bad guys or greedy guys or whatever but you first have to recognize the spectacular advancements that's been made in imaging. What's available is just unbelievable.

You know what? We all love it. The consumers love it and the aging baby boomers, we have tremendous appetite for this ourselves so there's a lot of demand out there as it is.

And I would point to the inpatient hospital side where we live under fixed rates. And if you looked, I suspect, at for example use of CT in the inpatient side when we have all the incentives to do less rather than more, I don't know if it's going up as fast as the data that you show here but it's escalating a lot. We are putting CT scanners in our ERs and it's not in our financial interest to do so but it's right for patient care. So there's a lot of demand out there that really is pretty independent of the self-referral types of issues.

Now having said that, let me just comment on two kinds of groups where I've seen this in more than one

setting myself. Let's take the large orthopedic group that owns their own MRI, that has board certified radiologists involved in reading the exams, that has a first-class service. It's kind of hard to say that that's necessarily a bad arrangement. It's great for patient care from both the quality and a service standpoint. It's a question about do you put some governor on the volume side? And how do you address maybe some payer mix issues where they refuse to treat certain kinds of low-paying patients? But that's a very different kind of scenario for me from the primary care side on the other end of the spectrum.

And Bruce, you're an advocate of paying primary care physicians more, I know, but they got into this dilemma because they're looking for other revenue to support a tough office situation. So it's not just the per click arrangements but it's also bone density and things like that that they've put in their offices that isn't always high quality.

But the worst of all is where I see a primary care group that is on the campus or next to a hospital having per click arrangements with MRI freestanding operations that are as far as 15 miles away, and then they're getting real

income for the leasing or the per click arrangements. Those things are the things that really ought to be -- there's no reason that we shouldn't close those loopholes as soon as possible.

So two different examples but I think you have to begin to separate some of these and due pick off some that are early opportunities.

MR. HACKBARTH: Any reaction from the panel?

DR. CASALINO: I would just say that I agree. I haven't yet heard -- as I hope I implied in my presentation maybe there are good arguments for per click arrangements and similar kinds of things but I have yet to hear one. And I think you have described it very well.

MR. BERTKO: A quick question probably for Bruce. I've been on site with one of the biggest RBMs and their claim was that for some of the most expensive procedures their denial rate was almost always upheld. I was wondering whether you looked at the rate of appeals and appeals overturned for any of those RBMs you might have visited?

MR. STEINWALD: No, we didn't try to independently validate what we were told by the plans and the RBMs. But it's very interesting. In fact, when our report was in

draft we had two organizations review it in our office. One was AHIP, American Health Insurance Plans. The other was AMIC, the Access to Medicare Imaging Coalition. And you can imagine they have different views of prior auth.

What AHIP said is that they believe that the rate of outright denials is very low and becomes lower over time as the prior auth radiologists work with the physicians who were requesting prior authorization. I don't have a statistic but it's very, very low. And they see prior authorization more as an educational tool as well as a cost control tool.

AMIC sees it very differently, sees very little education benefit. It says that the reason for outright denials being low is that doctors get tired of jumping through hoops and they withdraw their request, as opposed to waiting for it to be denied.

So who's right? I suspect a little bit of both but I can't cite you any statistics.

DR. KANE: I have one question which is actually two but I'm going to combine it into one.

In a way, it's a bit -- I guess the question is to what extent is imaging growth any different than what we saw

10 or 15 years ago in physical growth and rad growth when physicians start to self-refer? And what is the threshold at which somebody decides this is too much?

We've done it before, it's kind of a whack-a-mole problem. You take away one source service that you can self-refer to and then another one pops up. I'm just wondering, should there be some standard level of evidence at which self-referral is no longer allowed? And that wouldn't necessarily pick on imaging. There's other types of services.

I guess the other part of the question is all of these different methods, how much of these problems would go away if Medicare patients who were not poor had to pay the 20 percent copay out-of-pocket?

I'm sorry, that was two questions.

MR. STEINWALD: I don't know.

DR. BAKER: I don't think there are direct studies of the latter question on imaging, particularly. There are, certainly, bits of economic evidence that suggest that if you made patients pay more for this they would use less. And one could start to build from there a case that there would be some effect. But I wouldn't even want to begin to

speculate about how big that would be at this point.

Is imaging different? I think it's a good point that you make. There are certainly differences in spending on different kinds of things and it seems to me that when things get expensive we start to look at them. We spend a lot of time on MRI but there's also self-referral for x-ray and that gets less attention other than in the global imaging kinds of calculations. But one would find the same kinds of effects for x-ray in our work. If you buy an x-ray machine you use more x-rays, as well. We just don't spend time on it because actually they're only reimbursed by Medicare -- well, for 5 percent of the cost of an MRI or something like that.

It's a good point and it seems to me that it's the dollars.

MR. STEINWALD: And imaging really does kind of stand out. I appreciate your remark about at being other services at different points in time. But when we look at it it's partially an affordability issue as well. It may well be, as Larry said, there are some services that are of benefit to patients for different reasons other than strictly speaking clinical benefit. At some point, Medicare

I think needs to, as you well know, look at its spending trends from an affordability and financing standpoint as well as clinical appropriateness.

DR. SCANLON: I really appreciate this because I think it really highlights beyond the question of getting the prices right and deciding who are the right people to provide a service. You really need to look at the individual services that are being provided.

My question would be shouldn't we give post-claims review a decent chance to work? Bruce, you characterized the current situation has pay and chase. I think we could review and then decide to pay as one option.

The other thing that I think that we need to think about, and this is maybe in part CMS's response, Medicare is different. It operates with very skimpy administrative resources and it has to operate in a world where everything is transparent. I think those two things are very important to consider when you think about prior authorization because, as Mitra said, it's got a bad reputation already. And if Medicare starts to do it badly it only continues to tarnish the reputation.

So the question that is giving post-claims review

a decent shot would involve improving the resources that are available to do this, doing it in some ways in an enlightened way. Maybe pick up on Larry's idea that we're going to target this to particular providers. Not everybody is going to have post-claims review. Not everybody's going to have to submit additional documentation. But we're going to expand what was now under focused medical review in the imaging area in a very broad way so that we actually can deal with the kinds of trends that we're concerned about.

MR. STEINWALD: No question about the skimpy resources. And if CMS's response to our recommendation had been we think it's a great idea but we need the resources to implement, our response back to them would have been we think you should have them. But of course, that's not the dialogue that occurred.

As far as giving post-payment claims review a chance, obviously we didn't criticize CMS for highlighting imaging as an area for focusing on post-payment claims review. We said that that's a good idea but of course that's more fraud-oriented than appropriateness-oriented. Maybe it will have an effect and we will know that within a few years.

I would hate to wait for several years to implement a more front-end approach if that's what the implications of giving post-payment claims review a chance. I think our position would be to do both in conjunction. And if CMS needs more resources for a more front-end approach, I think we believe they should have them.

DR. CASALINO: I'm sympathetic to what you say about the problems with prior authorization. I'm not so sympathetic of Congress not spending $1 to get $5 but that's another debate.

But I don't have much optimism that post-claims review could do it. If you're doing it just on claims you might detect some fraud but I don't think it would get at the broader problem.

I think if you start to demand documents, that gets labor-intensive and it's much more intense than prior authorization because here you have people who have provided a service and now you're saying you won't pay them so it even multiplies the problem.

So I think it's an interesting point but I would be surprised if it would do it.

DR. MILSTEIN: In the GAO report one of the

findings I found very compelling which Bruce didn't have a chance to draw out was that the commercial HMOs that have put these pharmacy benefit management firms in into -- have implemented them, if I'm going to quoting this correctly, have experienced a 50 to 75 percent reduction in imaging studies compared to their pre-implementation state. I assume I have that approximately right?

MR. STEINWALD: I didn't emphasize that other than I think I said that the plans that are doing it believe they have achieved savings that warrant the added cost. But since we didn't independently try to verify their claims, I didn't think I should emphasize that.

DR. MILSTEIN: My question is as follows: the more precise the control tools one wants to apply in either assuring quality or appropriate utilization, as a general rule the more burden they tend to impose both for those applying the controls and those subject to controls. So there's a trade-off between precision of control and amount of burden in implementing it or being subject to it.

And I think prepayment review against guidelines is very precise. Essentially you're attempting just to pick off those services that don't meet guidelines. But they

unfortunately bring along with them a non-trivial implementation burden both for those being reviewed as well as those doing the review.

I wondered, obviously Medicare has begun to put its toe in the water with respect to low administrative burden but obviously blunter tools. I'm thinking of things like the code creep automatic offsets that have been applied I think to the Medicare Advantage plans and perhaps hospital DRGs. I don't know, but that's an example of a blunt tool but it has low administrative burden both on those doing the implementation and those being judged.

I wonder if any of you could comment on the pros and cons of something similar in relation to self-referring physicians with respect to imaging? That is, based on research that might still need to be a little bit more refined, if we can infer what the incremental use is of physicians who are self-referring relative to their peers who do not own the equipment, what would be the pros and cons of simply a fee adjustment to offset the detected percentage increase that is purely associated with owning rather than not owning imaging equipment?

MR. STEINWALD: Well, I find it hard to respond to

that. Again, in Medicare a fee adjustment of that kind would probably require statutory change, and it could be quite difficult to both design and implement. And so I'm not saying it's a poor idea. I think getting the prices right, as Bill said, could be service and physician practice-oriented specific. But I think very hard to implement, especially if statutory changes required.

MR. EBELER: Thank you very much for your presentations.

As I hear the sum of them and move to policy, it sounds like one would think about some targeted approaches possibly looking at inappropriate arrangements. I think Peter flagged some of those. Some of you mentioned them. Prior authorization may be targeted to places where we have particular concerns. It sounds like an interesting package. It's difficult obviously technically in a lot of ways.

For everybody to put that in context of other things that we've talked about both yesterday as in other Commission things, none of these sector-specific constraints are fun. And when we look at just imaging it's sort of like why are we picking on imaging? I guess to go back to the context chapter yesterday, we are sort of looking at

everything. And sort of as the Commission processes this, it's sort of looking at this in the context of the total cost discussions we're having. And I think particularly within the physician community the growth here implicitly, and in some cases explicitly, constrains sort of fees for all the rest of physician services. So this is not -- just that total cost context, I think, is important.

Second, I would be curious of any of the panel's recommendation about other -- sort of the broader way arrays to deal with this. We're talking about utilization now but I think just the last two questions -- one would look at this growth and say we probably still have a fee problem here. When you have this kind of growth one suspects that one is overpaying. We've also talked a little bit about the Resource Use Measurement project that we talked about yesterday, getting information about total resource use.

If you could elaborate beyond the particulars here about the breadth of tools one might use to get to some of these problems.

MR. STEINWALD: Actually you, MedPAC, have done work in this area and have come to the conclusion that a lot of the fees that are set for new technologies assume a level

of usage that may be accurate when they're in the early diffusion stage but inaccurate once they more thoroughly diffuse. I think your work in that area is very apropos of imaging as a technology that's advancing and diffusing very rapidly.

One of the interesting things about that advancement and diffusion is how suitable the new technological advances seem to be for doctors' own offices.

So this whole issue about well, what's an appropriate level of use is sort of setting dependent, too. On the other hand, one could argue that the payment level ought to be at the efficient level of use. And if a given practice is unable to achieve that level of use, that doesn't mean that the payment rate should be higher.

But you've done the work on this area I think that's most definitive.

DR. CASALINO: Conceptually, I don't think this is -- politically this is a hard problem to fix. Conceptually, there's always going to be problems as long as we're in a fee-for-service system. But even in this present system I think most of the problem could be taken care of in terms of cost and quality if the conditions -- if there were

standards for what you had to do to do imaging things. And certainly Medicare could do that.

Consider prior authorization, especially for -- this is technically harder and politically as well -- but for the high users. Ban some of the more obviously abusive arrangements like per click. And take a good look and see what's going on with IDTFs. And I don't know if there need to be any policy changes there or not.

Personally, I think those things are -- well, you know better than I do whether they're doable. But I think if they were done they would reduce the cost problem a lot and we'd also have much higher quality overall of the imaging that's done in the country.

DR. BAKER: Let me take a slightly more concerned view of the ability of just standards and other related control mechanisms to be effective over the long run because the technology is evolving quickly. Because as we put more of these things in the idea about what's appropriate practice will change over time. And so I would actually think that you probably need to do things beyond that to really make progress.

So without knowing exactly how the DRA fee changes

and so have affected things, I don't want to take a strong point of view. But I would certainly believe that changes in fees could be a way to change the incentives here and would probably have a noticeable effect on things. I think there's just lots of economic evidence from other places that that's something that you could consider. But it would be very informative to see how some of the last couple of years have played out with the DRA fees as a starting point to start to understand that better.

DR. CASALINO: If it may, I just want to emphasize that we do need to see how that plays out because if you lower fees for physician visits you may -- well, there is some data on what happened with that. But because it takes you no time to order a scan, as long as you're making some money on it, if your fees are cut you may get fewer people buying machines. But the people who have machines, they're not necessary going to do fewer scans because their fees are cut. They may do more scans. But we'll see what the data shows.

DR. BAKER: That's a good point.

DR. REISCHAUER: Just elaborating on a couple of things that have already been talked about. And Bruce might

have answered this question but we're all concerned that financial incentives might lead to inappropriate utilization.

My first question in listening to the presentations was why hasn't somebody tried to compare the level and growth of imaging in fee-for-service Medicare with that that occurs in capitated plans? And that might not come up with what's necessarily medically appropriate but it would be what's politically feasible and medically threshold there. And maybe the data aren't available and, Larry, maybe you've looked at it and know the answer.

But going to Jack's point about the payment levels, one would think it must be too high. Having sat on this Commission for nine years, any time that I see a tremendous expansion in service delivery in a certain area, an increase in the fraction of services provided by the private sector, and the development of innovative financial arrangements, bells begin going off and you think well, we're probably paying too much.

This is a very difficult area because of the nature of the costs of the services which a huge chunk of it is a capital cost. And so the way you reduce your per

service cost is to increase the volume. One would think well, then maybe we should either set prices assuming a very, very high volume or we should have the prices vary with the total volume of images for both Medicare and other providers that this machine serves. But that gets you into then a whole bunch of other problems.

And I come back to where I think I've been for a long time, which is is there any way out of this except bundling and capitation to get the incentives right?

[Laughter.]

DR. BAKER: The first question is easier to answer about why haven't we compared capitated settings? And it's a data issue. It's that there's a lot of data on non-capitated settings on utilization and there's not a lot of data on capitated settings. There are a few that we have made some not too energetic attempts to analyze and failed. So one of these days somebody will have some data and there will be a chance. But it just hasn't been done.

DR. REISCHAUER: I think people like Jay might have the data if we ask for it. Somebody should.

DR. BAKER: It's not that it's impossible. It's just that it's not the low hanging fruit in the area that

people have looked at.

As for other bundling kinds of incentives, it's certainly the case that those kinds of incentives would change the game a lot and would probably lead to the development of efforts to be more efficient in a way that would happen much faster, in my view, than with fee-for-service kinds of arrangements. I'll just say that much.

MR. GEORGE MILLER: Again, I enjoyed the presentation. I thought it was very well done.

I was struck by your comments about IDTFs and the fact that they were somewhat unknown. That causes some concern to me.

Do you have -- can we give you a challenge to get more information? I can only give you anecdotal information as a hospital CEO. A firm came into our community and told us they were coming and that they would be going to all of the primary care physicians and take and suck business out of the outpatient and inpatient hospital setting to do that if we were not interested in partnering with them. And I think this particular growth or this particular area has some major problems.

And so from a policy standpoint, what would you

recommend how to approach this particular issue?

Now I realize my statement is one person anecdotally but I suspect that more of this is going on, particularly since you couldn't find out a lot of information about who owns them and their method of operating.

DR. CASALINO: I do think they need to be studied and I think it's the kind of thing that would be hard for a non-governmental person to do. Laurence or I can't really go out and demand -- first of all identify IDTFs and secondly demand that they tell us who owns them. But maybe Bruce can, or whomever.

So I do think it's an area that, much as I'd like to study it, I think that's an area that maybe has to be done by someone with some mandating authority. And I think it should be done.

It's hard to make policy when you don't know about them.

MR. GEORGE MILLER: Part of your policy recommendation is that we eliminate per click recommendations, that would include IDTFs, as I understand the way they operate or the way they told me they would

operate.

DR. CASALINO: Yes, but I agree. I have no idea how common per click arrangements with IDTFs are and I don't think anybody does. But that should be known.

MR. GEORGE MILLER: They take Medicare dollars.

DR. CASALINO: Yes.

MR. STEINWALD: Indeed, they do.

DR. CROSSON: I want to compliment all three of you for bringing us a very good mix of data and judgment because that's what we have to use to try to make our own judgments in the end. All three presentations are very good.

A lot of the ideas that I had had for questions have already been asked and answered.

I would just make one comment on Bob's comment. I do think that since where we're going to end up is likely to be some very targeted recommendations, the idea of trying to understand more thoroughly with the use of benchmarks what the ideal practice or the range of appropriate practice would be is possible. And I think there are benchmarks that we could use from both the prepaid group practice community but also the somewhat larger multispecialty group practice

community where the physicians are not necessarily paid in a way that would act as an incentive for increased utilization of imaging, salaried physicians and the like. And Dr. Baker, right next to you is Dr. Casalino who has the NSPO database which is one of the largest databases on the characteristics of those practices. So there is, I think, some room there.

I did have one specific technical question for Dr. Baker and it has to do with the question of whether the impact that you showed of self-referral could be understated a bit. I noticed that you chose a period of seven days after the initial office visit and the performance of the imaging procedure. It strikes me as a bit short. When you did a calculation of total costs later on you used 30 days.

I wondered why you chose seven days and whether or not you have some concerns that that might, in fact, understate what you were examining?

DR. BAKER: We chose seven days because we had to pick something and we had to make the analysis work. So we've actually done it seven days, 14 days, and 30 days. As you go from seven to 30 you increase that estimate slightly. So from the orthopedists it's 1.5 percent at seven days.

It's probably about 1.8 percent or 1.9 percent maybe at 30 days. So there's not a lot of action out there but there's some. And one of the things that we started to be worried about was just other things happening out past that visit so we thought seven was a little cleaner to present. But there's no reason that that has to be the case. It could be that all of that is associated with that index visit and that's a real estimate.

There are other somewhat technical reasons that the estimates could be slightly understated. There are other things that you could have raised that I will just maybe in the interest of time not spend a lot of time and effort on. But there are a couple of reasons, notably that the control group in our analysis for time trends include people who are billing to IDTFs who may have some increased use also. So our control group is not a perfectly clean control group of people who don't have any incentive at all. And so that may lead us to also slightly understate the effects, probably not by a lot but maybe by a little bit.

DR. CHERNEW: That was really fascinating. I will try and be really brief. I recognize given this and everything that we have to do something in the short run and

we have to work with the tools and the framework that we have. But my overall opinion is going forward we need to begin to think about diseases and patient groups, as opposed to services. I was encouraged as we have to address these things in the short run to try to think of ways to think about diseases and patients and not services because there is such a heterogeneity in this. I just think, thinking on the surface level, it sometimes becomes somewhat counterproductive.

I will go on the record because I'm told we have to go on the record that I'm skeptical of prior auth. I could be convinced otherwise. But for the reasons the Bill said and others, I think having prior auth work well in Medicare for a range of reasons I would need to be a little more convinced of.

Which leads me to my question, which is how much of these services could be bundled in an episode? How much of them would define their own episode? How much of this increase is in a new person getting one image versus one person getting more frequent images for the same thing? I think to think about this in this bundling way -- and I very much agree with what Bob said -- I need to understand more

if these are just within an episode we're just doing more imaging or if all of a sudden we have just have a whole bunch of new episodes that are going to be defined by the fact that there is now this image that was done?

Sorry.

MR. STEINWALD: It sounds like it would be useful information to have, especially as you continue your work on bundling, to know how much of these advanced imaging services are going to be captured in a bundle. That would be obviously very useful information. We don't have it, or at least I don't.

DR. BAKER: All I can say from our work is that there does seem to be plenty of expansion with a fixed definition of what an episode looks like. So an index visit to an orthopedist following a period in which you haven't had any orthopedist visits, start with an outpatient E&M code and go forward, there is plenty expansion of imaging holding that definition of an episode fixed over time, we see lots of expansion in imaging. Whether there would be other episode definitions that would start to shed light on your question more broadly, we have certainly not explored but it seems to me to be a very interesting question.

MR. STEINWALD: Just to add a little bit, we see a lot of the growth in imaging services in cardiology and orthopedics, both specialties that are -- where episodes occur. So I can't directly answer your question but I suspect that a lot of that growth in those two specialties is within episodes that would be captured, at least in part, through some bundling technique.

DR. MARK MILLER: Let me just say something quickly here. I'm not going to go into it because we don't have much time. We have some work going in the background using episode groupers and that type of thing for a couple of reasons and may be able to get at some of what you're asking.

DR. STUART: I would simply like to reiterate a point I made yesterday, and that is that CMS has recently promulgated a rule that requires that MA plans provide a complete 100 percent reporting of event level data and that this is an opportunity or presents an opportunity for MedPAC and others to provide the kind of benchmark data that Jay has mentioned and that Bob has mentioned if that data become available. So there's nothing that says we don't know the quality of the data, we don't know when it will be

available.

But it's just something that ought to be on our radar because this is one of a number of different kinds of studies that MedPAC could undertake that would help us get inside that black box of MA.

DR. BORMAN: Just trying to look at this in some sort of bring it back together way, cohesive way, for me as a surgeon and not an economist. I see this as having basically three pieces and I have some questions about how the pieces interrelate. One is sort of what I might term the technical piece. And that really is the facility, the utilization, the equipment, the delivery, kind of not the clinical appropriateness part. You've alluded to the previous work here about 50 percent utilization versus higher percentage time of utilization of the equipment. It seems to me that that may, in fact, continue to be some low-hanging fruit on the technical side.

Also, sort of on the provider side if you will, there's the appropriateness piece which your presentations I think helped inform very nicely.

And I see that as having two pieces. There's sort of an immediate potentially low-hanging fruit piece. The

American College of Cardiology, for example, has very nice guidelines. We had their presentation before. They have very nice guidelines about some things. You've identified cardiology as one of the explosive growth areas by comparison -- maybe for good reason but explosive growth area. Why are we not in a position to take those good guidelines that they have addressed and implement them as some sort of screen?

It needs to be done, as much as possible, in an automated way for all the reasons that people have alluded to Medicare, difficulty to deal with, potentially preauthorization things. And with Larry's point about protecting the 80 percent of people that are doing the right thing. But there may be some very ready to roll guidelines that could identify some egregious things that could, in fact, go forward.

I think on a more strategic level what I hear, to some degree, is going on is we have a payment system to physicians that grew out of an era that was dominated by hospital-based care. And in the RBRVS practice expense, back when it was developed, didn't really include owning a lot of equipment, not big-ticket equipment like MR machines.

So this, to me, says to some agree we've outgrown the practice expense component of the fee schedule. And are there some creative ways to move that outside? Looking at this over the longer term, is that part of the long-term solution?

And then finally on the beneficiary/consumer side, what I heard loud and clear that bothers me very much is the safety issue. And I think that that again should be low-hanging fruit. I have a bit of problem with accreditation versus privileging. But I think accreditation ought to be a no-brainer and low-hanging fruit.

And there are some basic standards about radiation safety, training of technicians, shielding of patients and things that every patient is entitled to with every radiologic study. We ought to stand foursquare behind that kind of thing now. And that brings benefit to the beneficiary right now.

So I see this as a three-pronged thing, sort of thinking about the piece we've already recommended about the utilization, a second piece of big picture does practice expense belong in the RBRVS for these kinds of things,

implementing guidelines that are ready to go now, and let's make it safe for the patient. And are there other things that we could do or could you tell me what you think about the practice expense piece particularly, how that interdigitates with what you've shown us?

DR. BAKER: I have not thought enough about that.

MR. STEINWALD: It's always good to think before you speak.

DR. BORMAN: You maybe wish I had.

MR. STEINWALD: That only works if you can think of something to say.

DR. MARK MILLER: I know you're struggling with this. I think really, particularly the last one you said, that's in our -- that's in our -- I mean, if you guys want to pick it up, too, knock yourself out.

MR. STEINWALD: I was going to hand it right off to you.

DR. MARK MILLER: I sort of felt that was coming. And if I had a pointer, I'd get the --

[Laughter.]

DR. BORMAN: Should we all chip in and buy you a pointer?

DR. MARK MILLER: It's a thing between he and I. Let me deal with it.

I think that one kicks into our court. There has been work done by Ariel and Nancy on the practice expense component and this Commission has raised this issue of the utilization rates and how that's built in. We talked about things like surveying. But the other thing -- and this came up but I want to make this point clearly to everybody in the room -- the other way you can think about this is what should be the standard? What is an efficiently run practice? And set the use rate at that level and make the payments on that basis.

And that also, by the way, has a price effect which was, in part, discussed here as well. But I think that one falls on us at the moment. We probably have the most work on it and something that we can very much bring up with the Commission and work through with you guys in the next few months.

MR. HACKBARTH: On the third piece, the accreditation piece, we had made recommendations I guess two years ago that there be an accreditation process applied to these services for both the technical and professional

components. In MIPPA, as I understand it, Congress picked up the technical piece and is requiring a process of accreditation, which I assume will include safety issues, as well.

MR. STEINWALD: For advanced imaging.

MR. HACKBARTH: Yes, for advanced imaging, thank you.

We're out of time. Great job. We really appreciate your investing the time and look forward to working some more on this issue. I'm sure it's going to be around for a while.

[Pause.]

MR. HACKBARTH: The next presentation is on Part D and a discussion of our work plan for the coming year.

MS. SUZUKI: Good morning. Rachel and I are here today to talk about our work plan for Part D. Even though it's just the two of us up here, we wanted to acknowledge our colleague Joan Sokolovsky, who's been central to our Part D work.

Medicare's Part D benefit is now in its third year. The program now has more than 25 million enrollees and an annual benefit spending of about $50 billion. During

the past three years we have reported on various aspects of Part D, including how the market for private plans unfolded, how beneficiaries chose among plans, and trends in plan enrollment, benefit design, formularies, and premiums. We've relied on information from CMS and data gathered through beneficiary surveys, focus groups, and interviews with relevant stakeholders to report on these.

The Commission has been recommending that we and other Congressional support agencies get access to Part D data for a long time. The recent change in Medicare law will give us and other agencies access to this data and, as Mark mentioned to you yesterday, we just received the 2006 claims data.

The claims information will significantly expand the types of analysis we are able to conduct and will allow us to better analyze issues related to cost, quality, and access. Over the next few months, we will be working hard to understand the data and also get a handle on whether program's initial startup difficulties and data reporting issues may have affected the quality of the 2006 data.

The potential agenda for Part D research is extensive. We've identified topics of interest group by

those that did not require analysis of claims information and those that do. In many cases, projects that do not require claims information are already underway and we are hoping to report some of the findings in the March and June reports.

Most projects that require claims information are not yet underway and they will take longer to analyze. We do not expect to have results that could be included in the March 2000 report but once we have a handle on the 2006 data we will begin answering basic questions about Part D with these data and we'll bring our analysis to the Commission as soon as possible.

Next we'll discuss the research topics in these two categories in a little more detail. We've identified four major areas of research that do not require claims information. The first area is our usual analysis of Part D marketplace, monitoring trends in plan enrollment, benefit design, formularies, and premiums using the same data sources that we've been using in our past March reports to Congress.

The second area is the Medication Therapy Management or MTM programs. Part D requires plans to offer

MTM programs for beneficiaries with multiple chronic conditions and high drug costs. One example of an MTM program is when plans pay pharmacists to speak with beneficiaries about the drugs they're taking and discuss safety issues and promote better adherence. Currently there are no standard performance measures to evaluate the effectiveness of the MTM programs. We are looking into various MTM programs under Part D and in the private sector to explore best practices.

The third area is beneficiary-centered assignment. Yesterday you heard a presentation by Jack Hoadley on this topic. We plan to explore this and possibly other approaches that may minimize the disruptive effects associated with changing plans.

Finally, we plan to look into the effects of using specialty tiers and the role of biologics. We've already touched on plans' use of specialty tiers in our past work. Remember from our presentation last fall that most Part D plans now use a specialty tier for drugs that cost $600 or more per month. Enrollees pay a 25 percent to 33 percent coinsurance for these drugs and cannot appeal those cost-sharing requirements as they can for drugs on other cost-

sharing tiers.

These drugs are often for serious conditions like rheumatoid arthritis and multiple sclerosis so their Part D cost-sharing is often in addition to cost-sharing for other medical services. NORC and Georgetown University is already working to help us understand which drugs are on specialty tiers using formulary data.

Many of the therapies and specialty tiers are biologics which are newer therapies that are more complex to produce than simple drugs. Biologics are a relatively small share of spending today but we expect that share to grow faster than for other kinds of drugs over time.

Because of features built into Part D Medicare may end up paying for a higher proportion of the cost of biologics than for other types of drugs. Therefore, the Commission may want to consider issues related to biologics and follow on biologics.

I'm going to turn it over to Rachel, who's going to talk about topics that do require claims information.

DR. SCHMIDT: I'm going to go through a pretty extensive list that could easily keep us busy for the next several years.

The first project is already ongoing. We've contracted with Dr. John Hsu of Kaiser Permanente's Northern California's Division of Research to look at Part D risk adjustment. This project is already underway because Dr. Hsu obtained Part D claims information directly from several insurers. He's using those data to see how the predictive power of risk adjusters changes when you add information about an enrollee's past prescription drug use and whether there are ways to do this without diluting plans' incentives to control drug spending. He's also looking at how well the risk adjustment factors perform for low-income subsidy enrollees.

Shinobu told you that we received 2006 claims information from CMS just this week. We are literally just looking at the files. So we're obviously just beginning to do that.

But getting these data out is a really complicated task. CMS has been working hard to do this and they're still preparing some additional files that both we need and external researchers need as well to analyze these claims information a little more thoroughly. This is going to be an ongoing process. We also hope to get 2007 data from the

agency sometime either at the end of the year or perhaps early next year.

We're going to use those data to analyze some basic questions that we all want to know about, such as those on the slide: the number of enrollees who are reaching the coverage gap, average out-of-pocket spending and the drugs and drug classes that are used mostly widely by the population.

Another topic that we think will be important is geographic variation. Remember that at the Commission's planning retreat last summer you decided that you would like the staff to look at geographic variation on a topic by topic basis. So here's an example of that. For Part D, we want to know whether there's as much variation in drug spending as has been observed in Part A and Part B spending.

Shinobu described the issue of specialty tiers and the fact that we already have some work underway on that issue using plans' formulary information. But if, in addition, we start using claims information to look at that topic, another avenue of research would be to identify the enrollees who use the drugs on specialty tiers, look at their levels of out of pocket spending, whether they're

hitting the catastrophic cap, and those kinds of questions. So claims will help us better analyze some of the questions about equity that surround specialty tiers.

In past work, we've talked about special groups of beneficiaries that we want to keep an eye on. Enrollees who receive low-income subsidies are one example because CMS reassigns some of them to different plans each year. We've also talked about beneficiaries who live in nursing facilities and how Part D works in their context. With claims information we could look specifically at these groups and see whether they've continued on the same medications or whether they've switched to a different drug in the same therapeutic class. We'd also like to know how many have discontinued therapy but we'll have to be careful there because all that we have are Part D claims. We won't know, for example, if someone started buying drugs on their own or off-formulary, outside of the Part D plan. The goal here is to look at their access and medication adherence.

Claims will also help us identify all sorts of beneficiaries who are spending at the levels that put them into the coverage gap and how they respond to paying for the full price of their drugs out-of-pocket. What are the

effects of that higher cost-sharing on adherence to their drug regimens? And more broadly, linking Part D claims to Part A and Part B claims will help us think about whether at an aggregate level there are relationships between adherence to medication therapies and spending for other types of medical services.

There's evidence that adherence to drug therapies can help patients control some chronic conditions and keep them out of the hospital but that may not be true for all drugs and all conditions. Also, spending for some types of services like office visits or laboratory use may increase rather than decrease with drug therapy. With claims we will be able to dig a little deeper into those kinds of questions.

Medicare beneficiaries who live in rural areas all have access to Part D plans and probably all of them can get mail order pharmacy services. But some have less choice of retail pharmacies because of where they live. With claims information we can look at the utilization patterns of rural enrollees. Do they have lower cost-sharing on average because they use mail order services more extensively, where there's a little benefit to using -- in terms of out-of-

pocket spending -- to using mail-order? Or do they face higher cost-sharing because they rely more on out-of-network pharmacies?

Several of the projects we have in mind relate to cost and spending. With claims data we will be able to analyze how different benefit designs relate to spending. For example, how much more does an enrollee in a plan with no deductible spend relative to a similar enrollee in a plan that has a deductible? Does the presence of low-income subsidies or enhanced benefits lead to higher spending? Those kinds of questions.

The Commission has talked before about the fact that Medicare Advantage prescription drug plans may have greater incentive to keep their enrollees adherent to drug therapies than stand-alone plans because MA plans are also at risk for Part A and Part B spending. Now we don't have Part A and Part B claims for enrollees of MA-PDs, although Bruce has talked about the encounter data, but we may also be able to look at whether prescription drug utilization patterns are systematically different between MA-PD and PDP enrollees.

And finally, we plan to build one or more price

indexes so that we can monitor changes over time and average prices that beneficiaries pay at the pharmacy counter for Part D drugs. This would help us monitor changes in average prices for specific plans as well as for the Part D program as a whole.

That's our list of topics that we think are going to be important to address in order to help the Commission evaluate the Part D program more thoroughly and we look forward to your questions and comments.

MR. HACKBARTH: Thank you.

DR. MARK MILLER: I should emphasize two things really quickly. I just want to say again how much we appreciate the efforts of CMS in getting the data to us. And this agenda will take a really long time.

DR. STUART: You've done a wonderful job on this chapter. As someone who has been working in this area for a number of years, one of the things that the delay in the data have done is that it's given us a couple of years to think about all the different kinds of studies that we'd like to do. And so trying to put that in an agenda is a challenging prospect.

The one suggestion that I have here is that

because the nature of the data will only be available from CMS and they will be coming through a porthole known as ResDAC, it would be I think useful for MedPAC to monitor the access to Part D data on behalf of both other Federal agencies as well as private researchers. And that would help when you see the kinds of projects that have been proposed and approved, we hope, we will have some sense of where your research agenda falls within the larger research agenda of the private sector as well as other Federal agencies. And I think that might help you as we go forward on this.

The other thing that I would mention in this regard is that there is some question in terms of the availability of certain data elements to the private research audience and it's really too soon to say yet whether that's going to be problematic. But monitoring that I think would also be helpful, because there are just way too many questions to be answered just by MedPAC and it would be useful to put this in that larger context.

The only other comment that I would make -- I have a number but in the interest of time I'm going to restrict myself to the MTM evaluation which you've indicated can be

done without claims data. I would suggest that there is a real potential in this program for doing some good in terms of improving the quality of medication management, particularly for those with very complex disease. And an evaluation of this I think really does require claims data. And so I would put that in your list of studies that if you had claims data.

Now I know that the actual information you have about what is done within MTM service contacts is limited or nonexistent, but at least know who has been administered these services and to look if that has had any effect on both their utilization of Part D as well as Part A or Part B services.

And then finally, I'd also suggest that you look at the mechanisms by which MTM services are targeted. This program was set up without a lot of prior information in terms of what is the best way to target utilization management services. And frankly, some of the targeting mechanisms that are used today in terms of identifying the number of chronic diseases that should be used, we know there's a lot of variation out there in the market. But all of them are based upon a threshold of drug spending. And

we've done some work on utilization of medication by Medicare beneficiaries with diabetes and we actually find that those that have high drug spending tend to have fewer problematic issues with respect to adherence and other things compared to some people that have lower spending.

And so using drug spending may, in one sense, be counterproductive. You might want to look at other types of spending. So looking at the ways in which this kind of service could be better targeted, I think would be a good study for MedPAC to entertain.

Thank you.

DR. CHERNEW: I first will echo what Bruce said, that there's going to be so much private study of Part D and things related to Part D that the more you can find activities other people are doing, you may be able to target what you want to do better in the light of that. Certainly I'd be willing to talk to you. I know a lot of different things that are going on.

The only comment I will make is again I want to echo as much as you can to think about things in sort of a clinical orientation, as opposed to not. So an example would be specialty drug tiers. I don't know a lot about

them but I would just be very aware throughout that some of the things if you have to pay 30 percent could be really bad and others could be really good. If you have a general conclusion specialty drug tiers make people pay a lot, it's very hard to assess what we should think of that because there are certain situations where you think this is a huge amount of waste and when I hear people are paying a lot and they don't have access to certain things I think great, we're doing our job. And other times when I hear the exact same sentence, I say this is a travesty. We have a program that requires beneficiaries to have access to good care and they can't do that if they have to pay 30 percent.

So I'm much less interested in broad statements about certain things like specialty drug tiers or many of the other things or out-of-pocket payments as being good or bad as opposed to understanding clinically what we want the people to have and what they don't.

So just like I said in the imaging where I was very concerned that we saw imaging was going up -- and I think a lot of people echoed this point -- is that good or is that bad? Having the separation in that nuance I think is really important to be maintained throughout all of the

work.

DR. CROSSON: Rachel, thank you. I'm looking forward to this. I think this is going to be a valuable piece of work.

I want to emphasize the point that you emphasized and that is the opportunity to look at the relationship between benefit design and cost and quality. To me that's the center of this. Part D has an unusual benefit design. It was sort of bumped into in the night as a design issue.

What we've observed subsequently is a couple of things. One is that the cost of the Part D is a lot less than what was anticipated. It's not clear exactly why that is and what relationship that might or might not have to the benefit design. It's also unclear as to what the impact of the set of benefit designs that are out there have on quality. As Mike said, probably some of them are salutary and some are not.

So it seems to me that the more that we can understand about this the better not just for the possibility that we could make recommendations to improve Part D but that we might, in fact, learn more about variations in benefit design that could extend to other

parts of the Medicare program and begin to add that as part of the list of perhaps more impactful changes that we might want to consider to answer the question that we discussed yesterday, which is what among our recommendations actually match up to the size of the problem that we described in the context chapter?

MR. GEORGE MILLER: Thank you, Shinobu and Rachel, very interesting reading. I'd like to pull out just one part of it and just ask a question about disparity. And that's in dealing with Part D and the program, if under the design and the special subpopulation groups we had the opportunity to look at disparities, particularly in health care in general. As an example, Afro-American men who have the same insurance, Medicare, do not receive the same standard of care for catheterizations in one study that I read.

So will you have the opportunity to look at that type of data? Will you drill down as it relates to drug use and see if a subgroup like minorities or poor will receive the same drug benefit or receive the same efficacy of drugs to treat different diseases?

DR. SCHMIDT: That's a good question. We do have,

in addition to claims information, some enrollment information from CMS that does tell us about race. And we can look at geography, as well, as another angle on that.

It's not a perfect measure but to the extent that we find it's valid, yes, I think that we will try and take a stab at that as well.

MR. GEORGE MILLER: Thank you.

DR. MARK MILLER: Was that one of the extra files that we still hadn't --

DR. SCHMIDT: No, we do have that one.

DR. MILSTEIN: One of the potential uses of the actual claims data that wasn't on the list really would be some kind of a reference to all of the episode-based analyses that we have underway on which a lot of our recommendations hopefully for this year will depend. I think Nancy and other commissioners have made the point that episode-based analyses minus drug data are potentially, at a minimum, attackable if not potentially exposed to wrong conclusions.

And so I wanted it to ask -- maybe this is not for you but a combination also a question for Mark -- is the degree to which it's possible for the Medicare A and B data

that we've already mobilized for purposes of doing our episode-based and quality analyses, whether it might be possible to at least take the subset of the beneficiaries in that sample for which we do have Medicare claims data and accelerate the prioritization of merging that data in and moving ahead with analyses even if it has to exclude a certain percentage of our episode-based analyses for which we don't yet have Part D data that's passed the screens. In other words, we could at least focus in on the subset for which we have screened Part D data and move ahead with more robust episode analyses for a whole variety of uses that will be relevant to our March and June reports.

DR. SCHMIDT: There are some technical issues we need to work through with respect to doing those kinds of merges. I can understand your sense of urgency behind that.

One thing we've learned from CMS, for example, is that in drug it's less common to have UPIN or NPI prescriber ID than a DEA number. And that could or could not -- we do not know yet, be a complication in terms of trying to identify the physician who was actually doing the prescribing in the grouper kinds of analyses. So that's just one kind of technical point that we need to work

through.

MR. BERTKO: First, Mark said it correctly, that I think, Rachel, you and Shinobu have 10 years of work ahead of you here.

And then secondly, I'd to make a disclosure. I'm on the John Hsu team. It's in my little part, but I'm a reviewer on there.

A couple of comments. The first one is the 2006 data is somewhat unstable because of the enrollment patterns in the first part of the year. So good to start with, good to draw some things with. But from what we've seen so far the 2007 data becomes much more stable, even though there was a little bit of reallocation of the low income, the rest of it was fairly stable.

Secondly, and this kind of goes to Arnie's question, the big question that Mike, Bill and I asked on the 2004 Technical Panel was do drugs save money on A/B costs? And this is the perfect time for a natural experiment if you can go that far but that might be five years of work in and of itself. And I would just encourage you to think about it not only in the way you've listed it, which is the adherence one, but even beyond that. I would

point out that as we collectively think about plan design, Mike's done work in value-based insurance design, as well as Arnie? Knowing, for example, that statins were always cost-effective it might be useful to say statins are always free in the coverage gap or something like that, and drawing out those things as opposed to broadly saying everything is available in the coverage gap.

And then adherence I think is a big, big issue across the board. And there are perhaps 20 questions on adherence that you could ask, from whether it's the coverage gap or how long people actually are adherent when they've got clinically chronic conditions, things like that.

And then lastly, not only on the low-income risk adjuster but the part of moving from the current risk adjuster which uses A/B data to predict to moving to a Part D data to predict Part D, I think would be a vast improvement at least in theory. And I think having had a preview of John Hsu's work, it's already evident that this is good.

So I would look for us to at least be ready to think about that some time and maybe prod CMS to moving a little faster than I think they're moving today.

MR. BUTLER: I guess I'll just make the same point in a different way, as I first looked at this. We divide our organizations into subcomponents and we end up with silos that kind of suboptimize performance sometimes within those silos. So where we do with Medicare, we've got A, B, and D, that are set up. And so the tendency is to do the early research just within the D column.

I think we ought to, because it's there and it's new and it's just how we set things up. So I wonder if there's a way over the years that this is covered that we just make sure that we kind of just look at the balance, the percentage that is sitting within the D column versus the A/B/D collectively to make sure that that is getting appropriate focus. Because I think a lot of us would believe that in the end that's where the biggest opportunity is, maybe, not just in the D column by itself.

DR. REISCHAUER: John made the basic point that I was going to make, which is 2006 is a very uncertain year, both for the reasons you mentioned. But it's a new program both for the PDPs and the beneficiaries. And so I would hope that, first of all, we get the 2007 data in a timely fashion.

Secondly, that it's in the same format so that you could quickly do some very rough checks on what you find out. Because the worse thing in the world would be for lots of conclusions for all researchers coming out of 2006 data and Congress going wild about the problems associated with it, and then it turns out it's not really a huge issue.

I was wondering whether for people in the coverage gap and adherence issues there is any way of getting -- whether they are fulfilling prescriptions through drugstore.com or some other way totally outside of their PDP?

DR. SCHMIDT: We haven't really explored collaborating with other external sources of data. But I guess I'm a little bit skeptical on how we could pull that off, frankly.

DR. CHERNEW: Because they have their true out of pocket cost requirement to get to the catastrophic coverage. They don't have to but it behooves them for someone to keep track of what that is. Otherwise, the catastrophic won't potentially -- if you don't think you're ever going to there.

DR. STUART: I'd be dangerous about making

assumptions here. The answers should be available from the Medicare Current Beneficiary Survey next year. And so I would check with Frank Eppig to see if you can get information about the way drugs are going to coded in the 2006. Now that's 2006, so that's problematic, as well.

But because of the way MCBS has traditionally collected drug information, you should be able to identify non-Part D drugs during the time that the person was in the doughnut hole. The drug use data isn't nearly as good as what you're going to get from Part D but at least it's going to be something that would allow you to know whether you've got a missing data problem.

DR. SCHMIDT: Mike, on your true out of pocket point, Elizabeth Hargrave reminded me yesterday that actually if they go completely and buy an off-formulary drug, the true out of pocket is not going to capture that.

DR. CHERNEW: [off microphone] I understand but it would be true if they were buying off-formulary drugs --

DR. SCHMIDT: Right. If it's a covered drug but they're 100 percent coinsurance, we would get that.

DR. MARK MILLER: [Off microphone.]

MR. HACKBARTH: Any others? Okay, thank you very

much. Good job.

Now we'll have a brief public comment period.

Sharon, you know the basic ground rules well.

MS. McILRATH: For the new people, I'm Sharon McIlrath with the American Medical Association.

On the imaging presentation, just a few quick points. There is one other way that could be used to try to determine or help with the appropriateness issue, which is the claims edits that would get at things prior to payment. There are several thousand of those now but maybe you would want to look at those and see if there is another way you could use that.

There also is a demonstration of the use of appropriateness guidelines that is being set up as a result of MIPPA. There are two of them, actually. One will definitely be using the cardiology guidelines.

And then just in terms of what happened in 2007, the final data is now out and people get use that. But in the future you might want to think about another file that we get in March or April every year from CMS which is 96 percent complete data. It's everything through December. That data did show that there was a 23 percent reduction

average in the price, much heavier than that on the PET scans. In addition to that then there was a vast reduction in the growth, down to 5 percent, for the advanced imaging services.

And one other thing, there was a slight shift back into the hospital outpatient department from physician offices. But just as a future thing to think about when you're looking for data earlier in the year, that file might be something that you'd want to take a look at.

MR. HACKBARTH: Okay, thank you. We're adjourned.

[Whereupon, at 11:27 a.m., the meeting was adjourned.]