MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Monday, September 13, 2010
9:40 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, JD, Chair
ROBERT BERENSON, MD, FACP, Vice Chair
SCOTT ARMSTRONG, MBA
KATHERINE BAICKER, PhD
MITRA BEHROOZI, JD
KAREN R. BORMAN, MD
PETER W. BUTLER, MHSA
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MICHAEL CHERNEW, PhD
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MARY NAYLOR, PhD, RN, FAAN
BRUCE STUART, PhD
CORI UCCELLO, FSA, MAAA, MPP

AGENDA PAGE

P R O C E E D I N G S [9:40 a.m.]

MR. HACKBARTH: Would you take your seats, please?

Okay. Welcome to our guests for our first meeting in our new cycle.

As always, we will have brief opportunities for public comment at the end of the morning session and then at the end of the day. I will remind you again that we invite comments so people will take advantage of our brief public comment periods, but they will be brief, and I urge you to use other available avenues to communicate with the Commission and its staff about our work, the most important one being direct communication with the staff. They make an extraordinary effort to seek out input for our work. We also have a place in our web site where people can offer comments on our work.

Our first session today is on the context for Medicare payment policy, a regular feature of our March report. It's a chapter that reviews some of the basic, but still very important, information about program expenditures, trends, the share of the budget, GDP, et cetera, going to Medicare.

And, Kate, are you leading? Okay, Kate.

MS. BLONIARZ: Hi. I'm going to present on the context for Medicare payment policy. In the beginning of each March report, a chapter lays out the budget and economic context for the Commission's Medicare recommendations.

The principles of Medicare payment require us to ensure beneficiary access to high quality care, give providers an incentive to apply effective, appropriate care and ensure the best use of taxpayer dollars. This presentation will discuss the first and third components of this mandate. First, I'll discuss the makeup of the health sector and briefly touch on the factors that drive health care cost growth at rates exceeding the growth in the national economy. Then I will discuss one additional factor affecting Medicare's financial outlook: the changes to Medicare in the Patient Protection and Affordable Care Act. Finally, I'll turn to Medicare's specific funding challenges and the federal government's overall fiscal picture.

Currently, the health care sector makes up 16 percent of gross domestic product. Public sources correspond to 47 percent of the spending, and private sources correspond to 53 percent of the spending. Total

spending on health care is projected to grow by 6.1 percent annually over the next 10 years, reaching 19 percent of GDP by 2019.

Medicare is the largest single payer in the $2.3 trillion health care sector, comprising 20 percent of spending in 2008. As you can see from the table, Medicare spending growth has exceeded GDP growth by 2.5 percent on average over the prior 35 years.

Finally, what is also notable is that health care spending growth in excess of GDP doesn't just affect public payers; it affects all payers.

When comparing Medicare spending growth and growth in the private sector, there are periods where Medicare per capita spending grows faster than private per capita spending, and vice versa. Between 2000 and 2009, Medicare spending growth averaged 9.7 percent annually. Some of this growth is due to the increase in the number of Medicare beneficiaries. However, per beneficiary growth was still 8.5 percent over the same time period.

Again, in this graph, you can see the persistence of spending growth in excess of GDP for public and private payers.

The reasons that health care costs grow in excess of GDP growth are likely familiar to you. Technology, broadly categorized as new products, processes and treatments, is identified as the largest single driver affecting the growth in health care. Analysts have estimated that technological improvement can explain between 25 and 50 percent of the growth in health care spending.

Health insurance coverage is also believed to have an effect on health care cost growth by increasing the amount of health care consumed at the individual level and also shaping the market for new medical interventions at the economy-wide level. Changes in health insurance are estimated to contribute to between 10 and 13 percent of the growth in health care spending.

I will just quickly touch on the next three factors affecting health care cost growth. First, the prices for health care services grow faster than non-health care products and services. Second, provider consolidation is also theorized to affect the growth in health care spending. And finally, medical malpractice is thought to affect the practice of defensive medicine; however, some people have looked at the role of medical malpractice on

overall spending growth and found only a small effect.

Next, fee-for-service reimbursement used by most public and private insurers results in an emphasis on volume, not care coordination.

Aging has not played a substantial role in explaining historical health care cost growth, between 2 and 3 percent, but it will play a large role in the future growth of Medicare Medicaid, accounting for 45 percent of the growth in the programs between 2010 and 2035. It will then diminish in effect over the longer term.

Finally, higher household incomes increases the demand for health care, with one recent study finding that the income, or wealth, effect on health care consumption was almost as large as the technology effect.

In 2009, Medicare spending was just over $500 billion, corresponding to $11,700 per beneficiary.

As you can see from the chart, Medicare's financing is a mix of dedicated taxes, general revenues, premiums and cost-sharing and other sources such as taxation of Social Security benefits. Overall, approximately 23 percent of Medicare's revenue was from beneficiary contributions, 33 percent from payroll taxes and 37 percent

from general revenue. The share that is paid by general revenue is projected to rise to nearly 50 percent by 2030. Currently, 18 percent of all revenues collected by the federal government goes to Medicare.

The largest share of Medicare spending goes to hospitals, 27 percent, and the second largest share, 22 percent, goes to Medicare Advantage plans. Spending for physicians and prescription drugs account for 13 and 12 percent, respectively.

Before I discuss Medicare's long-term financing, I want to touch on the Medicare provisions in the Patient Protection and Affordable Care Act. The law specifies yearly adjustments on varying schedules in the next 10 years for most Medicare providers in addition to a yearly reduction in the market basket equal to economy-wide productivity. The Medicare trustees, in their 2010 report, assumed that the productivity assumption would equal 1.1 percent a year.

The law will reset the benchmarks for Medicare Advantage plans and introduce a bonus system based on quality.

The law also establishes an Independent Payment

Advisory Board which is required by statute to make further modifications to Medicare if per capita spending exceeds thresholds set out in the law.

The law has three main provisions affecting current Medicare beneficiaries. First, it phases out the Medicare Part D coverage gap by 2020, it freezes the income thresholds throughout the 10-year budget window for the Medicare Part B income-related premium and establishes an income-related premium for Medicare part D. And finally, for current workers, it expands the hospital insurance payroll tax by 0.9 percent for individuals making over $200,000 and couples making over $250,000.

With respect to delivery system reform, the law establishes a process for testing a number of interventions: bundled payments for inpatient hospital care, accountable care organizations, a shared savings program and value-based purchasing for hospitals, among others. The Center for Medicare and Medicaid Innovation is charged with conducting pilots on changes to health care delivery systems that have the potential to reduce spending or improve quality across Medicare, Medicaid and private insurance.

Over the 10-year budget window, the provisions

affecting Medicare in the Patient Protection and Affordable Care Act are estimated to reduce Medicare spending from baseline by $575 billion over 10 years, with the market basket and productivity adjustments making up the largest single share, the Medicare Advantage changes total $145 billion over 10 years, and the other fee-for-service provisions totaling $135 billion over 10 years.

As seen from the table, Medicare's fiscal picture is projected to be improved as a result of PPACA. Overall growth in the next 10 years is projected to be 5.8 percent annually, as compared with 7.1 percent as projected prior to the passage of PPACA.

The current law assumptions are as follows: First, current law assumes that the Medicare reimbursement to physicians will be reduced by 30 percent over the next 3 years. Second, current law assumes that the productivity adjustments to the provider payment updates in PPACA will be implemented as scheduled and kept in place throughout the projection period.

It is important for you to know that this year the Medicare trustees also discussed an alternative scenario in the 2010 report. This alternative scenario assumed that the

productivity adjustments are in effect through 2019 and phased out thereafter over the subsequent 15 years, and that physician payments will be updated by the Medicare Economic Index. Under this scenario, Medicare's 10-year growth rate would be 6.9 percent.

On this next slide, I just want to emphasize why it is important to constrain Medicare's cost growth. Rising Medicare spending directly affects beneficiary cost-sharing. Currently, Medicare pays for approximately 55 percent of the average beneficiary's current health costs. Out-of-pocket spending and other sources such as Medigap or employer coverage cover 19 percent apiece, and Medicaid covers 7 percent.

The growth in Medicare spending will result in cost-sharing that consumes a larger share of beneficiary resources. For example, the average beneficiary contribution for Parts B and D, which is premiums and cost-sharing, corresponds to 27 percent of the average Social Security benefit in 2010. By 2030, the cost-sharing and premiums for Parts B and D are projected to have grown to 50 percent of the average Social Security benefit.

Rachel and Carlos will present on beneficiary

cost-sharing more in their presentation after lunch.

Finally, a discussion of Medicare's fiscal picture is incomplete without a discussion of the federal budget. This last point is one that I will spend a little more time on.

This chart shows debt held by the public under two scenarios. As you can see here, public debt is projected to be just around 60 percent of GDP in 2010. By 2019, it is projected to reach nearly 70 percent, even under favorable assumptions. I want to clarify that in these slides we are not just talking about Medicare or health care; this is the fiscal position of the entire federal budget.

The Congressional Budget Office also presents an alternative fiscal scenario. The CBO's alternative scenario assumes the following changes from current law, all of which would increase spending or reduce revenue: The 2001 and 2003 tax cuts are extended. The thresholds for the Alternative Minimum Tax are increased. Medicare payments to physicians grow over time. And two provisions in PPACA are modified -- first, that the Medicare productivity adjustments are phased out after 2019 and the health insurance subsidies are indexed to health care spending

after 2019. Under this scenario, the debt would exceed all historical precedent by 2024.

So why are these debt levels important?

CBO and other observers have discussed a few potential outcomes from high federal debt. First, it could crowd out private investment. Second, it could lead to inflation which would ultimately depress wage growth. And third, it could limit the ability of the government to respond to cyclical downturns. One final outcome is that the credit markets could require higher interest rates on federal debt which would dramatically increase the government's interest payments.

Over time, interest payments on this level of debt will start to dominate federal spending. In 2010, interest payments on current debt will be approximately $200 billion or 5 percent of total federal spending, and approximately $1.3 trillion of federal spending will be deficit-financed. By 2019 and 2035, under current law, the amount of debt-financed government spending will have decreased from current levels, but spending on interest payments will rise to $570 billion in 2019 and approximately $1 trillion in 2035.

Under the alternative fiscal scenario, interest payments by 2035 would be $2 trillion, the yearly deficit would exceed $4 trillion and current revenues would be sufficient to pay for only 44 percent of the government's total spending that year.

You may be asking why this is important for Medicare. These debt levels call into question the ability of the government to pay all of its obligations including Medicare, and, because of Medicare's increasing claim on federal revenues, addressing the program's cost growth may be one component in improving the government's overall fiscal position.

I would like to conclude this presentation by asking for your comments, questions or other topics of discussion.

MR. HACKBARTH: Thank you, Kate. Well done.

Let me just provide a little bit more historical context for why we have the context chapter.

Mark, maybe you can remember the exact year. I can't. But a number of years, seven or eight years ago, Congress amended the statute governing our activities, to ask us to consider in our deliberations the budgetary impact

of our recommendations. And I think it was at the same time they added the language about efficient provider, that we should make our recommendations, update recommendations based on what is adequate for an efficient provider of the various types of services covered by Medicare as opposed to the average provider. The point in each case was that the Congress expected MedPAC, as an advisory body, to carefully consider the fiscal impact of what we're doing.

So we initiated this context chapter as part of the response to that. Another thing that we did was the efficient provider analysis that those of you who have been on the Commission have grown accustomed to, which we're still, incidentally, expanding and developing. And then also at the same time we started including estimates of the budgetary impact of recommendations, not point estimates but sort of, as we refer to it, in buckets and do that with some consulting advice from CBO.

So that's the context of this. We are responding to specific requests from Congress, now seven or eight years ago.

Okay. So let's open this up for discussion among the Commissioners. We will use our usual process. Round

one will be strictly clarifying questions: What did you mean by Table 3, Line 4? That sort of thing. And then we'll follow that with a second round of broader comments and questions.

So let me start over here on this side. Let me see hands for clarifying questions. I have Ron, Mary and Peter to start.

DR. CASTELLANOS: Very nice presentation. Kate, it wasn't in your discussion or your presentation, but in the material, the briefing material sent to the Commission, I see there's a pretty strong statement that says that "Despite growth in health care spending as a share of GDP, there's no significant evidence that this growth has resulted in any commensurate improvements in quality or outcomes."

You know, as a practicing physician, really that kind of bothers me because I can show you a lot of statistics with neonatology, cancer outcomes, et cetera, where spending has increased outcomes and quality. So I'm not opposed to your giving me a good example of why you put that, but sometimes these statements carry on to the March report, and I would like you to think about maybe toning

that down a little bit.

MS. BLONIARZ: Sure, we can absolutely do that.

MR. HACKBARTH: There's some literature on this that I'm not nearly as well versed in as others are, but we can come back to that if Mike has something he wants to offer, or Kate or others. We'll come back to that in round two. I think it's an important point that you've raised, Ron.

Mary?

DR. NAYLOR: It was a terrific report. Thank you.

CBO, in the report that we had, estimates that the aging of the population, as you mention, is going to contribute significantly to the growth of Medicare and Medicaid, at least in the short term, and I'm wondering if you can help me understand. Did the CBO estimates take a look at that growth in the context of people living longer with multiple complex conditions? And was it taking a look at it in the context of the current system design, or did it take into consideration some of the estimated changes as a result of the Affordable Care Act?

MS. BLONIARZ: With respect to your first question, those are measured as per capitas, and as the

population ages the risk profile will change. And so their per capita measure does incorporate a little bit that people may live longer and have longer, have higher costs over their lifetime, but that's a pretty small effect. I mean the bigger effect will be the number of people who are receiving Medicare over the next -- Medicare and Medicaid over the next 30 years.

DR. MARK MILLER: To the second part of your question, yes, my sense about the way these estimates are done is that there are sort of broad assumptions about how much growth is above or below GDP as opposed to trying to capture specific effects of this particular change in policy. That's how they do the long-run projections.

DR. CHERNEW: They separate out the demographic component and what you would call an excess cost component. The demographic component takes into account explicitly nothing. It's just there are more 85-year-olds, and then they have a separate component which is an 85-year-old costs this much more.

MR. HACKBARTH: Peter?

MR. BUTLER: Okay, on Slide 5. So I'm getting my kind of accountant's hat on. I try to figure out how much

of the increase is due to each of these categories, and I'm struggling more than usual on some of this.

We talk about technological. We always lead with that, I think almost every year, and it used to be and it says in here about half of the expense increase. Then there's a more recent study that says maybe it's 27 to 48 percent of the growth is in technology. Then it also says in prices it's somewhere between 5 and 19 percent of the growth is due, but that's not -- but my math says that's as much as 70 percent due to those factors.

I'm not sure that's true or not, but I think my real question relates to the technology. I've never quite understood the definition because I think of, well, you've got a PET/CT scanner, and not only is it new, but it's used a lot, and that's part of the technology. I'm not quite sure how you categorize what.

I think it's a lot of the utilization. It's not just the technology. It's buried in technology, and I'm just not sure it's the right label.

MS. BLONIARZ: Yes, I think. So, on your first point, definitely different studies have come up with different ranges, and each study will add to 100 percent.

But if you try to break out all the components across different studies you could definitely take the high end of the range and get above that. The study that found a slightly lower share of technology as a driver actually was also the one that assigned a larger share to improvements in income and wealth, household income and wealth, as a factor.

On your question about technology and how it's defined, this is absolutely something that I've seen discussed in the literature a lot because it isn't clear whether a set of new procedures that are delivered to a new category of patients, whether that is classified as technological change or something else.

Most of the studies take the broadest possible view that changes in procedures, processes and treatments for a given condition is what they use for this bucket, but I'm sure others could probably speak to this as well.

MR. BUTLER: Just my quick comment then, in the chapter it makes it look like it's just new services as opposed to the utilization of existing services as well, and I think most definitions would at least include some of that, I think.

MS. BLONIARZ: Right. Yes, we'll clarify that.

MR. HACKBARTH: Mike?

DR. CHERNEW: I'll wait until round two. Okay.

MR. ARMSTRONG: Just very briefly on this point, you, in the slides, refer to "technological improvement" and in the report you talk about "technological advancement," and given the comments just made it seems like "advancement" is the more appropriate label to give to this.

MR. HACKBARTH: Mike is, at the start of the new year, being exemplar of round one etiquette.

[Laughter.]

MR. HACKBARTH: Jennie?

MS. HANSEN: Yes, this is round one on Slide 6, and, you know, in looking at this, it is helpful to -- it corresponds with the text about how much per beneficiary. But in terms of the expenditure pie, the MA plans, you know, assume 22 percent in terms of Medicare payment, but in reality, they're paying also for physician services, hospital services, and Part D coverage. So in some ways, it's probably -- the percentages are then in actuality different in terms of the actual use?

MS. BLONIARZ: That is right. We could take out

the MA piece of the pie and distribute it among all the other categories.

MR. GEORGE MILLER: My question has to do with the definition on Slide 5 of "industry consolidation." My question is: Does it include also expansion of -- we have seen growth in physician-owned hospitals as an example, so does consolidation also include expansion just by definition? Or is truly just industry consolidation?

MS. BLONIARZ: I believe that it does refer to -- you know, actually I'm not sure and I can get back to you on that.

MR. HACKBARTH: So clarify for me, George, what you mean by your reference to physician-owned hospitals and how that plays in here.

MR. GEORGE MILLER: Well, 10 years ago we didn't have physician-owned hospitals, and this question deals with the health care cost growth as an example, and I just used physician-owned hospitals. So if you have consolidation, does it also include the growth of other providers over the last years? And is that net of that effect, by definition?

MR. HACKBARTH: Yeah, so --

MR. GEORGE MILLER: Or is that a whole different

category that I may be missing --

MR. HACKBARTH: Yeah, so correct me, Kate, if I'm not thinking properly about this, but I would think of physician-owned hospitals as new entrants and competitors, potential competitors, to existing providers. So it's sort of the opposite of consolidation. Generally, consolidation means you've got fewer purveyors of a particular service in a given market, and so fewer hospitals, not more hospitals -- or fewer whatever service we're talking about.

So your point about physician-owned hospitals could be valid in terms of it being a cost-increasing force, but it would fall under another category as opposed to consolidation.

MR. GEORGE MILLER: Correct. And my question was it in industry consolidation or is it in another category, if I didn't put it correctly.

MR. HACKBARTH: You know, potentially that could fit under a category like payment incentives in fee-for-service. MedPAC's analysis was that at least part of the physician-owned hospital development seemed motivated by taking advantage of pricing anomalies and targeting particularly profitable services. So, you know, this --

MR. GEORGE MILLER: [Off microphone]

MR. HACKBARTH: Yeah, yeah. Other clarifying questions?

DR. DEAN: More on the technology issue. In the written material, it talks about the fact that technology expands in health care in a different way than it does in a lot of other industries, and you say introduction of a new product generally doesn't result in high levels of demand until the price falls. I wonder the basis behind that. I'm thinking of, for instance, robotic surgery, which has expanded rapidly. And to my knowledge, there has been no cut in price at all. In fact, prices, if anything, are more expensive. And that seems to be more the typical experience that I'm familiar with rather than the utilization being controlled by price.

MS. BLONIARZ: I think there we were just trying to make the point that, outside of health care, in consumer products, generally the price starts out high, and it's when the price decreases that demand will pick up. And that doesn't -- kind of that story doesn't fit as much in health care. So I think your point is consistent with that.

DR. DEAN: Okay. Maybe I misread that, because

that's exactly -- I mean, my experience is that is not what happens in health care.

DR. MARK MILLER: We'll make sure that's clear. I think there may be [off microphone].

DR. DEAN: Okay. Maybe so. And I think it is an important point because it would seem that everywhere else, technology increases efficiency and helps to control costs. In health care it has done just the opposite, and we seem to have accepted that, I guess, and I think that's unfortunate.

MR. HACKBARTH: Okay, round two comments.

MS. UCCELLO: I just have a quick comment. I think this chapter does a great job setting the context for things, and I was very pleased to see that the alternative scenario was included in the discussion. I just think it might even be moved up more, acknowledged sooner on, and then I think it would also be appropriate for us to say that the alternative scenario, and even the current-law scenario, really emphasize the need to pursue aggressively these health care payment and delivery system reforms.

DR. CHERNEW: First, in response to Ron's comment, I think he's right. There's literature -- the cites I would do would be like Cutler and McClellan -- on spending growth

over time and quality. And the issue is a lot of the stuff in the chapter that shows we don't have good-quality sort of cross-sectional comparisons, but not about the growth. So I think that Ron -- there's a difference between sort of inefficiency at the margin and saying we didn't get anything because we spent more. And we could talk later, but I do think, in response to Ron's comments, there's a lot of academic research that says on average we've spent more and we've got better. And there's also a lot of academic research, much of which you show, which says we're still not doing really very good at all in a number of ways.

With regards to the technology discussion that we've had, I think it's important to say, to be clear, none of these studies are as detailed as some of the questions might imply that they were where they measure a whole series of things, and there's a lot of interaction effects. And despite the definition of technology, which they often will give, which I think you correctly cited, it's really everything else that's not in the things they measured, and they often didn't measure a lot of stuff.

There are some very specific studies that look at, like, revascularizations and what technology is. The

problem is the existing services often increase with the new technology. So you have a new test for prostate cancer, and that's the thing that's new. But the spending isn't just on that test. The spending is on all the other related things that were existing, and so separating that is hard. And what you generally see in this literature is because of these interaction effects -- the 27 to 48 percent thing, for example, the question is you see people are wealthier and then you get more services. If you count those more services and the newest technologies as just technology, you get closer to 48 percent. If you assume it was the underlying wealth and industry spread that generated the demand for all that stuff, then you take all of that stuff and assign it to wealth.

So a lot of this is sort of an accounting exercise trying to disentangle things which are inherently un-disentagleable -- which isn't a word.

[Laughter.]

DR. CHERNEW: But in the spirit of that poor use of words, technology is also a very complicated word that in the general population has meaning and people think of it like Jetson-esque -- which is also not a word -- Jetson-like

things of special equipment, and really it's a whole broad set of practice pattern changes which would often include specialty hospitals, which many people would say are really made possible because of medical technology advances that enable us to have them. Whether they're physician ownership or not plays in as a separate question. But I think it's useful to have the chapter written as clearly as possible, but not to give the impression that these are that precisely done.

MR. HACKBARTH: Mike, can I just ask you a question about that? Your very first point that technology is actually a residual --

DR. CHERNEW: In most of the studies.

MR. HACKBARTH: In most of these. So I have sort of, as a lay person, looked at Joe Newhouse's stuff over the years, and Joe I think is considered one of the people who --

DR. CHERNEW: And an author on that Smith one that gave the --

MR. HACKBARTH: Yeah, that folks look to for this, and it was his estimate, the 27 to 48 percent, and that's lower than estimates that he did in the early 1990s. His

most recent work is still a residual. Technology is still a residual.

DR. CHERNEW: That's right. But you could still find -- you could find studies which we call affirmative which could show you in a particular clinical area -- NICUs, revascularization, advanced drugs, you can find a lot of specific technologies in very specific clinical areas, but the overall numbers that we're talking about here, when they try and put it all together, tend to be residual studies, including Joe's.

DR. BAICKER: And just to build on what Mike was saying, the stacking order is really important. Analogous to when you think about demographic changes versus spending per person, the way you stack those things affects which share you attribute to which. In some ways, I think the stacking order might be chosen based on the policy levers that are able to be deployed. You know, a policy lever that affects health insurance coverage, if you think health insurance coverage affects technological growth, that certain health insurance characteristics drive technology growth, maybe you want to put the health insurance coverage first, and then look at the downstream implications.

Because there are -- you know, many -- two different ways that you could stack those, and I would choose that stacking order to maximize the ability to draw policy implications from the policy levers that are on the table. And with technology being a residual in all of the aggregate ones, I think that's not so much the case with some of the subcomponents where you can do a better aggregate breakdown as opposed to technology, where you'll usually have to look at very narrow cases to identify affirmatively technology, and it can't be done across the board in the same way.

DR. CHERNEW: And these interactions, like consolidation and price -- the chapter actually makes -- although it probably could be written more clearly, consolidation leads to higher price. So if you treat them as separate, price and consolidation, you miss the fact that they're not really separate, and those interactions are -- these are all contributing things, and one should recognize that you're not trying to take a bunch of additive things and just add them up, because they all relate in very complicated ways.

I just want to say I'll be -- I didn't do round one. I just want to point that out.

[Laughter.]

DR. CHERNEW: Tom made a comment about technology and other industries and stuff, and the only thing I'll say about that is it's important to keep the difference between cost, price, and spending. In most other industries where there's technology advancement, we see unit prices go down, but spending goes up. IPhone, you know, phones, information technology, some of the highest spending growth industries have been the high-tech industries, although the unit cost goes down. And so I think we talk about spending, and it's not a price we're talking about in general when we talk about something. It's price times quantity, and those things matter a lot.

Now my quick comment. I really do apologize. I am in a short time window. You made a point in your comments about that it might be important to address the federal issue by controlling Medicare spending. That really doesn't come out in the chapter, but I would have said it, like Cori said, even more strongly. I don't see how we solve that problem without addressing the projected -- I don't see any scenario with reasonable tax rates that you can finance this unless health care spending growth is on

the table. And I think it's really important to lead -- wherever you put it, to make that point that it is going to be imperative to address this problem to include health care. It's not just one of the things we might want to do. I think for much of this budget debate, it's one of the central things we have to come to grips with.

MR. HACKBARTH: Your gold star for round one has been revoked.

[Laughter.]

DR. CHERNEW: I anticipated that.

MR. BUTLER: First of all, I would think we ought to relax round one so he can get part of it out.

[Laughter.]

MR. BUTLER: Okay. He's talking like an economist, and I'm a little lost. I'm a lay person on this. I think what we miss in the chapter a little bit -- and tell me if I'm wrong -- is that people want to know what the cost -- and first you hear, well, of course, we have a growing aging population. And I think the chapter says that's not really it; that's part of it.

Second, we have prices that are going up. Yes, that is a factor, but it's still not the big factor.

Then we have the third thing, what it is we're buying and how much of it we're buying is the real issue, whether it's new technology or new drugs or whatever. And I don't know if we quite simply kind of say those themes -- and I may not have them exactly right, but if you weed through this, I think the public thinks maybe a little something, oh, we're all getting old and using more because we're getting older and sicker, or we're paying a lot more in prices. And I think it's more what we're buying, how much of it.

MS. BEHROOZI: To take the entire context in which Medicare operates and, you know, put it into a few pages is a Herculean task, and you've done a great job of bringing a lot of things together.

I'm going to express -- I guess it's a dissenting voice a little bit or a different view on the issue of the focus on what the bad consequences of federal debt are. I think it's really important, what you said, Kate, that the alternative scenario assumes two actions to be taken: extending tax cuts that are also -- restore tax level -- or not restore. I'm sorry. Create tax levels that are not historically consistent with what we had seen in prior

decades in this country, and not addressing the AMT inflation factor. Those are choices separate and apart, and big choices, and they mean a lot -- have a big impact on the balance of the federal budget and long-term debt, as do other choices about how to spend the money.

So I think it's -- that doesn't mean to say I think we should keep spending all the money that we want to on health care and it should keep growing. I think it's important to note that it can crowd out other priorities, but to talk about the impact of the federal debt on the interest rate that the federal government pays just seems like going farther afield into other areas of economics and federal financial policy, whatever -- that's not so much our role.

I think that it's also important -- you know, we've been talking about the impact of aging on cost growth. While it's true that we can't sustain an ever growing share of the federal pie going to health care, on the other hand, it is an aging population, and not every additional health care dollar that will be spent is a bad health care dollar spent. Some of it will be necessary.

So I think to say 45 percent of cost growth you

can attribute to demographics, whatever that means, however you break it down, and then say, oh, my God, the federal government is going to have to pay much higher interest rates because of this, you know, it's attributing too much of all of our problems to Medicare.

But as I said, that doesn't mean I think that we shouldn't emphasize the importance of controlling cost growth. But I think that we then have to look at what are the right ways to do it, and what separates out the good dollars from the bad dollars that will be spent in addition.

Another broader context issue -- so there's the -- you know, broader context for federal spending, there's also the broader context for Medicare beneficiaries, and that's the economic collapse that many are still not, you know, even seeing the surface of the water from, they're so far underwater. On page 9 of the paper, you do talk about people struggling and many people not having access to adequate care. But I think that there's a more specific recognition that can be made. There has been a lot of work done on how people have changed their utilization of health care. The National Bureau of Economic Research just came out with a report showing that over a quarter of people --

this isn't Medicare beneficiary, but over a quarter of people responding said that they had reduced their utilization of routine health care because of their own economic circumstances, the change in their own economic circumstances. And, by the way, that was like more than twice as much as in countries that have had universal health care for a long time.

I think this kind of feeds into my last point. This really is my last point, if we could maybe look a little harder at the effective health insurance on growth of health care spending relative to other factors. Again, maybe because of the economic collapse, maybe because we've reached a tipping point or something in terms of health care cost growth crowding out wage increases. Workers -- the Kaiser Foundation employer survey, employer benefit survey, showed that workers are paying a higher share, somewhat dramatically higher share last year than the year before. You know, because of a combination of those factors, employers are not paying more. They're paying more both in terms of share of premium and cost sharing at the point of service. And so in other countries where they've had more insurance available for a longer period of time -- I know

there has also been dramatic cost growth, but, you know, those are people who have been insulated, one would think, from -- they've had the benefit of insurance, and maybe we could look at cost growth here as compared to cost growth there and get a little better handle on what insurance contributes to it.

Just in terms of the statistic on page 13, or the data point, health spending paid out-of-pocket by enrollees in private insurance shrunk significantly, from 55 percent in 1960 to 14 percent in 2007. As I said, I think we could update that and maybe it might be a little bit higher now. But also I'd be really interested to know what 55 percent of the cost of health care in 1960 was as a share of the average income as compared to 14 percent of health care costs in 2007 given that health care cost increase has so dramatically outpaced wage increases. So I think that kind of as Kate said, you know, if you think health insurance has a lot to do with it, you're going to find data that supports that, if that's your starting point. But I think we could unpack that a little bit more.

MR. ARMSTRONG: Two quick points. First, I do think that the paper generally accomplishes the goal we have

for setting context for this report.

One issue I would raise is that we declare that costs are high and we make an elaborate argument as to why we would say that. We also declare that quality is low relative to various comparitors and so forth. But we're fairly indifferent as to whether there's a relationship between the two, and I think that we could be stronger in stating that we believe that there is a relationship between the two, and that that will have policy implications -- actually, it already is having policy implications within the Medicare program, and our belief is that as we make improvements in one area, we should be able to make improvements in the other, and I think we should be stronger in that statement.

DR. BERENSON: Just on the reasons for health care cost growth, I mean, obviously this is a -- I think it depends on whether you're a lumper or a splitter as to whether you have the eight or 25 or whatever. I tend to be a splitter, not a lumper, so I would add one more, consistent with Kate's notion of let's identify things that have policy levers. I would throw fraud as a potential -- well, not as a potential, as a reason for cost growth,

anticipating some of the work we're going to be doing this year.

MR. KUHN: I'd like to visit the issue where we talk about in this paper about some of the work that Rick Foster, the CMS Chief Actuary, some of the work that he did and his projections of impact of ACA that's out there. And I think we talk about the productivity adjustment that Rick opined on, as well as the excise tax on high-cost employer health plans, and the fact that both of those are going to be critical that those are totally fulfilled if we're going to be able to achieve the savings that are envisioned in this legislation.

But Rick went on to opine a little bit, too, the fact that he didn't believe that some of the productivity adjustments were sustainable throughout the decade long of ACA. And, you know, part of his thought process on there was that the ability of providers to respond to the incentives that are out there and whether the policy levers were powerful enough. But we don't put that part of activities that Rick opined on in this paper. And I'd just like us to think a little bit more whether we want to be more inclusive and talk a little bit more about some of

those downsides that Rick also put out there, that unless the policy levers are strong enough, are we going to be able to really achieve the savings that people envision that's out there in terms of the productivity adjustments that might be possible.

DR. KANE: So when I look at this list, I just get depressed. I think I read that same list, you know, 30 years ago. I think it would be useful to maybe go at it as where do we think the big opportunities are to reduce cost, you know, or where's the low-value dollar as opposed to the high-dollar value, and then attach to that some of the things we could do to try to address them. I mean, frankly, technological improvement could be almost anything to anybody. Here it's a residual, you know, in economist terms.

So I just think it would be interesting or maybe more useful and maybe more relevant to the public audience that we serve to describe more where do we think we're not getting value and what are some of the tools that we would like to work on to try to improve value.

One thing that's not on the list that I think should be is individual health behavior, and especially when

we're talking about what's coming down the pike, the under-65 population and what they're bringing into the Medicare environment. I think there's a real need to talk about what's coming down the pike in terms of individual health behavior and what that might mean for Medicare if we just do nothing or don't try to coordinate kind of more of a population-based approach.

And then my last comment on the paper is -- and it's got a lot of stuff I recognize. You know, we've been talking about this for a while. But the little tag endnote on page 30 about the need for coordination across payers I think needs a lot more beefing up. I think the whole fragmentation of policy efforts is a huge part of why we have crazy costs and lack of value for the dollars spent. And I think we really need to think much more seriously about how we can have consistent across payer policies, across insurer policies. Maybe we should be looking at what Medicare can do to leverage what the private sector does instead of always vice versa of how do we get the private sector to kind of follow Medicare.

You know, there's just a lot of things that we need to be, I think rather urgently, thinking about to get

the signals kind of all going in the same direction. As long as we keep giving mixed signals -- some payers are fee-for-service, some payers, you know, don't pay for preventive care. As long as you keep giving those mixed signals, you're not going to get the kind of push that we need to really start to get a handle on the cost growth.

So I just would like to see the chapter be a little more hopeful and oriented towards things that we should be doing and focusing on rather than, ah, that technology, ah, those agers, you know, what's the solution to the aging population? I mean, poison the drinking water? I don't know. But it doesn't give me a solution and a hope, and so I'll stop there.

MS. HANSEN: Thanks. Well, I will just first underscore the sense of urgency of possible action, you know, as the tone for the chapter. I think it's been said by several people here, but I think that is definitely one.

The second one is relative to page 23 in the text that begins to identify, you know, what has some of the impact of health care reform been, and it alludes to the component of opportunity with people who are dually eligible. And I just would like to see if we could enhance

that division a bit, because you mentioned how much cost growth will come about, you know, between the two programs that you mentioned orally, but having something to that effect convey that since our June chapter likely will have something that will follow the dual-eligible work.

And, in particular, one other piece that's in the context chapter, that since the Medicaid program has been expanded to 133 percent of poverty for the under-65 population, that portends a much larger number of people coming down the pipeline who may be not the dual eligibles of today but kind of the dual eligibles of the future. So our ability to get that model more effectively correct and understood as to how big of a piece it already is and that conveys a sense of further urgency to really understand how important the care delivery system needs some changing as well as the incentives.

DR. BAICKER: I thought all the pieces that were laid out here were incredibly helpful, and in trying to knit together these issues that have come up, I didn't know whether it might be helpful to frame things focusing on spending growth, where those two words are very important -- spending is price times quantity, and some of these seem to

push on price, and some seem to push closer to -- can you hear me now? Some seem to push more on quantity, and that goes back to the stacking issue. Prices charged by providers may be affected by industry consolidation, et cetera. But framing it in that way and for the spending and then thinking about the growth, we're talking about increases at the margin, not average, and the issue that Mike alluded to as well is that we might think that on the margin we're not getting a lot of health for the spending or we're getting less health than we were getting on average. So thinking about price times quantity and defining quantity as either services consumed or as health produced then might help drive an analysis of how the dollar allocation maps to the outcomes that we care about, which then pushes us towards certain policy levers that are going to affect the channels differentially.

DR. DEAN: Maybe to just follow up on some of the comments that have already been made, I think it is important to somehow continue to try to convey the idea that it is possible to reduce costs without hurting quality, because that's a great fear and continues to be a big fear in the public, and all the furor about cutting Medicare and

the fact that that is going to harm beneficiaries, and we know that -- we believe at least that that's certainly possible to cut expenditures and not harm anybody. I think we need to try to clarify that a bit and expand that that is possible and maybe explain that, in fact, we have put, for instance, a huge amount of emphasis, in my mind too much emphasis, as a society on the fact that you control costs by shortening hospital stays. And we have to the point, I think, driven down hospital stays where they almost don't allow for the natural history of some of these conditions that we deal with, especially as we're dealing with a more elderly population that just simply don't recover as quickly. And the fact is that if you look internationally, Americans use hospital services significantly less than most of the countries that we're compared with. The number of hospital days per capita is significantly lower than most of the countries that spend significantly less on health care.

So I guess what I'm getting at is I think it might be helpful to lay out more specifically what exactly are the drivers of the cost increase, and you've done that. But I think another area that hasn't been mentioned that I think is of concern, and that's just the overall amount that we

spend on administration and the cost of managing the system and shuffling the papers, which is substantial compared, again, to a lot of the other systems around the world.

Finally, just a comment. I've been uncomfortable for some time about the productivity adjustment and using the term "productivity," which I, first of all, don't know how you measure productivity in this context and, second of all, as I understand it, how it's applied, it really is just an across-the-board fee cut -- which may be appropriate. I'm not arguing that part. But I think it isn't really entirely accurate to call it a productivity adjustment when it's an across-the-board adjustment. Given the fact that many of us believe we have an underlying pretty seriously distorted fee structure, it has a lot of -- it's a very blunt tool, and I think it has some unfortunate implications. I know it's something that's been in place for a long time, but I guess it's something that has made me uncomfortable for quite some time.

DR. BORMAN: Being a plain Jane general surgeon, I'm going to try and come back to some pretty simple concepts, I think, about this chapter.

First, I'd like to say I think it's a really -- in

the main, it's a wonderfully done chapter. I think it comes across as quite fresh. I think many of the references are quite current, and I really think it's extraordinarily well done.

I think when we step back -- and I've heard from, you know, different folks here that we need to be more aggressive or we need to stay away from areas where we don't belong, which are somewhat, you know, conflicting views. I think maybe the answer to that is to remind ourselves who's the audience here, and our first audience is to advise the Congress. And so I think that -- frankly, I think that the tone here has been pretty well balanced in terms of some things that try and get at things that are within the purview of the Congress to do without stepping into -- trying to or appearing to tell the Congress what to do. On the other hand, I think to ignore the place that health care first in the federal budget would be a huge mistake and clearly misleading. But I think it's very important to remember, you know, who is our primary audience and to tailor it. And I thought the tone of this was very well done and that I really liked the tone on the section that relates to the OECD comparisons, which I personally have had

some difficulty with over time because I'm not sure it's the right comparison group for some of the reasons that Tom Dean has mentioned, and also because in this whole quality thing -- and, Scott, I guess I would take a little bit of issue with your blanket statement that quality is low, because I think that depends on how you define quality. And to some degree as a society we've defined quality as a moving target over time. Originally, anything we did that just made people live longer we said was as good thing, was a good outcome in health care; and now we're kind of into things of can we get the error level to zero, can we get ventilator-associated pneumonia to zero, whatever. I think we've had some shift in what quality really means. Quality isn't where we want it to be, but low implies we have a clear standard against which to judge it, and other than some really clear things like mammography, Pap smear, prenatal care, some of those kinds of things, I think that that level of absolute value is perhaps lacking in the health care quality arena.

One of the things that I would consider adding in some place here because it's consistent with our prior work is the absence of good quality comparative effectiveness

data. Really, that limits our ability to make intelligent choices that really then rolls into the prices and the volume and the use of technology and everything else. There's this fundamental absence of good information by which to at least compare therapies and at least engage the patient and their family in making good choices and enable us as a society and stewards of money to make better priorities about our investment.

And then I would echo the comment that the end there, the coordination of care part, seems to just kind of dangle out there at the end and not yet reach its full potential. And I think that might be a place to reiterate that some of the benefits of the coordination that you envision would relate to potentially reducing disparities; more patient-centered and patient-directed care, and better understood care by patients, more streamlined care for patients, less complexity, particularly for the vulnerable and the frail. I think it's an opportunity there at the end to just sort of roll up some of the themes that could all be benefits of better coordination of care and kind of bring it back to it's a contextual big-picture chapter, because right now it just kind of hangs on there as a little end thing,

and I'm just not sure what we want to do with it. But that might be one way to make it contribute to the value of the chapter.

Then, finally, just one last comment. We allude in there to our ability to sustain people to later ages with more complex conditions. And in some ways, you might regard that as a success of our medical climate, but it has also created all these challenges. And I think that just heightens the importance of considering comparative effectiveness and end-of-life and palliative issues, you know, which we'll be going into further.

But I would kind of try and keep this at a relatively general level as it is a context chapter. We have other methodologies for getting to specifically this, that, dah, dah, dah, or the menu of options, and I think at least for me you've struck a nice balance in addressing many of the issues.

MR. HACKBARTH: Okay. I'm not off to a very good start this year. I never even got a gold star that I can have revoked, so I am even behind Mike.

I had asked -- this is something I should have said at the outset and failed to, and that's why I'm off to

a bad start. I asked the staff to try to shorten this chapter. Over the years that we've been doing it, five, six, seven years, it sort of keeps growing every year, and in ways that add useful information. I don't disagree with any of the points that have been made here. But if the context chapter becomes where we comprehensively address everything, it becomes unworkable, and it becomes a real struggle for the staff to write. It drains from other activities that they're doing to try to square up the work.

So I had asked Mark to shorten it up, and let's focus more on a descriptive chapter, which is, I think most responsive to what Congress asked us to do seven or eight years ago, and say, you know, we get it, we understand the budgetary context in which these decisions need to be made. So focus on a description of the trends, in particular the Medicare trends and the federal budgetary trends and the context that that creates for Medicare policymaking; perhaps a little bit about the causes, but really stay out of the solutions. The solutions is what we address when we have our various chapters, whether they be on update recommendations or other policies. And so I've tried to define a smaller and somewhat clearer box for Kate and Evan

to work in here.

Again, that's not to say that I disagree with -- there wasn't a single comment that I would disagree with, but if we try to put it all in this package, I think it's a big diversion of resources.

So we will take this input, and we will try to strike an appropriate balance in the next chapter and get back to you, but I did want to make it clear that that's the direction that I had given Mark and the staff. I still think generally it's the right direction, but we'll try to include some of this as we can fit it within that framework.

Thank you, Kate and Even.

MR. HACKBARTH: Let's move on to our second topic for today, which is the Medicare Shared Savings Program for ACOs.

DR. MARK MILLER: Can I just say something here?

MR. HACKBARTH: Yes.

DR. MARK MILLER: For those of you who are standing, I'm sorry, there are not enough seats, but there are a few open. I see four here at the front, and if there is anything in the midst that I can't see, maybe people who have an empty seat next to them can raise their hand for a

second. I apologize, but we don't have -- we didn't anticipate this many people.

DR. STENSLAND: All right. This spring, as part of the Patient Protection and Affordable Care Act, Congress enacted a new Medicare program for Accountable Care Organizations, known as ACOs. The ACO is a group of health care providers that take responsibility for the costs and quality of care delivered to fee-for-service Medicare beneficiaries. If the providers score well on quality and cost metrics, they receive higher payments from CMS, and the program will start on January 1, 2012.

Today, we will describe what Medicare ACOs are and outline their mechanisms for controlling costs. Then we will talk about four issues that CMS will have to decide in regulation, and the proposed regulation, we are hopeful it might come out in the fall. It might take until January or February. There are a lot of complex issues for CMS to work through.

But my objective here today is to give you all the background on the ACOs to set the stage so you can discuss some of these regulatory issues that CMS ought to grapple with.

So ACOs are health care organizations formed around a core group of primary care physicians. The primary care physicians could be part of an integrated delivery system, a large group practice, or a Physician Hospital Organization. The ACOs can take many forms, but the common element is they have a core group of primary care physicians that serve at least 5,000 fee-for-service Medicare beneficiaries. While an ACO must have these primary care providers, having a hospital or a specialist is optional.

In addition to primary care capacity, the ACO must also show CMS that it has certain capabilities. These capabilities include distributing bonuses, defining processes to promote evidence-based medicine, reporting on quality and cost metrics, and being patient centered. Obviously, CMS is going to have to make a judgment call as to whether an ACO applicant meets these criteria.

One important characteristic of Medicare ACOs is that the ACO's patients are still free to use providers outside of the ACO, and if they choose to use a specialist or a hospital that is outside the ACO, the ACO remains responsible for their spending. The net effect of this incentive is to convince the patients -- is that the ACO has

an incentive to convince its patients that it's delivering the highest quality care. If the patients don't believe the ACO physicians are providing the best care, they will use physicians outside the ACO and the ACO physicians will then lose their control over the patient's resource use.

This is just an illustration of how an ACO could work. At the center of the ACO is some administrative system that will distribute bonuses and collect quality data. These administrative functions could be housed within a group practice or a hospital or even an IPA. The ACO must have some primary care physicians. These are the light green circles. After CMS is told these physicians are part of the ACO, CMS will then assign patients that use these primary care providers to the ACO. The ACO is then responsible for the quality and cost of care provided to these patients. There could also be hospitals and specialists, as you see in this picture with the little dotted lines. However, adding these providers to the ACO is optional.

The basic thrust of an ACO design is to give physicians and possibly a hospital joint responsibility for the quality and cost of care delivered to the population of

patients. They get a bonus if they keep cost growth below a fixed dollar target. For example, if the growth in spending target was $500 per beneficiary per year in an area with an average input cost index, that would mean that the ACO would get a bonus if it keeps quality high and restrains cost growth to less than $500 per beneficiary per year.

And the ACOs are also required to coordinate care. They should coordinate care with all providers in the local delivery system, even if those physicians are not in the ACO. For example, the ACO should coordinate care between primary care, specialty care, hospitalists, and skilled nursing facilities. It could also be argued that the ACO should have some system in place with the local hospitals and know when their primary care doctors' patients are admitted and when those patients are discharged.

So we have talked about the ACOs' incentives to constrain Medicare spending growth, but exactly how could they do it? First, we often hear about plans to constrain volume growth. ACOs could expect to reduce spending if they prevent unnecessary admissions, prevent readmissions or other services. However, reducing volume growth is not the only option for reducing spending growth. The ACO providers

could reduce the price of a surgery by directing a patient to an ASC rather than a hospital if that level of care was appropriate, as long as the referral to the ASC does not result in additional induced demand by the ASC owners. Switching to this lower-priced sector could end up reducing spending. Finally, even within a sector, such as within the hospital center, there are different Medicare rates. ACOs could reduce spending by recommending a lower-priced hospital when that hospital is appropriate for the patient.

So the whole point of this slide is to say that ACOs could save money by eliminating unnecessary services, but they could also save money by reducing the price Medicare pays for some of those services.

And that is the brief overview of what ACOs are and how they can save money. Now we are going to shift to talking about issues that were not settled in the legislation. These are issues that could be addressed in regulation.

The first issue we will talk about is random variation in cost metrics. Then we will talk about a bonus penalty model as an alternative to the bonus only model. Third, we will talk about random variation in quality

metrics. And then, fourth, we will discuss how to inform patients about ACOs.

Before we discuss the potential regulatory issues, let us just review how a bonus-only model would work. First, remember the ACO would continue to receive fee-for-service payments at current fee-for-service rates. They get a bonus if they meet the quality and cost targets. The cost target is set equal to the prior year's spending, or based on the prior three years' spending plus a national growth amount, such as the $500 I discussed, minus a threshold. The threshold is the amount of savings that must be generated before CMS starts to distribute savings as bonuses. For example, CMS could keep the first two percent of savings itself and then start distributing savings to the ACO once the two percent threshold is met.

Note that Medicare needs the threshold to prevent the system from costing Medicare money. Recall in the bonus-only model, there is no penalty for exceeding the spending target, so there will be some bonuses distributed due to random variation, and these won't be offset by random penalties. The idea that random bonuses are paid by CMS makes CMS come up with some alternative offsetting revenue

and the offsetting revenue would be keeping that first two percent of savings. And, of course, they could set a different threshold than two percent.

So how will CMS address this random variation issue and set the size of the threshold? In the PGP demonstration, which was a test of the ACO concept, CMS required that the first two percent of estimated savings stay with CMS and then they would share the rest with the providers and CMS. This was what was known as the two percent threshold. However, the PGP demonstration sites had an average of 20,000 beneficiaries. The new Medicare ACO program will allow smaller ACOs, as small as 5,000 beneficiaries. This will result in more random variation than we saw in the PGP demo.

So how could CMS deal with this greater random variation in Medicare spending? One potential solution is to have a bigger threshold for the smaller ACOs, meaning a bigger amount of the savings is going to go to CMS before they start distributing any savings, and the reason being they are not sure if that savings is real or just a function of random variation.

A second potential solution is to pool the

performance data of small ACOs over several years. Basically, they would receive a bonus based on a rolling average of their performance. And this raises the question of how much variation is there in these 5,000 pools of beneficiaries and how does that compare to, say, a 20,000-beneficiary pool.

Here we show that the smallest ACOs have much more variation than the larger ACOs. To create this table, we looked at 2006 and 2007 Medicare A plus B spending for randomly selected pools of Medicare beneficiaries. We then examined whether spending growth from 2006 to 2007 is more or less than the average.

In the first column, we show that ten percent of the pools of beneficiaries with pools of 5,000 beneficiaries had spending that was 3.6 percent or more below the expected level, and ten percent of the pools of 5,000 beneficiaries had spending that was four percent or more above the expected level. As we move to the right-hand column, we start to look at larger pools. At the farthest right-hand column, we show random variation for pools of 20,000 Medicare beneficiaries. We see the variation is lower, with about ten percent of these pools having spending that was

2.1 percent or more below the expected level and about ten percent having spending that was 2.1 percent or more above the expected level.

The point of this slide is to show that smaller pools of beneficiaries will have more volatility. To limit payments due to random variation, CMS will either need larger thresholds than the two percent that it used in the PGP demo or some pooling of data across years.

And I want to be clear that this is just an illustrative example up here. We aren't saying that for pools of 5,000 beneficiaries you necessarily need a four percent threshold because there is a judgment call involved here and there is some data involved here. What this shows is that with a four percent threshold, roughly about ten percent of the ACOs, even if they did nothing, would still get a bonus. People may say that is not reasonable. Maybe we only want to give bonuses to five percent of people who aren't doing anything. And if that is the most -- if they are going to have that more stringent criteria, then you would need more than a four percent threshold because there would be more people getting -- or you would want fewer people getting random bonuses, if you didn't like the ten

percent threshold.

So there are two types of incentives to reduce Medicare spending. First, there is the rather strong incentive to reduce other providers' Medicare revenue, and then there is a rather weak incentive to reduce your own Medicare revenue. In the mailing, we went into a detailed discussion of why the incentives under the bonus-only model to reduce the ACO's own Medicare revenues are limited by two factors. These are the threshold and random variation.

First, let us talk about the threshold. The ACO may be reluctant to reduce their own fee-for-service revenue if they are not sure they will be able to reduce the spending by enough to get it by the threshold. For example, even if an ACO reduced its spending by one or two percent, they would not receive a bonus. They would lose their revenue but get nothing in return. That is one mechanism to reduce their incentive to control spending.

There is also the issue of random variation. For example, if they had a particularly bad flu year and had a significant uptick in pneumonia admissions, they may not get a bonus, even if they were successful in cutting other Medicare spending by more than the two percent threshold.

The bottom line is that even if an ACO reduces some unnecessary services, it cannot be guaranteed to receive a bonus due to random variation and the threshold.

So given the relatively weak incentives in the bonus-only model, is there a model with stronger incentives? And an alternative to the bonus-only model is a bonus penalty model, and this has greater incentives to control spending for two reasons. First, there would be no need for a threshold. And second, the addition of a penalty creates a second incentive. Together, the incentive of getting a bonus coupled with the incentive of avoiding a penalty is greater than the bonus incentive alone. The downside is that the providers have to take on more risk, but they may be willing to take on risk of a penalty if CMS gave them some downside protection, perhaps in the form of a risk corridor, and if CMS removed the threshold in the bonus penalty model and let providers share in the first dollars of savings that they can generate.

Now we just want to compare three types of payment models. The first is the bonus-only ACO, which is in the first column. The second column has the bonus and penalty ACO. And for comparison, in the third column we have the MA

model.

In the first row, we compare responsibilities. In the bonus-only model, the ACO takes no risk, but it gets bonuses for good quality and cost performance. Then in the bonus and penalty model, the ACO takes on partial insurance risk. So in this sense, the ACO with penalties is more like an MA plan in terms of its incentives.

In the second row, we compare operational responsibilities. The two ACO columns have to distribute bonuses and coordinate care. Now, this is very different from the MA plan column, where the MA plans have to negotiate prices and pay claims, and we have talked to organizations that are interested in managing care, but they have no interest in engaging in paying claims or negotiating prices with providers. That is why some of these groups want to be an ACO but not an MA plan.

Finally, in the bottom row, we show that incentives are limited in the ACO bonus-only model. They earn stronger incentives in the bonus penalty model and the MA plan.

Now, David will talk about quality.

MR. GLASS: So how quality is measured and

evaluated will be crucial to the ACO concept. The quality metrics chosen should reflect the outcomes the ACO program is designed to achieve. Ideally, ACOs would improve the health of the population they care for, so you might want to measure the average risk score of the population and see how that changes over time. Also, care coordination between, for example, hospitals and physicians could be important, so you might want to look at care-sensitive admission rates and readmission. Finally, the patient experience of care is something the ACOs should also improve, so you might want to look at patient safety as well as self-reported measures.

After deciding what to measure, the CMS will have to set quality targets and assess if those targets are being met or not. An initial issue will be does every measure have to be met? Some of the measures, or maybe a composite? Remember, if the target is not met, no bonus will be paid.

CMS will face a similar problem assessing achievement of quality as it does with costs, the same issue of uncertainty and how to deal with random variation, and how much certainty should CMS demand. CMS could require that the ACO show with 90 percent certainty that its outcomes are above average, or at least average, or maybe

not worse than average. Or it could set some other measure of confidence.

The measures chosen by CMS as indicators of quality, how the target is set, and how achievement is assessed could influence how big of a sample of patients are needed to accurately measure quality and may indirectly affect which types of organizations choose to become ACOs. For example, including hospital safety measures could encourage including hospitals or hospitalists to be members of an ACO. All these could be issues CMS addresses in regulation.

We now want to turn to the beneficiary and how they should be informed of their physician's choice to join an ACO. Remember, unlike MA plans, patients do not enroll. They are assigned to an ACO by CMS based on which physicians they use. So first, the physician chooses to be in an ACO, and then second, CMS assigns patients to the physician and thus to the ACO.

The assignment could be retrospective. That is, after the end of 2012, for example, CMS could use 2012 claims and tell the physician, these were your patients and tell the beneficiary, you were in an ACO last year. The PGP

demo used retrospective assignment. Or the assignment could be prospective. For example, under prospective assignment to evaluate the ACO on 2012 performance, CMS would have to look at 2010 claims to assign patients.

If we want the patient to know in advance that their physician is in an ACO, then assignment has to be prospective and use the older claims information. Why would we want to tell the patient in advance that their physician is in an ACO? It could be that one feels a patient has a right to know what incentives his or her physician is responding to. Following this logic, presumably, then, the patient should have some choice to make knowing this new information.

So the patient could stay with her physician and her data would be used in the evaluation of the ACO over the coming year. That would be the default option. Or if the patient had some strong objection to ACOs, the patient could choose to switch to a different physician who is not in an ACO, and perhaps inform CMS of that choice. Or a third option might be to let the patient stay with their physician, but opt out of the ACO and not have her data count in the ACO's evaluation. This last option might give

the beneficiary the greatest choice, but it could also be an administrative complication for CMS and raise selection issues. Of course, selection will be an issue for any ACO design. The strategies will have to be chosen to deal with it.

DR. MARK MILLER: Hey, David, I thought also when we were talking about this, another reason that you might want to have the patient informed is so some people make a fairly strong argument if you want these things to work, you have to engage the patient and kind of talk to them about what the plan of care is and that type of thing --

MR. GLASS: Right, you can make the patient an active --

DR. MARK MILLER: -- so it is beyond just the patient rights issue. It is also sort of if the model has that component.

MR. GLASS: Right. So we have outlined several issues that CMS will eventually have to address in regulation and that you may want to discuss during the session.

The first issue is the random variation that occurs in Medicare costs per beneficiary. Should CMS set

high thresholds before bonuses are distributed? And the related issue is, if thresholds are large, will they discourage small ACOs?

Second, should CMS be encouraged to create an alternative model with bonuses and penalties? If small ACOs have big thresholds in the bonus-only model, they may be interested in the bonus penalty model without a threshold.

Third, what quality measures should CMS collect? How should it set quality targets? And what degree of confidence should CMS require with respect to assessing achievement? These choices on qualities may have implications for what entities are in ACOs and how large ACO patient panels need to be.

Fourth, when should the beneficiary be informed? Should this be done prior to the start of the patient's expenditures and quality metrics counting toward the ACO scores? And what should patients' choices be?

We would be happy to answer your questions and look forward to your discussion.

MR. HACKBARTH: Okay. Thank you. Let's start on this side this time with round one clarifying questions, Kate, Jennie, Bruce, and Herb.

DR. BAICKER: In thinking about how to deal with the problem of random variation in smaller ACOs, is it within our choice set to think about different lengths of moving averages depending on the size of the panel, or does it have to be sort of a one rule independent of the size of the panel?

DR. STENSLAND: I think in the -- that would be under alternative models that the CMS could implement, and the first look that we have in terms of the way the law is written is the broad ability to implement alternative models. So I don't think there is anything necessarily that is off the table in terms of whether you have one common number of years or a smaller number of years for larger ACOs.

MS. HANSEN: Yes. Thank you very much. On page 14, when you spoke about -- excuse me, Slide 14, the difference of prospective and retrospective, and I think bearing in mind what, Mark, you brought up about the consumer participation, with the PGP demos, was there the experience that people opted out for any reason, since, you know -- or was it really not significant?

MR. GLASS: Well, in PGP, it was retrospective

assignment --

MS. HANSEN: Right.

MR. GLASS: -- so no one could opt out because they didn't know --

MS. HANSEN: Right. I'm sorry.

MR. GLASS: -- in advance that they were in there.

MS. HANSEN: Okay. So then this is more theoretical at this point that they could opt out, but --

MR. GLASS: If you did it prospectively, then they could have perhaps a choice to opt out.

MS. HANSEN: Right. Okay. But in the third little bullet there, it says, say in the PGP, they stayed with the physician, so that is how the model was? Once they were already in, yes --

MR. GLASS: Well, the PGP -- so it was retrospective, so at the end of the year they said, this patient was indeed in your PGP for that year.

MS. HANSEN: Okay. Understood. Thank you very much.

DR. STUART: Thank you. I really enjoyed reading this chapter, but I think there is a framing issue that bothers me, and it was brought up by Kate, and that is what

do we define as random. And rather than talking about random, I would like to flip it on its head and suggest that this really should be focused on the goal of having persistent savings, cost savings, and persistent improvement in quality, and then we can think of random variation as impersistent. And the reason I say that is I think that the difference between a benefit only, bonus only, and a penalty only is really kind of artifactual, and I will just give you one example, and in the spirit of round one and round two, I will stop at the end of that.

Here is an example of a benefit, what I would call bonus-only program. You have an ACO, doesn't matter what size it is, and they meet the quality target and they reduce the cost target, and so you credit them with this bonus payment. But you also tell them that they're going to have to have some evidence of persistency in this over time. Otherwise, there's going to be a clawback and we're going to take it away from you next year. Or we could say, well, we're not going to give it to you this year, but we're going to give it to you in your account for next year and if you're persistent, then you get to keep it.

And I think that's important from a framing

standpoint, because I think, frankly, this idea of having high thresholds for small plans is a killer. I just don't see how that is going to bring in plans. So the framing is the point that I'd like to emphasize here.

MR. KUHN: Just a quick question on page nine, and if I can go back, just one quick thought on here, Jeff, is that I understand the graph and understood when I read the materials about the fact that you could have some of these plans, at least in the top decile or the top ten percent could just achieve a bonus for doing essentially nothing. But I just want to make sure I understand, is that they also, in order to achieve a bonus, would have to meet certain quality thresholds, as well. So they're not mutually exclusive. There are some interdependencies here between the two. So this was just for illustrative purposes on the random variation, but also to achieve a bonus, you're going to have to hit quality metrics and other things that are out there, is that correct?

DR. STENSLAND: Quality metrics still have to be defined, but there will be something there.

MR. KUHN: Thank you.

DR. KANE: Just a quick question on Slide 14 about

the beneficiaries being assigned retrospectively. Can the physician then say, I never saw this person or heard of this person? I mean, is there some way for the physician to say, even though whatever metric you've assigned them to me, I've never heard of the person? I mean --

MR. GLASS: Well, they would be assigned based on -- in retrospective, they would be assigned based on the claims in that year. So if the physician never saw the patient yet had put in a claim that they had seen the patient --

DR. KANE: Well, I guess it gets to where it's only a very small, you know, like if it's a very small -- they might have gotten a claim, but it might have been for a small thing relative to a larger thing going on with that patient. I mean, I guess it has to do with being assigned in models --

MR. GLASS: It's usually a plurality --

DR. KANE: -- and how good they are and whether or not people can say that --

MR. GLASS: Yes. It's usually a plurality of E&M visits or something like that would be the assignment algorithm. And it could be to any physician in the ACO,

perhaps, will be how they do it, as opposed to a particular physician.

DR. MARK MILLER: So you catch that, that there's usually some critical mass that you have to clear before the patient gets counted as yours.

DR. KANE: And what I think I just heard him say is it can be to an ACO rather than a specific physician if there's a group of physicians --

MR. GLASS: That will have to be determined by CMS and regulation --

DR. KANE: That would make more sense.

MR. HACKBARTH: Bob and Scott, and everybody else?

DR. BERENSON: On Page 11 -- this, I guess, is for Jeff -- in talking about risk corridors to protect the ACO from large swings, you've established here it looks like sort of an aggregate, what I would -- not being an actuary and I'll defer to Cori here -- sort of an aggregate protection. In the paper, you talk about an individual level corridor.

I mean, in fact, should we think of this the way actuaries do reinsurance with individual and aggregate sto-loss? I mean, both of them could be on the table as the way

to approach this.

DR. STENSLAND: It's wide open so they both could be on the table.

MR. ARMSTRONG: I just wanted to clarify. We say in a couple of places that -- same slide, actually -- that CMS may have the authority to create alternative models. Do we know whether they do or not, first?

And then second, the alternative model that we've evaluated here, the two-sided bonus penalty model, is that ours or is that proposed from somewhere else? And is there a reason why subcapitation or other variations on a similar theme might not also be a possibility?

DR. STENSLAND: First, we try to put it in quotes, you know, because we're not going to make a legal judgment as to whether CMS actually has this authority. At first reading of the sentence, it looks like broad authority, but maybe that's up for the general counsel at CMS to decide. So I think there's a couple sentences where we give you the sentence in the mailing materials where it appears to give broad authority.

The reason we put the bonus penalty in there is just to show the most simple example we could come up with

where they have both upside and downside risks, and there certainly is all these other options on the table such as partial capitation, and people have different ideas what they think partial capitation is. And those are all potentially on the table.

MS. BEHROOZI: On behalf of everyone else, I should know the answer to this question. So you're talking about staying within the fee-for-service payment system. Does a provider have the option of varying the beneficiary's co-insurance amount? Can they decide to accept less, because you talk about keeping people in the ACO has to be through persuasion of one kind or another. Can they use economic persuasion or incentives in any way?

DR. STENSLAND: There's nothing specifically about that in the law. I guess this would be under, if CMS decided to do something, under the alternative models option or under their demo capacity. They could do something in that range. But there's nothing specifically stated in the law.

MR. GLASS: And they'd probably have to waive certain provisions about kick back and that sort of thing. I'm not sure which provisions exactly would apply, but I

don't think you can just unilaterally say, no, we're not going to charge you cost-sharing on something.

MR. BUTLER: So Slide 9 is truly around one question. So again, this says that if you had a pool of 20,000 or more, it's likely about 10 percent of the participants may get money for doing essentially nothing, irrespective of the quality issues at measurement. Is that right?

DR. STENSLAND: Basically.

MR. BUTLER: With the 2 percent threshold that had been shown in the model, right?

DR. STENSLAND: If you did nothing, you would have about a 10 percent chance of getting a bonus.

MR. BUTLER: Okay. So then on the far left-hand side, because the pool's minimum is 5,000, if that were not -- I'm going to back into the number. Instead of 3.6, if that were 2 percent, how many, do you think -- what's your guess at the percent that might receive a bonus with the smaller pool? Because right now that's what's on the table, the 5,000. You don't know?

DR. STENSLAND: I don't know. If you moved it up to 5 percent, it goes up to about 5 percent. So if you want

like something stuck in your head that's kind of a ballpark, about 5 percent of the pools of 5,000 people have spending that's 5 percent below expected.

MR. GLASS: But you're asking for the 2 -- if it was a 2 percent threshold --

MR. BUTLER: Yeah, a 2 percent threshold for the 5,000 group, would it get a third of the people, a third of, you know --

DR. STENSLAND: I don't know. I wouldn't speculate.

DR. NAYLOR: So this is really a great description of an effort to promote shared accountability and shared savings through care coordination.

In the actual provision, I think that the section talks about groups of providers, talks about health professionals, and defines that as physicians and other practitioners. In your sense of this, and consistent with other provisions in the Affordable Care Act to really grow access to primary care, period, through nurse-managed clinics and others, do these providers go beyond physicians in terms of who can be a part of these accountable care organizations?

DR. STENSLAND: In terms of -- they don't label it just as physicians in the Act. It is ACO providers, I believe, is the phrase, and there is physicians and other providers.

DR. NAYLOR: So, I guess explicitly then, this will allow nurse practitioners, others, to play a major role in these accountable care organizations?

DR. STENSLAND: I believe so. It refers to a certain subset of the law that I'd have to get into to see exactly who is under that subsection of the law, but I believe that's it.

DR. NAYLOR: I think so.

DR. CHERNEW: I have a question about Slide 7. It says, "The target equals prior year spending plus fixed growth amount minus the threshold." In the chapter it actually says three years prior, but apart from that, is that done on an individual basis? So if you save 10 percent of spending for an individual, the next year your target goes down by 10 percent because the prior year is now lower? If you keep someone in the ACO for five years, or however long it is, the more success you have, the lower you get paid as the prior year spending drops?

DR. STENSLAND: That's the way it looks like from the law, except I think I did say one year, but it should be the prior three years. So because you have this little rolling average thing, you don't get completely dropped down --

DR. MARK MILLER: Mike, you said individual in your sentence, but you meant the ACO?

DR. CHERNEW: It wasn't like an area-specific average like they do this for MA and stuff. It's the person who's there. The person in your ACO, they look at that individual person's spending and all the people who are assigned to you in their previous three years, as opposed to the spending in your HRR or something like.

MR. GLASS: Right, correct, the people assigned to the ACO.

DR. CHERNEW: That are counted like ACO.

MR. GLASS: Right.

DR. CHERNEW: It's not an MA version.

DR. CASTELLANOS: Part of our discussion last year and the years before on this, there's a very practical point. I live in Florida, I'm a physician, and we see a lot of snowbirds, people going and coming, and that's what

society is today. We discussed accountability at that time. Has there been any follow-up on that, how you're going to account for that?

MR. GLASS: I mean, that is another issue, how do you deal with people coming in and out of the ACO? And if that number ends up being a really high percentage, then it will make it difficult.

DR. CASTELLANOS: I would suggest that there's going to be tremendous geographic variation on that in the United States.

MS. UCCELLO: I think it's really important to differentiate different types of random variation, because that's going to have implications for what kind of risk-sharing mechanism makes the most sense.

And so, here I think we need to distinguish between variation that's specific to an ACO and variation that's systemwide. And so, I think I got stuck on this flu reference in the text because that seems to be more of a systemwide variation.

I'll follow up in Round 2 about this, but in terms of Slide 9, this is showing really more of the ACO-specific type of variation, perhaps. But is there any way we can

kind of figure out more of a systemwide variation from year to year?

MR. GLASS: Is your question then, if spending went up -- the way the ACO would work, as we understand it, is that CMS will estimate an increase in the fee-for-service spending average cross-nation. And you're saying, well, if there's a bad flu epidemic across the nation, that will go up versus the expectation and try to capture that sort of thing as well?

MS. UCCELLO: Well, that's the way I'm thinking, again for more of the Round 2 stuff, but I guess I'm just wondering, you know, how much does this truly capture the total variation?

DR. STENSLAND: I think this is definitely over-simplified because there are those two components. For example, I was thinking of the flu in your particular community and that would affect kind of your ACO, but not the whole nation.

But if there was something else that affected the whole nation, maybe a great new drug came out and it cost a gazillion dollars. It would also create some random variation that would be nationwide and it would affect your

odds of getting bonuses because it's all based on a projection of what spending will be.

So there's kind of this national projection number, and there's some variation around that. And then there's your individual characteristics and there's some variation around that. So you've got both of those two things taking place, which would add more variation.

MS. UCCELLO: I guess my question for this is, do we have any sense of the relative size with those two sources?

DR. STENSLAND: We could do it. We haven't done that.

DR. MARK MILLER: But I hear two things coming out of that question. One, can we quantify at all -- if there's going to be a national target, what kind of variation do you see around that. But two, in the exchange, in the exchange back and forth, my first reaction to your question is, as you think about issues like that that affect systemwide in setting the benchmark, and I'm wondering if that's kind of the way you're thinking about it.

MS. UCCELLO: I think that's one way to address that.

DR. MARK MILLER: And you're just saying that there may be some variation in that benchmark that needs to be considered?

MS. UCCELLO: [Nodding affirmatively.]

MR. HACKBARTH: So my question, I think, is related to Mike's. Mike said that to the extent that a provider is successful in reducing costs, it looks like they get evermore difficult targets if it's based on their historic costs.

Set aside that problem for a second, the law is quite specific in saying that the foundation for the target is provider-specific costs. So if you have historically efficient providers, they're going to get more challenging targets than providers who have historically been wasteful in their spending.

MR. GLASS: But the growth amount could conceivably be a higher percentage of their spending.

MR. HACKBARTH: Yeah, so --

MR. GLASS: So their target in that sense would be --

MR. HACKBARTH: So you're anticipating --

MR. GLASS: Sorry.

MR. HACKBARTH: -- what my real question was. So the language in the statute is national average growth, increased by national average growth. And the way you're interpreting that is the idea that we actually had in our ACO chapter, that it would be a dollar amount, a national average dollar amount, as opposed to a national average percentage amount.

MR. GLASS: That's correct.

MR. HACKBARTH: And if you calculate it as a dollar amount, that would be a higher percentage increase for the historically low cost providers and a smaller percentage increase for the high cost. That's the way you interpret the statute?

MR. GLASS: Yeah. Well, we're saying that because it says the projected absolute amount of growth in national per capita expenditures for Parts A and B services. It says that. That's how we were interpreting absolute.

MR. HACKBARTH: Yeah. I didn't think that absolute was the way I would phrase it. I would have said a dollar-specific national average dollar amount. Absolute doesn't make clear whether you're talking about absolute percentage changes or dollars, to me. So that was the --

MR. GLASS: Right. We're interpreting absolute as meaning not percentage, but rather, dollars.

MR. HACKBARTH: Okay. Let's go to Round 2. Again on this side, Kate and George, Jennie and Bruce, and Herb.

DR. BAICKER: So part of the reason I asked my original question and building on what Cori was saying, it seems like you have a classic signal extraction problem. You've got signal and noise and you're trying to figure out what tools to draw the signal about the provider inputs, and it seems like there are a number of different statistical tools in your toolkit and I don't know what the tolerance would be for doing something that seems non-transparent or fancy relative to some of the more basic measures.

But I know this has come up in other policy contexts, for example, in looking at teacher quality and doing teacher bonuses or retention decisions based on performance. They've had very similar signal extraction problems and I don't know how much we're drawing on that literature.

You've mentioned using longer look-backs for smaller ACOs to try to build up a big enough sample size so that sampling variation is less of a problem. You can also

try to net out national or regional trends using some co-variants or fixed effect so you could try to draw down common shocks across ACOs by controlling for other stuff.

And then you can also look at levels versus changes, and I don't know how that fits in with the statutory constraints, especially for smaller entities. If you do a mix, a weighted average of absolute performance this year versus changes over last year or changes over a moving window, then you may be able to net out more noise. That's going to result in some very different looking formulas for different ACOs, and maybe that's not acceptable.

But if I were purely just trying to extract signal from the noise, I would want to use all three of those statistical tools.

MR. GEORGE MILLER: My question deals with the smaller ACOs as well, particularly in rural areas. Do you have a sense if the variation for rural providers would have the same impact as a larger group? And just by the demographic, that they had longer distances to travel?

And particularly a concern for me is where they are on EMR and if that would help to effect some of the

savings by not having that infrastructure or not having EMR in place. Would you have a system that said to be an ACO, you need to have EMR in place, as an example? Have you thought about that and what the impact could be?

DR. STENSLAND: Well, I would kind of divide these rurals groups into two different groups. The independent, small rural provider. I think it's going to be a tough haul for the ACO to have 5,000 beneficiaries if you're a small, little six group practice. But if you are part of a big system, then I could see it happening, where you could have an ACO covering all the physicians in the system. Say you may even have an urban system that has some satellite clinics and hospitals and all of those people could be part of the same ACO.

MR. GEORGE MILLER: But wouldn't the problem be with EMR to get the same data and the data and the same information there if they all are not on the same platform? I mean, you're talking about a wide geographic area.

DR. MARK MILLER: I mean, just to pick up, you could think of something like a Geisinger which operates out and has a system that reaches out.

MR. GEORGE MILLER: I think more like Tom.

DR. MARK MILLER: I was coming to Tom. Actually, not, in all seriousness. Tom-like.

But what I would urge you to perhaps take that comment in just a slightly different direction. We've identified a couple of issues here that are kind of in-play, fairly large, maybe we have something to say about. But it doesn't mean you can't say anything about anything else.

One of the things that is going to be in play are, we talked about this a little bit, conditions of participation. What do you expect these groups to be able to do? For example, CMS's ability to bring data in in a real time has been shown to be somewhat difficult, okay, just to put it diplomatically. And I think some of the thinking for these groups is that they have the ability to track the patient and know when the patient goes to the hospital on their own. So some of your comments about electronic medical record or these types of conditions, if the commissioners feel strongly about these types of things, you should articulate it and it can be something that we can talk about as the process moves forward.

I know that didn't quite get to your rural issue, but I would use that comment to make a broader point.

MR. GLASS: And I would just add that if you're going to set quality measures that are going to require EMRs to report them, then that will also constrain who can become an ACO.

MS. HANSEN: Since it's right now quite open, one of the conditions of participation or considerations of participation and reporting is the population that presents with multiple morbidities and all.

It's an area that, many of you know, I consistently kind of have concern about to make sure that populations like this don't get left out, you know, when you try to gather an N of a population to have a slightly more hugely skewed well population, as we've had some experiences in the MA world and all, but the ability to at least elevate and focus some -- shine some light on this population -- but on the concomitant side, to make sure that the risk adjusters are there on the fee-for-service side, if this is the way it's going to be paid, so that the incentives would be there to probably maximize the best care coordination and show some impact, frankly, over a high utilizing population.

But I would just like to somehow convey an emphasis to elevate a focus on this because this is the

growing population. This is where, frankly, the Medicare and Medicaid, for that matter, money gets spent. So I just would like that elevation to be constantly visible. Thank you.

DR. STENSLAND: I think --

MR. HACKBARTH: Can I just make one thing before we get too far away from this exchange about conditions of participation? This is very tricky ground in that it's tempting to be very specific in terms of what these organizations need to look like and what sort of infrastructure and capabilities.

But there's a risk of sort of over-engineering the product. Frankly, I think some of that may have happened with Medical Home, where lots of very specific requirements are loaded on thinking, "Well, these things sound good," without a clear understanding of what really is essential to producing the product that we want.

You make it so that the cost of doing it is prohibitively expensive and that becomes a barrier to participation. So at one level, I think there have to be some minimum conditions of participation, but you need to be very deft in how you do it. Bruce?

DR. STUART: I'd like to follow up on my Round 1 point about persistency of the outcome, whether it's cost reduction or whether it's quality improvement, because I think this is important in terms of trying to get the incentives right. I used the example that I gave of a system that was set up with a clawback so that whatever your size is, you're given -- let's take the cost reduction and the quality stays the same.

You're given your bonus. It goes into the bank account. Now, you as an ACO are going to have to figure out what you're going to do with that bonus. So if you thought that you actually had earned that bonus, that you had taken activities which, in fact, internally you think can explain the difference, then you might well say, okay, well, we're going to distribute that bonus to the individual physicians within the group.

But what if you said, well, you know, I don't know whether we earned that. Then a prudent organization would say, well, at least some of that bonus ought to stay in the organization, in the account, until we figure out whether that reduction is a persistent reduction. Now, the persistent reduction could be varied. It could be last

year, it could be a moving average, it could be some combination of this, and I'm not suggesting that this is necessarily straight-forward, but at least in principle, it would put the onus on the organization to make a determination of whether it's earned it or not. Frankly, it seems to me that's where it ought to be.

And I think from just a language standpoint, you could say a bonus payment with a potential for a clawback is just a bonus only. It's not a penalty, because if it gets taken back, you just didn't earn it in the first place. So it's not there and you didn't deserve it. And so, it's not there.

Having said that, I think that once you put that onus on the accountable care organization, then I'm wondering, are state insurance commissioners going to say, well, you know, you're acting like an insurance company and so you've got to behave like an insurance company, you've got to meet reserve requirements, and I worry about that.

And then last, but certainly not least, this idea of persistency in behavior, in performance, rather, on the quality side strikes me as being fundamentally the same as on the cost side. But from a measurement standpoint, as you

note in the chapter, it's different because quality standards apply to specific patients with specific services that they should have received. Whereas, the cost standard presumably is across the whole panel.

But the idea would be the same, that you really do want to have persistency in these changes over time before you set up a system so that additional funds were going to go to these organizations.

MR. HACKBARTH: Bruce's point about running afoul of insurance regulations is, I think, an important one. It seems to me that would be an issue. If you go to not the shared savings, but a risk corridor model, that now you have a risk-bearing entity, albeit with the risk constrained by the risk corridors.

My recollection was that was one of the issues with the provider-sponsored organization option under MA. Your table listed, well, they didn't want to be in the claims business and all that insurance stuff, but I think there was also a question about whether they would then become regulated as insurance companies and have to deal with that. Do I remember that correctly?

MR. GLASS: It does ring a bell, right.

MR. HACKBARTH: Do you know, Bob?

DR. BERENSON: For better or for worse, I was at CMS when the PSO option came in. The point is that the PSO option was for entities that, for whatever reason, did not get qualified as an insurance entity. They had to demonstrate a reason why they were not an insurer, and essentially gave CMS the option of designating them in lieu of being regulated by the insurance.

But it was all in the context of solvency requirements and giving appeal rights and essentially treating them as insured entities, but permitting Medicare to do it rather than the states. That's what that was about. But I think it's definitely relevant here.

DR. KANE: The whole discussion about conditions of participation, I think, made me think more about not so much what the individual ACO might have to have in sort of structurally and processes, but also what conditions in the environment of the ACO we may want to consider, and that would include things like are there other payers willing to go along with this in the environment?

And also, is there some type of inter-operability in the electronic medical record so that when you do a

multiple -- if a physician group practice admits to three systems or two systems, that there's some way for them to actually build an information system so they can manage the care.

So I don't think it's necessarily conditions of participation for the ACO itself, but it's that there are some environment contexts in which we should talk about what fosters their success and how can Medicare help foster the success of an ACO, and then maybe choose ACOs that already are in those kinds of better oriented environments, and what are those conditions looking like.

MR. KUHN: This is a good list of questions that we have, and I agree with Glenn, I don't think we want to over-engineer what an ACO is. At the same time, I don't want us to try to boil the ocean. I think that's just too much for us to kind of reach out and get a hold of.

Having said that, I would like to just talk about one area on the issues up there, and that's the area of quality and the measurements in the quality area. I think the areas that we have in the paper dealing with population health, care coordination, patient experience, and hospital care were all appropriate measures and ought to be explored.

I think there's other things that we can perhaps look at as well in terms of efforts to really improve health in terms of smoking reduction, maybe obesity measures that might be out there. Other areas in terms of patient engagement measures might be useful to look at as well as we go forward.

But at the same time, I think there needs to be a trade-off and there needs to be kind of a value proposition of those who want to go into the ACO, and that again gets back a little bit to the COPs. But, for example, you know, if you're going to be doing all this additional quality reporting as a result of your engagement in the ACO, do you really need to continue to report on the PQRI measures or the RHQDAPU measures that are out there? Is that a redundancy in the system? Is that asking providers to do too much?

Another thing that you might want to think about, if you're in the ACO, do you really need to be participating in the readmission policies that are coming forth as a result of ACA?

Again, I think it's a redundancy and probably doesn't need to be there.

So, you know, to the extent that we can -- like I said, I don't want us to boil the ocean, but I do think we need to think about some of these interdependencies here of some of the parts of fee-for-service, how that's out there, so that ACOs, you know, on the quality side and some of these other areas, you know, get the maximum potential and make it as attractive an opportunity for providers to want to engage in these new efforts as we go forward.

My final comment would be just making sure that it is attractive for providers to look at. I know we're looking at some of the different payment models here beyond the bonus only, and I think you called it, Jeff, a bonus/penalty model. I think nothing sends shivers down the spine of providers more than calling something a penalty. So if we can eliminate that from our future conversation, I think that would be --

DR. STUART: [Off microphone.]

MR. KUHN: Yeah, an earned bonus or something else. I don't know what the term would be, but I think just branding these that there's a penalty out there somewhere I think creates some perception problems that I don't think we'd want to perpetuate.

MR. GLASS: One awkward thing might be that a physician or a hospital, if it were part of an ACO, could also still have fee-for-service patients who weren't assigned to it. And so if they didn't report measures for their ACO patients, would they still have to for their non-ACO patients? And complications would ensue.

MR. KUHN: Yeah, and that's going to be part of the complications as a result of the new things in reform as we get into these transitional modes on a lot of different payment and delivery models that are out there. But to the extent we can think of ways to help streamline the process to make it as attractive a model as possible would be the goal.

DR. BERENSON: Yeah, I want to just address the 5,000 threshold number. I have a concern about that being much too low. My understanding is that it first came about related to an analysis about statistical validity of quality metrics and you needed 5,000. But there's sort of a disconnect in the law. On the one hand, they identify organizations that include ACO professionals and group practices, networks of individual practices of ACO professionals, which I interpret at IPAs; partnerships or

joint venture arrangements between hospitals and ACO professionals, and hospitals employing ACO professionals. So PHOs, integrated delivery systems, large multi-specialty group practices, IPAs -- to me those are the correct organizations, and yet you can do 5,000 patients with -- an eight- or ten-member primary care practice can have 5,000. I don't think we want to -- in my mind, the ACO concept is not to do shared savings with a practice of ten docs. The medical home is there. I'm not concerned about putting -- making the threshold such that small practices or little tiny aggregates, you know, a tiny IPA, would not be able to participate.

I really think we need, practically speaking -- I know the law says 5,000. But my own view is that the design should be encouraging larger organizations that are capable of taking over, providing the continuum of care, and have the opportunity to either directly provide or arrange for the whole range of services. And so I would be looking at, you know, practically speaking, around a 20,000 threshold, and that's what I understand the PGP groups are talking about, that below that there's just no sort of efficiencies. So that would be my view on that one.

MR. ARMSTRONG: I didn't know I would be doing this, but I guess I'm building a bit on Bob's points.

First, like many of us, I come to this with a mind-set that sustainable lower medical expense insurance, which is what we're trying to achieve, comes from care systems that have certain elements, and we're trying to use policy to advance those elements. With that in mind, I would first affirm in my experience 5,000 seems like a number that is difficult to work with and creates risks that I don't think are worth. And I'm very glad to see that we are looking at alternatives to the bonus-only model. I don't think we've gone very far yet in exploring what those alternatives might look like, and I think that will be good work for us going forward.

I don't see how this could work if there isn't prospective identification of patients. One element in a care system that drives lower expense trends sustainably is a patient's relationship to the care system and a kind of engagement. And so my view on that question would be that we do need to be prospective in identifying patients.

Finally, I would just say that I would expect that piloting ACO-type models of care systems will be taking

place in markets all across our country, independent of this regulation. And my advice to CMS would be to look for ways in which, whether it's through their own innovation funds or through what will be hundreds if not thousands of other pilots, you know, coming to life in markets around the country, I would encourage CMS to look for ways to understand what the lessons are from all of those as well as it applies its own thinking to developing its requirements for these pilots.

MS. BEHROOZI: I just want to weigh in on the informing-the-patient factor. I don't see how you can not inform the patient and provide for prospective enrollment, or at least an opportunity to opt out. I mean, I think you can do both. You can look at retrospectively -- because I think the statute actually is pretty directive about that, look at utilization retrospectively and assign people to providers. But then from the point going forward where the provider is subject to the bonus or the other thing that we're not going to call a penalty -- which I think you do need to have -- then at that point I think the patient needs to know it up front, and I think other people need to have the opportunity to decide they want to be part of a system,

partly because of what Scott says about engagement, but partly because of something you clued me into, Glenn, the messaging. The messaging has got to be affirmative. You've got to talk about how these accountable care organizations will be accountable for quality and overall cost so that it's not somewhere down the line that a beneficiary says, Oh, wait a minute, they save money if I go to those cheapo whatever provider down the street, that cheapo lab, as opposed to the glamour lab with, you know, the nice curtains and everything. Oh, wait a minute, this is on my back that they're going to save money.

It's got to be affirmative messaging. It's got to be positive. It's got to be about accountability for quality and it's all good for the patient. And so the question that I raised in the first round about whether there's any way to build in economic incentives to patients, I think, you know, may be a little farther down the line, but I think it's an important one because, again, in the context where people are finding it harder and harder to pay for health care, they would say, hey, if the doctor and the hospital and whatever stand to save money by improving the quality of my health, well, maybe I should, too. And that

would also help drive more business to the better organized systems.

MR. BUTLER: I'll start with agreeing with Bob and Scott on the threshold participation number. First of all, we don't really want really small groups, even if -- that's not the intent, and if it's a bigger group, you need more than 5,000 to convert a culture anyway. So I would agree that -- I don't know whether 10,000 is the right number, but more than 5,000.

Now I'll step back a little bit on philosophy. Of the things we've talked about in the last couple of years when I've been here, this has been -- and we've always said how are we going to, you know, manage the continuum, what tools do we have available. I've always thought this one had maybe the most promise because it wasn't as invasive, did not require you to accept and hand out capitation, and had the opportunity of getting the mainstream in a different mind-set. And paired with Medical MA plans, I said maybe this could be kind of the broader longer-term solution.

So if you start with that and you say a majority over time you're trying to move into either an MA plan or something like this, then I draw the conclusion you want to

make the ease of entry easy if you want to try it nationally, because you're not going to get a lot of traction doing pilots that not many participate in because we've shown that that doesn't move too fast.

So, philosophically then, I would favor having ease of -- you know, which it steers away from penalties. I mean, people that take this on are going to put a lot of their dollars, a lot of their energy, a lot of their leadership behind it to get it started, which by itself is a fair amount of time and effort to get going, I think. And the reason I say to make it easy -- which means I'm not even for the penalties at all. I understand the math. But I think you want people in markets to feel that if they're not in it, somebody's going to get their patients. That's one way to think about it, because that would be an incentive: I better get in this, or I'm not going to be part of an organized system. And, therefore, that would get somebody to get off the dime, which requires a pretty significant participation in a given market.

The alternative is maybe don't make it so easy to entry, and at the risk of adding some of the regulatory burden that you talked about, have a statewide waiver, get

all payers into it, really try to do something along those lines that would really accelerate and intensify the effort in a given market so that you could really test it would be another way to go, or you could do both in some fashion. But consistent with my ease of entry, I would not spend a lot of energy -- I know this sounds wrong, but on the quality measures and letting people, patients know prospectively. I understand all the benefits of doing those things. We've already struggled with quality measurement in MA plans as we demonstrated last year. What makes us think we can just lop them onto these efforts when we really haven't had a lot of success in the MA plans?

So ease of entry, make it simple, and cast the net wide and far, you might get a lot of takers, as demonstrated by the interest in the room. If you add a lot of regulatory things and expenses and look at just the short-term incentives, as Bruce has pointed out, you're not going to get the sustainable commitment that we're trying to encourage.

MR. HACKBARTH: Just a clarification, Peter. So you are emphasizing ease of entry in terms of not a lot of detailed requirements and no risk bearing -- is the two

1 themes I heard most -- but then deal with the threat of
2 bonuses based on random performance by escalating the
3 minimum size requirement. Is that the combination? Do I --
4 MR. BUTLER: Yeah, there may be ways, though, that
5 you can get at the -- I understand the math. If it's
6 random, you may be spending more than you had thought you
7 would spend. There may be ways to handle that. Maybe some
8 of Bruce's longer-term pull it back or whatever is a way to
9 do it.
10 I think that -- believe me, the penalties and some
11 of those things are worth pursuing, but I would view the
12 innovation -- I would use that home that the Secretary has
13 to really push some of the more aggressive models as opposed
14 to doing it in the voluntary model that the regulations are
15 supposed to address this fall.
16 MR. HACKBARTH: Okay.
17 DR. NAYLOR: Just briefly, because I agree with
18 many of the comments. I think the great opportunity here is
19 around a chance to take accountability for a population and
20 focus on the population as well as the individuals within
21 it. And it does -- we haven't paid a lot of attention to
22 what it's going to take for systems to build the capacity to

do that. The thing I like about the act is it places emphasis on evidence and using what we know and what we don't know and creating the right kind of network of providers.

I think there's where there's also an opportunity to focus not so much on individuals within this group, but the team of providers. How are we going to maximize on the contributions of all team members? So in terms of models, alternative payment models, one that we might want to explore is not just shared savings to the individual typical providers, physicians or hospitals, but to the team who shares accountability for the outcomes here.

On outcomes, I think that this is as really great opportunity to focus on a simplified set of outcomes that really focus on people and what they want. So they do want to be engaged in their plan of care. Their families do, too. They want shared decisionmaking. They want something that's going to work in terms of improving the way they get up every day and function and quality of life.

So I think we pretty much know where we should be focusing our energy on performance measures, and I do think we should be encouraging that. What we do know is

interoperability isn't going to work unless we have the right data elements in there. And right now the meaningful use criteria pay little attention to the data elements that are going to allow providers to function efficiently and effectively as a team. So I think we should be pushing for the next generation of the high-tech meaningful use act to really focus its attention on those elements that are going to make it work better for people.

DR. CHERNEW: So first I'd like to say that my general preference would be for a smaller program that's better designed than a program we make bigger so we get more people in but don't design very well. And that said, I would generally be supportive of having some downside risk, whatever you term it. I think that's going to end up being important. If we see this is the wave of the future, I think we're going to need a program that has some of that.

I'm very worried about the current proposed payment rate process. I think it's not very tenable to have this heterogeneity across ACOs based on how they've done, particularly a system in which the better you do means there's a growing gap between what you're getting paid and other people are getting.

It sort of penalizes you by capturing all your efficiency gains in ways that I don't think are useful. In the same spirit, I would generally support a process that's a little bit more like a MedPAC process for the update as opposed to some sort of national spending growth update, because that just seems to raise the target based on what everybody else is doing as opposed to where we want to actually get to.

So I think in designing a sort of ACO model which many people talk about as being the wave of the future, the solution to a lot of our problems, we really should think about a design in which that's likely to come to pass. And at least in some of the things that Jeff and David presented, I don't see it quite there yet on some crucial points.

DR. CASTELLANOS: I'd like to make two points. Carrying on what Mitra said, I look at it from the beneficiary's viewpoint. What is the benefit for the beneficiary? Every beneficiary expects that doctor to provide the best quality, and if they go into this ACO model, especially prospectively, he or she expects excellent quality. If she or he doesn't go into that model and has

that chance of outgoing, he or she is still going to get the same quality.

So you got to look at it from the perspective of the beneficiary. What is the benefit and what can that person get by going into a system that may -- and I didn't say it will provide a lower-priced provider and a lower-priced sector. I don't see the benefit unless you give some economical benefit to the beneficiary.

The same with the physician. As a physician, and as a businessman, because I'm running a business, I say, What's the advantage of myself going into a bonus-only model? Well, one of the things I remember Nick Wolter saying when he went into the PGP model was there was no upfront costs. And I know he mentioned that to me, and we had a lot of discussions that it was expensive for the Billings Clinic to go into this model, and they never got that reimbursed.

So I think if you're going to look at this, you got to understand why would a physician go into this, or a business, especially a primary care doctor who really doesn't have a lot of excess income, and why would a beneficiary, the patient, go into it.

The other issue -- and, again, Bruce, you kind of mentioned it earlier this morning about resolving some of the regulation issues. If you expect the primary care -- and this is going to be a primary care model. If you expect him to take care of a lot of the urologic issues, a lot of the general surgical issues, and as long as that person follows evidence-based medicine and guidelines and clinical pathways, et cetera, he's going to be okay. But he's going to need some protection from defensive medicine. He's going to need that to cut down on his costs.

Now, I know there was an earlier discussion today, and I know Bob Berenson and myself had some brief talk about this. This is a big cost for the physician, and there's a good study now in Health Affairs that shows that it probably accounts for 2.4 percent of annual expenses for health care. So we need to get some protection under regulatory issues on defensive medicine.

MS. UCCELLO: Okay, I'm just going to circle back to the risk sharing.

I think the text provides some pretty compelling case for a two-sided risk-sharing mechanism. But, again, just to restate that it's not going to be truly symmetric if

there can't be some kind of adjustment to the threshold to reflect this national variation.

To do that, however, you know, by definition that's going to have to be retrospective. So does that make -- so the target is not necessarily going to be known in advance to the ACO. Is that going to be problematic? I don't know. But I think we have to recognize some trade-offs with that.

In terms of Bob's questions about reinsurance, I think aggregate reinsurance is pretty much akin to a risk corridor. But an individual reinsurance is really just looking at specific outliers. And that could be incorporated into either this one-sided or two-sided approach in that if you have an outlier, they could be top-coded at a certain amount; they could be -- but I don't think you'd want to do that because you want to hold that ACO responsible for at least some share. You want to encourage care management above that level so you can have some kind of cautionary, in a sense, accounting for that. But either way I think that could be incorporated into this. But, again, you're making the target more fuzzy. Does that make it difficult to achieve or to know how to get to?

MR. HACKBARTH: I continue to have concerns about non-enrollment models. I agree with some of the points that Scott and Mitra made about the desirability of engaging the patients actively, and that can only happen when they're exercising a choice to participate. But there's also -- so that's a positive reason for favoring an enrollment model. I have some negative reasons as well, and they relate to what happened in the 1990s with the managed care backlash, which I still have nightmares about. At the time I worked for Harvard Community Health Plan, a very good organization that got tarred with a lot of nonsense in sort of a national reaction to managed care. So it was a traumatic experience for me. And so I've thought a lot about what were the lessons that we could have, should have learned, and one of the lessons that I think I came away with is that the explosive combination was patients feeling like their care had been changed without their making an active choice to choose that new style of care. And often that happened because an employer eliminated options for them; they were forced into some model of managed care as opposed to making an active choice to enroll. And so they felt herded, compelled. They didn't like what they got. And what I

think was the match that set off that potentially explosive gas was there were providers who didn't like it, and they had every incentive to foment unhappiness among their patients. And as we move into the ACO world, there will be providers who are losing, or the ACOs aren't working, frankly. And they will have an incentive to raise doubts in the minds of their patients about what's happening to them. And if those conversations go like, Oh, do you know that you are now participating, getting your care from an organization where people have an incentive to withhold care from you? Oh, you didn't even know that, did you? That is just the road back to where we were in the 1990s, and it wasn't a happy place.

So I really feel that -- and there are a number of different ways that it might be accomplished, but I think there needs to be serious thought given to how to engage patients in this in a positive, constructive way, and if the patient doesn't want to participate, they need to somehow be protected.

Now, I know that's more questions than answers, but I think we could end up having a very bad experience again. And I know all the reasons for the non-enrollment

models, you know, that, Oh, what we want to do is get as many patients into this, and it's only if a lot of patients are involved that there are economic incentives and rewards are going to be strong enough. But to skip over that step of getting the patients involved I think is just very, very risky.

Unfortunately, as I listened to the conversation, I did not hear unanimity on a number of key issues, so I think we've got some work to do to identify issues and see if we can bring ourselves to resolution for purposes of providing advice to CMS and the Congress. I think it was a very good discussion. I think it was very focused and substantive. But I think we're in different places on some important issues that we'll need to work through.

Thank you, Jeff and David, for your good work in framing the issues, and obviously there will be more on this soon.

Now we'll have our public comment period.

[No response.]

MR. HACKBARTH: And it looks like nobody's racing to the microphone, in which case we will adjourn for lunch and return at 1:15.

[Whereupon, at 12:13 p.m., the meeting was recessed for lunch, to reconvene at 1:15 p.m. this same day.]

AFTERNOON SESSION [1:15 p.m.]

MR. HACKBARTH: Okay. It's time to begin the afternoon session.

Our first session is on recent changes affecting Medicare beneficiary financial liability.

Carlos.

MR. ZARABOZO: Good afternoon. In this session, Rachel and I will provide you with background information about how recent regulations and guidance prepared by CMS and how the recently enacted Patient Protection and Affordable Care Act, or PPACA, affect beneficiaries' financial liability. We're going to walk you through recent changes in fee-for-service as well as changes in the Medicare Advantage program and Part D of the Medicare drug benefit.

As we go through the slides and describe the details of recent changes, here are some issues you may want to think about for discussion purposes:

For the past several years, the Commission has been dealing with the question of attempting to seek a balance in Medicare's cost-sharing, protecting beneficiaries from high out-of-pocket costs, while at the same time trying

to keep patients somewhat sensitive to the costs of care, particularly in situations where care may be more discretionary in nature. So one issue to consider is whether changes to Medicare cost-sharing are moving in a direction that gets to that balance.

In past meetings, we have examined the question of ways to redesign the cost-sharing structure of fee-for-service Medicare. Later, in our current cycle of meetings, we will return to the issue of innovative benefit design and whether there are models in the private sector that can be applied to Medicare. Within the Medicare program itself, through Medicare Advantage, private plans can modify the cost-sharing structure of fee-for-service Medicare within certain limits. Some of the features found in MA plans may be applicable to fee-for-service Medicare in achieving the balance that we have talked about.

With regard to MA, as you are aware, there have been major changes in MA payment policy. Later this fall, we will provide an overview of those changes and their possible impact.

In terms of learning from the experience of MA plans, in the March 2010 report to the Congress, the

Commission recommended that MA encounter data be collected in such a way as to allow quality comparisons between fee-for-service and Medicare Advantage. The encounter data, which CMS expects to begin collecting in 2012, will also enable researchers and others to evaluate the effect of MA plans' cost-sharing structure on utilization of care and whether the quality of care is affected by different cost-sharing structures. When encounter data or aggregate utilization data become available to us, we anticipate undertaking such an analysis.

And now, moving on to the gory details of our presentation, Rachel will discuss the situation in fee-for-service Medicare and recent changes.

DR. SCHMIDT: Thanks so much, Carlos. I get the gory details, yes.

So let's start with changes to cost-sharing in fee-for-service Medicare.

The biggest thing to note here is there are few direct changes to it, with the exception of preventive care. Most of the cost-sharing requirements for Part A and Part B services remain the same as they've been, and much of it takes the form of percentage co-insurance on Medicare-

approved amounts or is otherwise tied to rates of growth in Medicare spending.

Fee-for-service Medicare has no cap on beneficiaries' out-of-pocket spending, unlike Medicare Advantage, which Carlos will tell you about in a minute. The relationship between many of the changes in PPACA and fee-for-service Medicare's cost-sharing is more indirect. If the new law's measures are able to slow growth in Medicare spending, then they will also slow growth in fee-for-service cost-sharing and premiums over time.

One direct change in the new law that affects fee-for-service cost-sharing relates to preventive care. Beginning in 2011, beneficiaries will not have to pay any cost-sharing for preventive services covered by Medicare that have been recommended by the U.S. Preventive Services Task Force with a grade of A or B. The law also gives the Secretary authority to modify Medicare's coverage of preventive services based on Task Force recommendations.

Turning to the Part B premium, what I'm about to tell you is not a change in law but is a projection of how the Part B premium will look to different categories of beneficiaries. Under law, Part B premiums are set each year

to equal 25 percent of the average cost of Part B services for elderly beneficiaries. However, the law also contains a hold harmless provision in which the annual increase in the Part B premium for a beneficiary cannot be larger than the dollar amount of the annual cost of living adjustment in their Social Security benefit.

In 2010, there was no Social Security COLA and about three-fourths of Medicare beneficiaries were protected by this hold harmless clause, keeping their Part B premium flat at $96.40 a month. However, under law, Medicare still needed to recoup the aggregate amount of premium dollars it would have received. So that aggregate dollar amount was spread out only among the remaining one-fourth of beneficiaries who are not protected by the hold harmless provision. They faced a Part B premium of $110.50 a month. The four categories of people who face the higher premium are shown on this slide. The Medicare trustees expect a similar situation for 2011.

There is one particular change in PPACA that relates to the Part B premium that Kate mentioned this morning in terms of the context chapter. Remember that in 2007 Medicare began using an income-related premium. In

other words, beneficiaries with higher incomes receive less of a subsidy than everyone else.

In 2010, the highest income earners with modified adjusted gross incomes of $214,000 for an individual, or double that for a couple, paid $353.60 per person per month for Part B. Under the new law, the income threshold at which people start to face the income-related premium will stay at 2010 levels over 2011 to 2019.

CMS's Office of the Actuary projects that the number of beneficiaries who face higher premiums will increase from about 4 percent in 2010 to more than 10 percent by 2019. An open question is how many of these individuals will choose to drop out of Part B as a result. The Office of the Actuary thinks it will be small, but no one really knows for sure yet.

There are a couple of other changes in PPACA that do not affect fee-for-service cost-sharing per se but do affect supplemental coverage. Last spring, we talked about how PPACA includes a provision in which the Secretary will request that the National Association of Insurance Commissioners revise standards for the most popular types of Medigap policies -- Plan C and Plan F -- to include nominal

co-pays in order to encourage appropriate use of physician services in Part B. The new law doesn't say exactly what those co-pays will be. It leaves that to NAIC, but directs them to use peer-reviewed evidence or examples from integrated delivery systems. The new standards are to be ready by 2015 and will affect policies issued after that date. So this effectively grandfathers current Medigap policy holders.

While not part of PPACA, NAIC recently went through a similar exercise for a new type of standard Medigap policy called Plan N. This summer, insurers began offering Plan N policies which include $20 co-pays for office visits and $50 co-pays for emergency room visits. These new policies will have somewhat lower premiums in return for co-pays at the point of service. However, we may want to watch to see whether Plan N will be used as the role model for revisions to Plan C and Plan F. A concern in doing this is that co-pays apply in a more narrow fashion than may be desirable. Basically, in Plan N, they apply to evaluation and management services but do not apply to other types of services that may be more discretionary in nature. For example, Plan N covers all of Medicare's cost-sharing

for durable medical equipment and imaging. The Commission may want to keep future revisions to Medigap standards on its agenda.

The new health reform law contains other provisions that may affect retiree health coverage, such as the introduction of state-based health insurance exchanges and requirements that large employers offer coverage t their workers. Many of these changes are aimed at individuals who aren't yet Medicare beneficiaries, but the responses of employers and workers to these changes will affect the future distribution of secondary coverage to Medicare.

MR. ZARABOZO: Thank you.

On average, Medicare Advantage plans have cost-sharing below Medicare fee-for-service levels for the Medicare Part A and Part B services. In 2010, the monthly dollar value of cost-sharing reductions for MA enrollees was, across all MA plan types, about $38 or about 30 percent of the $132 a month that is the average value of cost-sharing in fee-for-service Medicare.

Plans use rebate dollars to finance cost-sharing reductions. As you may recall, when a plan's bid to cover the Medicare benefit package is below the MA benchmark for

the plan service area, a share of the difference goes back to enrollees in the form of a rebate to provide extra benefits and the remainder of the difference is retained by the Treasury. The most common extra benefit for MA enrollees is the reduction of Medicare A and B cost-sharing, as we discuss in the mailing materials.

Looking at the differences among plan types in MA, some of the rebate dollars that HMOs have are generated because they are bidding below Medicare fee-for-service payment levels in their market areas. However, on average, it is only HMOs that are bidding below fee-for-service levels. For all other plan types, rebates are possible because MA payments exceed fee-for-service payment levels across market areas.

Because of various changes in payment policy for MA plans and because of provisions tying payments and rebate levels to quality measures, the level and distribution of rebate dollars is likely to change in the future. As I mentioned, later in the fall, once we receive plan bid data from CMS, we will have a presentation on the MA payment changes and their impacts, including how quality measures will be a factor in determining rebate levels.

In terms of the details of what cost-sharing for Medicare services looks like in MA plans, the cost-sharing structure can be quite different from cost-sharing in fee-for-service Medicare. Two general statutory rules apply:

One rule that has been in place since the original statute authorizing risk plans is the requirement that, on average, the actual value of cost-sharing in MA cannot be greater than the cost-sharing of fee-for-service Medicare for Part A and Part B services.

The other general rule introduced in 2003 is that cost-sharing provisions in MA plans cannot be discriminatory in a way that would discourage enrollment of sicker individuals or people with particular conditions. This non-discrimination provision in the law has been the basis of a number of rules that CMS has imposed with regard to cost-sharing in MA plans. Recent legislation also imposed additional rules for MA cost-sharing.

Before reviewing the specific rules that apply to MA plans, here we show some of the ways in which a typical MA plan will have cost-sharing that differs from fee-for-service Medicare. For physician services, for example, MA plans will typically have fixed dollar co-payments rather

than the 20 percent co-insurance that applies in fee-for-service. Often co-payments will be higher for specialists than for primary care physicians.

For inpatient hospital care, MA plans usually do not have deductibles, but plans will often have daily co-pays on the first few days or weeks of inpatient hospital care with no limits on the number of days covered. This compares to the fee-for-service approach of having a large deductible, co-pays in the later days of the stay and a limit on covered days.

I would also note that MA plans may cover as a Medicare-covered service, skilled nursing facility care that is not preceded by a three-day hospital stay. MA plans often have cost-sharing for durable medical equipment as does fee-for-service Medicare, and about 10 percent of plans have cost-sharing for Medicare-covered home health care. Fee-for-service has no home health care cost-sharing.

Finally, something we will talk about in more detail is the MA feature of having an upper limit or cap on a member's total out-of-pocket expenditures in a year.

I mentioned that CMS has used the general statutory provision prohibiting discrimination to impose

certain rules on cost-sharing in MA. These include the rules that limit cost-sharing for emergency room services to $50 and a rule that imposes a limit on cost-sharing for certain services such as Part B drugs, so that cost-sharing is not higher than fee-for-service Medicare. A new regulatory requirement is that all plans must have yearly out-of-pocket expenditure limits or caps, which I'll discuss in more detail in the next slide.

The PPACA legislation included limits on cost-sharing in MA for the specified services listed in the slide; that is chemotherapy administration, dialysis and skilled nursing facility care. PPACA also gave the Secretary specific authority to limit cost-sharing to Medicare fee-for-service levels on other services. At the same time, the legislation reiterated that plans could impose cost-sharing for services in which Medicare fee-for-service did not have any cost-sharing, such as home health care.

Earlier legislation provided protections to Medicare/Medicaid duals in special needs plans, protections that CMS extended to all duals through regulations, regardless of the type of MA plan.

Beginning with the 2011 contract year, all MA plans must have annual caps on members' out-of-pocket expenditures for Medicare Part A and Part B services. The required cap will be $6,700 per year for all plans except that regional preferred provider organizations set their own limits under the prior law.

Now plans can also have a voluntary cap of $3,400 or less. Plans that use the voluntary cap are granted greater leeway in the amount of cost-sharing they can charge for individual services at the point of service.

Local PPOs, like regional PPOs, must have caps for in-network care at either the voluntary level or mandatory level, but they also must have an overall cap that applies to the combination of in-plan and out-of-plan services. Since 2003, regional PPOs have been required by law to have in-network and overall out-of-pocket expenditures.

Now Rachel will discuss cost-sharing under Part D.

DR. SCHMIDT: PPACA made several changes to Part D, most of which broadened the Part D benefit and decreased beneficiaries' cost-sharing obligations. The most notable change is to phase out Part D's coverage gap -- the range of drug spending where enrollees now pay 100 percent co-

insurance. That phase-out starts this year by giving beneficiaries who reach the coverage gap and do not receive Part D's low income subsidy a $250 check. CMS estimates that about one million of those have been mailed so far, and they expect that number ultimately to be closer to about four million.

Beginning in 2011, there will be a coverage gap discount program provided by pharmaceutical manufacturers that I'll describe more in a minute.

In addition, Part D's cost-sharing requirements in the coverage gap will fall over time, from 100 percent today to 25 percent by 2020. That reduced cost-sharing starts a little earlier for generics than for brand name drugs, which I'll show you on some slides in a second.

Also, today the parameters of the standard defined Part D benefits -- the deductible, the start of the coverage gap, the out-of-pocket limit -- change each year by the average increase in Part D spending. Under PPACA, the out-of-pocket threshold will increase more slowly between 2014 and 2019.

This chart is borrowed from Kaiser Family Foundation because it nicely shows the overall difference in

the Part D defined standard benefit before and after changes in the new law. You can see on the left that the standard benefit has a deductible, then a period where the enrollee pays 25 percent co-insurance.

Most Part D enrollees don't reach the coverage gap, but if they do they pay 100 percent of their plan's negotiated price for covered drugs. And then if that enrollee has very high drug spending, they reach an out-of-pocket threshold where their cost-sharing falls back to about 5 percent co-insurance. So the beneficiaries' cost-sharing is in the dark blue and covered benefits are in light blue. On the right, you can see that the dark blue section is much smaller.

So Part D's benefit will broaden under the new law. Part of the benefit expansion is being picked up by pharmaceutical manufacturers through their discount program. Still, Part D will begin covering more of what has been enrollee cost-sharing. That's good news for those enrollees who have relatively high drug spending. However, it also means that there will be upward pressure on monthly premiums for Part D, and Medicare's program spending will increase somewhat.

Briefly, the year-by-year decrease in cost-sharing for brand name drugs is shown on this chart. The 50 percent shown in light blue reflects the manufacturer's discounts they'll be giving to non-low income subsidy enrollees who reach the coverage gap, the medium blue portion shows how the Part D benefit will expand over time, and the dark blue shows how enrollee cost-sharing will decrease.

And here's the same slide for generic drugs. There is no manufacturer discount program for generics, but Part D's benefit will broaden over time to cover 75 percent of the price of generics, with enrollees' cost-sharing falling to 25 percent for those who are in the coverage gap.

Here is a little more about how the coverage gap discount program will work. Pharmaceutical manufacturers that want to continue offering their products through Part D have signed agreements to participate in the discount program. Beginning next year, they are to give non-low income subsidy enrollees who reach the coverage gap a 50 percent discount on the price of their drugs. That is on the price that the plan sponsor has negotiated as payment with the pharmacies. So this is not considering manufacturers' rebates. So when a beneficiary goes to the

pharmacy and has reached the coverage gap, they pay the discounted price.

For purposes of figuring out when a beneficiary has reached the out-of-pocket threshold, where they pay about 5 percent co-insurance, the new law says that Medicare should include both what the enrollee paid and also the amount of the manufacturer discount. This has the effect of increasing the number of enrollees who will reach the catastrophic region of the benefit, where Medicare pays for more of the coverage. So again, this is good news for enrollees with high drug spending but will lead to upward pressure on Part D premiums and Medicare program spending.

Finally, the PPACA also initiated income-related premiums in Part D beginning in 2011, using the same income thresholds as in Part B.

Also, like Part B, the income thresholds will not increase between 2011 and 2019. The Medicare trustees estimate that about 3 percent of Part D enrollees will pay higher premiums in 2011 and this will grow to about 8 percent by 2019.

So here we are, concluding with the same slide that Carlos showed you earlier as a launching point for your

discussion about Medicare cost-sharing and beneficiaries' financial liability. We're happy to take your questions.

MR. HACKBARTH: Okay. Thank you, Carlos and Rachel.

Let's begin with round one clarifying questions. Cori?

MS. UCCELLO: Just a quick question, has the Commission ever commented in the past about the hold harmless provision?

DR. SCHMIDT: Not to my knowledge.

MS. UCCELLO: Has the Commission ever commented on the hold harmless provision?

DR. SCHMIDT: The hold harmless provision in Part B that we discussed earlier, not to my knowledge, no.

MR. HACKBARTH: Other clarifying questions?

MR. BUTLER: Two quick ones just on supplemental or Medigap policies. What is it, like 85 percent or something, of all enrollees have?

DR. SCHMIDT: It's 90 percent. There's only about 10 percent or so that have no supplemental coverage.

MR. BUTLER: Okay. Then the second question, I think can be best answered by asking on Slide 14 or 13, but

this will work. So I guess what I didn't fully appreciate is that the gap coverage that now is mandated, a lot of the responsibility is the plan, not the federal government.

DR. SCHMIDT: You mean as it changes over time?

MR. BUTLER: Yes.

DR. SCHMIDT: Yes.

MR. BUTLER: And so isn't that just passed along in premium increases to the individual then, in effect?

DR. SCHMIDT: Well, the premiums cover about 25.5 percent of the average value of the standard benefit. So it's split between the Medicare program and beneficiary premiums.

MR. HACKBARTH: Other clarifying questions?

DR. BERENSON: On Slide 4, I just want to understand the hold harmless/non-hold harmless groups. If in fact there was no hold harmless, would the premium have been somewhere between those two numbers, like around 100 or something?

DR. SCHMIDT: I should have done that calculation. I didn't. I'd have to guess.

DR. BERENSON: But I mean basically the group that's not held harmless has to make up for.

DR. SCHMIDT: Exactly.

DR. BERENSON: So what will happen in 2012? They might actually see a decrease? Is that allowable in there?

DR. SCHMIDT: We actually asked the actuaries that question, and no, it would not decrease.

DR. BERENSON: So they might be flat for a while until the others caught up to them, okay.

Although if, just continuing the same question, if we're in a low inflation era now or at least for the next few years, and the COLAs are very small or nonexistent, that means there's going to be more of a financing burden on the people who are not covered by the hold harmless and more pressure on their premiums, pushing them up.

DR. SCHMIDT: That's correct.

MR. HACKBARTH: So do I understand the system correctly, so one category of beneficiaries that's not protected by the hold harmless is the new enrollees? So it's like each class of new enrollees will have their own unique premium based on what's necessary to cover the residual cost when they enter the Medicare group?

DR. SCHMIDT: I think yes, but the limiting factor is how well economic growth is, and the economy as a whole.

So this is driven by a comparison of the Social Security COLA to what would be the increase in the Part B premium, those dollar amounts, and that's the constraint on it. So usually, say an average monthly Social Security benefit is on the order of $1,000 and you get something on the order of a 3 percent/4 percent COLA, that usually would be enough to cover the average increase in the Part B premium.

So hopefully, if we get to a point where there's more economic growth again, that will kick in again. But yes, in years where there's flat growth as we're seeing and no COLA increase, then yes, the new entrants, the people who are duals, who are in the Medicare savings programs, plans rather, those folks are going to be bearing for the aggregate dollar amount of premiums that would otherwise be paid.

MR. HACKBARTH: In the other cases, basically, the government is picking it up.

DR. SCHMIDT: Through Medicaid, yes.

MR. HACKBARTH: For the duals and the savings program people.

DR. SCHMIDT: There's the FMAP. So it's shared between state and fed.

MR. HACKBARTH: And then there's the high income people which is sort of a separate set of issues.

DR. SCHMIDT: Right.

MR. HACKBARTH: But the new enrollees are not having it picked up by anybody else. They're, by definition, not high income people, and this is getting loaded onto them disproportionately right now.

And did I understand you correctly to say that once their premium is set it doesn't go back down?

DR. SCHMIDT: Well, it's again this comparison of whether the increase in the Part B premium is bigger or smaller than the COLA. And my understanding, if I was interpreting what the actuaries said correctly, is it probably would not go down.

MR. HACKBARTH: Yes. Okay.

Clarifying? Bruce?

DR. STUART: I wonder what's going to happen to the people who come, who are eligible for Medicare under the new higher income limits for PPACA when they become Medicare-entitled. Would they be under the same rules as duals today because if they are then there's a substantially, fairly large number of people who will be

Medicaid-entitled in the years before they come into Medicare, who are not now and then they would be excused from all of these cost-sharings? Is that correct?

DR. SCHMIDT: I would have to go research that. I don't know the answer off the top of my head.

MR. HACKBARTH: Anyone else? Interesting question.

DR. STUART: It strikes me that that could be bigger in terms of the cost impact on Medicare than almost anything else.

MR. HACKBARTH: Right. To be honest, I haven't thought about that.

Jennie?

MS. HANSEN: I was just commenting earlier that I do think that because of that higher level of qualification we'll see a lot more duals. You know. Just by virtue of their --

MR. HACKBARTH: Joan may have some information for us.

MS. HANSEN: Joan has an answer?

DR. SOKOLOVSKY: Even at those higher income limits, even if they don't become full duals, as the income

limits work right now, they would still be eligible for MSP. So the government would still be picking them up.

MS. HANSEN: Sure, sure.

DR. SOKOLOVSKY: Without any changes.

MS. HANSEN: Right. So that does say that there will be more people getting some federal subsidies as a result. Right.

DR. MARK MILLER: Whether it's full dual or whether it's MSP.

MS. HANSEN: Yes.

DR. MARK MILLER: We can look more carefully at this question and get the specifics.

MS. HANSEN: My question is really relative to the new groups, especially the ones who are paying out of pocket.

I just wonder, between the Part B side and then the increase in income relating under the Part D, just what that co-payment trajectory is going to start happening for middle income populations, kind of not on the Medicaid qualified side and not on the $214,000 and above side, just what that's doing. It's kind of like the new Alternative Minimum Tax on the Medicare side for people.

So just wondering about our just tracking what happens there because that group seems to also once again the middle income ends up paying that much more.

MR. HACKBARTH: Yes, and within that group you could have greatly disparate premiums based on when you came into the program. So you could have the same $25,000 income beneficiary who came in 10 years ago, say, and they'll have 1 premium. And somebody who came in, in 2010, would have a markedly different premium. Right?

MS. HANSEN: Right.

MR. HACKBARTH: Same income level.

DR. CHERNEW: Higher.

MR. HACKBARTH: Higher, right.

DR. SCHMIDT: Income data are pretty difficult to get, frankly. So it's hard to make predictions or projections that we can feel very confident about, but they do exist, and we'll try and bring you what we can.

MR. GEORGE MILLER: Slide 4 is up there. No, Slide 3. I'm sorry. Slide 3. By removing all cost-sharing for preventive services recommended by, with Grade A or B, who pays that decrease in revenue for the providers with this happening? I understand why it's happening.

DR. SCHMIDT: That's a good question. That's kind of up in the air at this point.

MR. GEORGE MILLER: Thank you.

DR. SCHMIDT: I've seen some comments, I think, to the physician rule that are along the same lines, and I don't think we know the answer quite yet.

DR. BAICKER: You mentioned trying to draw lessons from the Medicare Advantage experience. I know the encounter data aren't available yet. I wonder what data are available from Medicare-based administrative sources and from surveys that may be non-comprehensive but informative, like the MEPS or the HCAP or things like that, both on the payment side and on the services utilization side.

MR. ZARABOZO: There are such data, like MCBS for example. You can use that for this kind of analysis if you wanted to do that.

DR. BAICKER: But you're missing a bunch of stuff that you will get in the encounter data in terms of utilization.

MR. ZARABOZO: Right.

DR. BAICKER: Is the only difference that from the MCBS you just have a survey sample but the same richness of

information is there, or are you waiting on utilization measures that aren't available anywhere else yet?

MR. ZARABOZO: I would think -- well, part of it is the same size, and the other may be more utilization information would be available from the encounter data. And also, there may be an issue with knowing exactly what the benefit package is for the individual.

DR. SCHMIDT: The MCBS's utilization is basically self-reported.

MR. ZARABOZO: Yes, yes.

DR. SCHMIDT: So we don't really have the hard data to know exactly what happened there.

DR. MARK MILLER: Possibly, but I may have misunderstood the entire exchange. But MCBS, I mean there are also versions of it in which they link the claims data.

DR. SCHMIDT: For the fee-for-service population.

DR. MARK MILLER: Right. And she's asking about the MA piece. Okay, right. Now I'm back in the game.

MR. HACKBARTH: [Off microphone.] Let me ask one other clarifying question about the hold harmless, now focusing on the high-income people who are paying an income-related premium, not protected by hold harmless so they have

to pick up a piece of this residual. So at the highest income level, just for the sake of simplicity, they pay up to 80 percent of the cost.

DR. SCHMIDT: Right, so --

MR. HACKBARTH: But the added piece attributable to the hold harmless is in addition to that, correct?

DR. SCHMIDT: Yes, that's right.

MR. HACKBARTH: So if this goes on for some period of time, they could actually start bumping up against 100 percent or more than 100 percent of the actual cost of their Part B benefits.

DR. SCHMIDT: Yes -- well, it seems --

MR. HACKBARTH: Well, a negative subsidy, not a --

DR. SCHMIDT: Well, it's more of an individual consideration in addition to that. That would be 100 percent of the average elderly beneficiary's utilization, and for some people, you know, their usage may be higher and for others, lower.

DR. SCHMIDT: So it's more of an individual level consideration, I'd say.

MR. HACKBARTH: Good point. Okay. So to go back to the original question, the hold harmless in a period of

low or no COLAs starts to have more meaningful implications because you're basically asking a small group of people to bear the whole cost of the Part B increases. And so this may be a particularly good time to be thinking about the hold harmless and its implications.

DR. SCHMIDT: And to pray for economic growth.

[Laughter.]

MR. HACKBARTH: And that's first, actually.

DR. BERENSON: I forgot to ask for Carlos, is there any reason why an MA plan can't offer a value-based benefit design with varying cost sharing? And do any?

MR. ZARABOZO: What is allowed is tiered cost sharing, and I think that's by choice by provider. Now, what was recently sent out by CMS is you cannot do tiered cost sharing sort of by a base provider. So the California situation where you pick a medical group within a plan and you're assigned to that medical group, your cost sharing cannot be based on the choice of that medical group. But, for example, among different hospitals you could have different cost sharing. They're trying to limit that tiered cost sharing. But in terms of, for example, can a diabetic have different cost sharing from a non-diabetic, that's not

possible. That's only possible under a plan design so that, for example, special needs plans can say, Here's our cost-sharing structure which is appropriate for this kind of beneficiary, but not -- so to do that, you would have to set up a plan that is for these people, and if it's disease-based, it would have to be a special needs plan.

MR. HACKBARTH: Okay, let's proceed to round two.

MS. UCCELLO: I just have a follow-up clarification for this hold harmless. So premium is 110 for the people who have to pay the whole thing. Say next year there's 3 percent or whatever COLA, that 110 stays 110 and the 96 goes up? Or they both go up?

DR. SCHMIDT: Well, for the people who are paying 96/40 this year, if there's a zero COLA again, they will still stay at the 96/40. The people at 110, if they're the entering cohorts just turning 65, they paid 110.50 this year, but they're not income-related or in any of the other groups, then they continue to pay 110.

MS. UCCELLO: My question is: Once we start getting positive COLAs again, what happens to that 110 and the 96 -- yeah, do they -- so 110 is frozen until they catch up?

DR. SCHMIDT: I'm not sure I'm following exactly. Do you want to --

DR. MARK MILLER: All right. So here's what I think, just to get you -- because I think you were speaking to this --

DR. SCHMIDT: Earlier

DR. MARK MILLER: -- when some questions were coming along here. So in the case where you start to get increases, and the question was, you know, what happens to the people who are paying the higher amount, you implied in your answer that what happens is they don't come down, they sort of stay there and people catch up over time. That's what was the implication.

DR. SCHMIDT: Right.

DR. MARK MILLER: I think that's what she's asking.

DR. SCHMIDT: Yes.

MS. UCCELLO: So they don't both move up.

DR. SCHMIDT: [Nodding affirmatively.]

MS. UCCELLO: Okay. Thank you.

Just in general, I'm troubled by the inequities of this. I don't know -- I mean, hopefully this is just a

short-term issue, so I don't know how much of a priority we need to make this. And I wouldn't want to freeze it for everybody necessarily because that's just going to increase federal spending on this. But I think it's something we should think about.

DR. CHERNEW: I have first some follow-ups on Bob's question, which might not be surprising, and then I have one other.

The first one is: My understanding about the value-based insurance design portion of it is they can't charge a co-pay above what the Medicare co-pays would have been. So say there's a cancer screening or treatment service which Medicare's co-pay would have been 20 percent of something, but it's decided by the plan that that's a very low-value treatment, I don't think the plans even in an actuarial sense are allowed to charge more than what the Medicare fee-for-service co-pay would have been.

MR. ZARABOZO: Correct. On the specific services where they're prohibited from doing so, and then they look -- - there are listed service and then they look at individual services and say these are services at risk for attempting -- -

DR. CHERNEW: But there could be other services like PET scanning. Say you thought PET scanning wasn't very high value -- and I'm not saying it isn't. I'm just using an example. I can pronounce "PET." That's the only reason why I picked it.

[Laughter.]

DR. CHERNEW: If you thought it wasn't very high value, they're limited as to how much they could charge enrollees for PET by what the regular fee-for-service benefit structure is, even though PET's not one of the things that has been pulled out separately. I think that -- I could be wrong. That's why I'm asking the question.

MR. ZARABOZO: No, that's what the actuarial value --

DR. CHERNEW: Oh, so they can as long as they keep --

MR. ZARABOZO: Right.

DR. CHERNEW: -- actuarial value.

MR. ZARABOZO: Right, unless CMS says this appears to be discriminatory.

DR. CHERNEW: My second question has to do with the diabetes example, which is how you answered his

question. If you look at the Preventive Services Task Force recommendations, there are many which are disease specific, so, for example, it's Grade A evidence to get screened for diabetes if you have high blood pressure, but not if you have low blood pressure.

MR. ZARABOZO: Right.

DR. CHERNEW: So when they try to put those services for -- no cost sharing for preventive services into practice, are they accepting that's going to be disease specific, or are they not?

MR. ZARABOZO: Well, I think that would be a coverage -- that is what is or isn't covered. I think it's more of a coverage issue.

DR. CHERNEW: But they would cover diabetes screening even if you had low blood pressure.

MR. ZARABOZO: For 2012, them they're telling them you have to adhere to the fee-for-service rules about here's how cost sharing will be done on preventive services. So to the extent that fee-for-service -- whatever fee-for-service does, they will also have to.

DR. CHERNEW: And fee-for-service certainly can't be disease specific because they won't know half the

information that you need to do the U.S. Preventive Services Task Force stuff, correct?

DR. SCHMIDT: I think it's left to the physician to determine whether they meet the criteria.

DR. CHERNEW: Right. And so my real question is: You didn't mention at all -- just really a comment. You didn't mention anything about employers. I think one of the biggest issues about how beneficiary cost sharing will change over the next however many years is going to have to do with the change in employer-provided subsidies for retiree coverage, both in terms of premium subsidies and in terms of generosity of benefits and a whole series of things, and I think that's an -- I think individuals will feel that as much as some of these other program-specific changes.

MR. ZARABOZO: One thing to mention about employers, the out-of-pocket costs apply to the employer group plans under Medicare Advantage, those limits. However, when CMS announced its policy, it says that employer group plans may come in under the waiver authority to change that if they want to. So I don't know whether they're inviting employer group plans to say we'd rather not

have these out-of-pocket -- or whatever the story is, but they can be treated differently from other types of plans with respect to that out-of-pocket cost limit.

DR. CHERNEW: [Off microphone.] Generally, employers are going to tend to drop or make less generous their provisions overall, and that will have big impacts for all the other charts you show us about beneficiary out-of-pocket --

DR. SCHMIDT: Let me take that point, and we tried to put a little bit about that in the mailing materials and didn't talk to it so much in the slides. There's a debate how much of that was going on way before PPACA versus now, and we weren't going to get into that.

MS. BEHROOZI: Thanks. This is a great place to find all of the information about how the premiums will change and co-payments change and things like that. But one of the things that I was looking for was, you know, somewhat similar to what Mike was saying, the impact on the average beneficiary. And in the context chapter, there was a little reference -- it's on page 25 of the context chapter -- to the projected impact on -- you know, to the beneficiary, like the co-insurance amounts that -- as I understand it,

what the long-term projection is of all the provisions of PPACA taken together on, you know, aggregate spending, because, you know, in this section, when we talk about improved benefits, like particularly under Part D, then what we refer to is the fact that, you know, the benefits are more generous, that means the premiums are going to go up. But taken together, we say in the context chapter, everything seems to have -- somebody thinks there's going to be a downward impact on what beneficiaries will pay. So I think if we can stand, you know, in that -- you know, take that perspective a little, what it means to the individual beneficiary and what they can expect to see over the long term.

And then on the preventive care actually, there are two points. One is that -- or two points made in the paper. One is that not charging people for preventive care will mean, you know, more expenditures for the program, which could have an upward impact on premiums, but that maybe people won't know about it and won't use it. But there's certainly a lot of publicity about the preventive care being free -- quite a lot of publicity about it. So I don't know how transferable the prior experience is that's

referred to here, and also the whole point of preventive care is to reduce long-term costs, you know, acute costs and the costs of chronic care. So that recognition of why the decision was made to make these services free sort of seems to be absent here. So I think we should note that.

DR. STUART: Following up on the preventive services, have you had a chance to go through the book and just see which services do get an A or a B? The last time I did that, there weren't very many, and I think it might be useful to have a table that just kind of listed them.

DR. SCHMIDT: I can't list them off the top of my head, but I do have the book to -- or a PDF of it, anyway. I'd be happy to.

MS. HANSEN: Yes, first of all, I just want to say that I really appreciate the mailed materials. There is a lot of detail there, an array of information that was very helpful.

In the course of our discussion, however, as we were talking about some of the various impacts to different groups, it became a little bit more complex and byzantine to me, and I wondered if we could array just what happens to the beneficiaries that are certain income groups and be able

to kind of almost play out what that scenario would be, both in this immediate term for -- whether it's the years until 2014 or 2019, I forget the year, and then what may happen afterwards with or without inflation, just to see what this whole out-of-pocket impact is going to be for, in many ways, all income levels, so whether you're eventually a lower income with Medicare savings plans to kind of this middle-income group that has such great variability to the highest income individuals, just so we can begin to understand what that trajectory may end up being in terms of people's financial impact in the long run. That would be helpful.

And then just a very quick question in terms of how out-of-pocket expenses are perhaps calculated in MA plans, so when we talk about $6,700 or so, that might be a max. There seems to be -- and I don't know if this is accurate. There seems to have been some variability as to how MA plans calculate out-of-pocket expenses. So is there a more standardized way to look at that now?

MR. ZARABOZO: You mean in terms of what is included or not?

That was a problem before, whether it was or was not included in the -- when they had caps. And now it's

every -- all the Part A and Part B services must be included under that cap.

MR. GEORGE MILLER: Yeah, just to follow up my question also on the providers who had decreased revenue, do we know what that number -- could you look and find out what that number would be, if you could find out what those in Grade A and Grade B, and I guess it would also have an impact for providers with the out-of-pocket cap as well on fee-for-service, what the financial impact would be and how pays it. Is that going to -- do the providers eat it, or will Medicare pick that up? I'd just be curious to know.

DR. BERENSON: I don't understand why they have decreased revenue, I guess. Isn't it just you're relieving the cost-sharing obligation from the beneficiary, so that means Medicare's picking it up, isn't it?

DR. GEORGE MILLER: [off microphone.]

DR. SCHMIDT: That would an initial guess. The reason I kind of hemmed and hawed in response to your question is that I did see some comments to some of the proposed rules out there where at least some providers thought this was ambiguous, and I thought I needed to go clarify that to be sure.

DR. BERENSON: Okay, that's fine. But I don't think we should presume there's going to be decreased revenue. We should find that out. Okay.

MR. GEORGE MILLER: [Off microphone.] That was my question.

DR. BORMAN: Two things. Number one, like Cori, I'm concerned, if I'm understanding the hold harmless piece, a little bit about the way that things are shifting around to different groups, and just sort of an idea about if I entered the program this year versus if I enter it next year or the year after, what would that look like under, you know, a zero COLA, a 3-percent or 5-percent or something. Just as a small comparison, not any huge undertaking table that I won't understand, but something pretty basic I think would help me a lot, because I'm troubled that there's something fundamentally wrong here, but maybe seeing it play out I'll have a better feeling about it.

The second piece is -- and it comes back to a couple of comments that were made about trying to think about as the income sources and amounts change, as people enter the Medicare population who no longer have such generous employer-sponsored benefits and who don't have a

defined benefit retirement plan but, in fact, are defined contribution and will be somewhat victims of their timing of retirement versus the market and some of those kinds of things, I'm interested in that, but I think we could be asking for very complex calculations and information that may not be available. I kind of get that sense. So at least for me, it might help. We talk about what percentage of the typical SSI payment will be consumed by the premiums, both the B and D premiums. Could we look at what will be just the share of the typical retirement income that will be consumed as opposed to trying to do fancy things for, you know, employer this and duals and whatever, just kind of do some simple contrast, or look at what percentage of people -- - just tell us what percentage of people will, in fact, be projected to still have an employer contribution at all to this. That would at least give us a very down and dirty sense of how big the problem's going to be, how it's going to change, because my guess would be, given the volatility of the economy over the last couple of years, and that we don't even have the data out of those, that being able to project downstream what a typical retiree's income will look like and what it will be and where their sources would come

from would just mire us in a huge speculative calculation that I'm not sure is of value. If we can just get a couple of benchmark kinds of things to help us think about, at least that is for me how I would think through it a little bit.

DR. CHERNEW: The Social Security people do -- the Social Security actuaries go through all of that activity to know that, and what they haven't done is merged that with these things particularly well, which we have a small project to try and do, but I think that income distribution stuff, there's other people that [off microphone].

MR. HACKBARTH: Like Karen, I'm still struggling trying to make sure I understand the implications, and so I agree maybe some more examples along the lines of the ones we've discussed here would be helpful in making sure that we've got it.

I need you to elaborate on something you said earlier, Rachel. A couple times you pointedly said, well, economic growth is key here.

DR. SCHMIDT: Yeah.

MR. HACKBARTH: As opposed to just inflation. I'm missing your point there. Part B premiums are determined by

Part B expenditure growth linked to that, and then we have the Social Security COLA link. Where does the rate of economic growth come into --

DR. SCHMIDT: That was my shorthand for speaking about the COLA, I suppose you could say.

MR. HACKBARTH: Okay. So you're assuming a correlation between growth and inflation.

DR. SCHMIDT: Right.

MR. HACKBARTH: Okay. And then I just wanted to make sure I correctly understood one other thing. I think it was an exchange with Cori.

So let's focus on the case of the 2010 new Medicare beneficiary, not covered by the hold harmless, so they've got the 110, whatever, dollar premium and they're picking up that big item. Then let's assume in 2011 there's a cost-of-living increase in Social Security that is high enough to cover the Part B premium increase. So the Medicare beneficiary who newly enrolled in the program in 2000 now is going to pay a higher Part B premium than they did this year up to the max of the COLA. They can't go up faster than that. The 2010 enrollee, they're held constant until the others catch up, or do they pay the high number

that they paid in 2010 plus the COLA, up to the COLA increase?

In other words, are they held flat --

DR. SCHMIDT: I believe --

MR. HACKBARTH: -- you have to close, or do they --

DR. SCHMIDT: Shinobu may want to jump in and help me, but I believe it's the 110 -- how about I come back and work out an example and bring it back to you rather than misspeak, check with the actuaries --

MR. HACKBARTH: Okay. So the question is whether the gap closes or whether they march up in sync and the gap stays constant.

DR. SCHMIDT: Right. I could speculate, but I could be wrong, too.

MS. UCCELLO: And I want to add a question to that, too. What does the new entrant in 2011 pay? Are they paying the 110, or are they paying the 96-plus?

DR. SCHMIDT: You know, I think the actuaries are starting to work this out just now themselves, so I'll see what answers I can get for you.

MR. HACKBARTH: Okay.

DR. MARK MILLER: Because you know how actuaries are.

MR. HACKBARTH: Yeah, right.

[Laughter.]

DR. MARK MILLER: Sorry about that. It was just right there. And what we'll probably do on --

MS. UCCELLO: I didn't --

DR. MARK MILLER: No, I know. Actually, we got this far without one joke. Just the tension was killing me.

What we'll do with some of these technical ones is put an e-mail together that everybody has looked hard at and send it to all of you, because I'm not exactly sure whether we'll have a session to follow up immediately on some of this stuff, so we'll make sure that either -- we'll get it to you one way or the other, either in a session or in an e-mail to all of you.

DR. KANE: I'm just trying to wrap up what all this means to me other than that the Greatest Generation is screwing the Baby Boomer Generation.

[Laughter.]

DR. KANE: I'm trying to get over that. The concern I think I'm taking away is that the healthier,

wealthier people -- and those tend to often go together -- you're going to start getting selection out of B and maybe even D, I don't know, but B, anyway, of the healthier people who have the higher -- you know, is that good or bad for the program? And is there a way to mitigate that? So you're going to actually -- you might actually start to make your costs worse, spiral worse relative to your income because you're going to lose the contribution of healthier, wealthier people and start getting stuck with sicker, poorer people. That's what I worry about. I don't know at what point that starts to happen, but I'll leave it to our actuaries to figure that out.

DR. SCHMIDT: Just to repeat something that Robert Reischauer used to say when he was on the Commission, it was: Even with the income-related premium, you're at least getting something like a 20-percent subsidy from the Medicare program of the average cost. So there still could be some selection because if you're wealthier, healthier --

MR. HACKBARTH: Well, that used to be the case. It's not clear to me that that will continue to be the case. So, yeah, this is sort of confusing, and I think whenever you say that certain people are exempted and the residual

are going to bear all of the costs, you're running a risk of unintended consequences, and what we just need to do is sort of sort through what those consequences might be.

Okay. Any concluding questions or comments?

MS. UCCELLO: Just one more question or comment. Is it appropriate for us -- and maybe this was talked about. Is it appropriate for the Commission to provide input to NAIC on how they're going to define services for eligible cost sharing for C and F?

DR. MARK MILLER: Yeah, I think the answer to that is yes. We have ongoing conversations with them as a matter of course. There's been discussions back and forth on defining the new Medigap --

DR. SCHMIDT: They have reached out to us to have some conversations about it, and we would like to. Their deliberations, as I understand it, have been on hold until next year, but there is room, I believe, for us to discuss -- -

MS. UCCELLO: And presumably one of our points will be not to define it too narrowly, right?

DR. SCHMIDT: [Nodding affirmatively.]

MR. HACKBARTH: Thank you very much.

[Pause.]

And our next session is on retainer-based physician practice. Go ahead [off microphone] whenever you are ready, Cristina.

MS. BOCCUTI: Okay. Given a sense that retainer-based physician practice, otherwise known as concierge care, has been growing, we on staff were thinking that it would be very useful if we learned a little bit more about this type of model of care. So we wanted to learn say, for instance, what it is, its prevalence, and how it's affecting Medicare beneficiaries' access to physicians.

To help us, we contracted with NORC at the University of Chicago to help conduct a study examining these questions. And so today I'd like to introduce Elizabeth Hargrave from NORC, and she, along with her colleagues from Georgetown University, conducted a study, and she's here to present the findings. And I will help push the slides for her, and I can answer other questions as they come up, too.

MS. HARGRAVE: Okay. I'll start just by giving a little background about what this is, retainer-based physician practice. It's most commonly called in the press

concierge medicine, although some of the folks we talked to actually really dislike that title, so we tried to pick a more neutral title as we're talking about it.

The reason we call it retainer-based practice is that the physicians that are using this model are generally charging a monthly or annual fee to their patients -- it's almost like a membership fee -- to be a part of the physician's practice, so thus the retainer, that fee that they're charging.

In exchange for patients paying this extra fee, the physicians generally limit the number of patients in their practice, which I'll talk about a little bit more later. And they market themselves as offering greater access and enhanced services to their patients. So they may promise, you know, same-day or next-day appointments, longer appointments. They may give out their cell phone number to all of their patients. And most of them offer a very extensive annual physical that may be, you know, 60 or 90 minutes with lots of tests and meeting about various issues. Some make home visits; some will attend specialty appointments with their patients. So a wide variety of different extra services. Most are also charging insurance

for the office visits that they're providing in addition to charging their patients this annual fee, and I'll talk a little bit more about that later in this presentation.

So just a little bit of overview of what we did for this project. We had three main goals, as Cristina mentioned. One is we just wanted to get a sense of how many physicians are using this model. There is sort of a constant trickle of attention to it in the press, but no real good source of how many physicians are doing this.

So to try and get a sense, we did a search of various online directories that are either aimed at marketing the physicians -- there's a professional association. Several of the management organizations that help physicians set up these practices have lists of the physicians that they've worked with. And as we were doing our literature review, we also sort of kept track of folks that we came across.

And then once we had as big a list as we could find of these physicians, we started to look at what are some of their characteristics, where are they, how do their fee structures work. And in addition to just looking at the list of physicians that we had, we went out and interviewed

just 16 that are actually using this model, but tried to get a little bit more richness to what's going on in their practices. And we also spoke with a number of consultants and management organizations that help physicians transition into using this type of practice. So from them, we sort of got more of an overview of the overall set of folks that are doing this.

And then, third, we wanted to see if we could get a sense of whether this is affecting Medicare beneficiaries' access to care, and that's hard to measure because this is a relatively small phenomenon and hard to find individual beneficiaries. What we did is we went out and interviewed several beneficiary counselors in areas that we thought might be sort of hot spots to see if they were getting a sense that within their particular market, whether this was affecting access to care or not.

So we, as I said, went out and tried to find as many of these practices as we could and found 756 of them -- or I should say 756 individual physicians that are using this model. That has grown from -- you know, 1996 was when the first practice opened. That was just two physicians. In 2005, GAO did a report that used a pretty similar

methodology to ours, and they only found 146. And I should say that both our count and GAO's are probably undercounts because there are probably physicians using this model that aren't listed in any of the directories that we used. But, you know, growing but still a very small fraction of 1 percent of all the physicians in the country.

When we looked at some of the characteristics of the physicians that were on our list, we found physicians using this model in all but 11 states, so it's pretty widespread across the country. This is a little bit of a change from the GAO study which found that it was a pretty coastal phenomenon. There are plenty of them in the middle of the country now.

But almost all are in metropolitan areas, and mostly in large metropolitan areas. There were three that accounted for a quarter of our list: Los Angeles, Miami, and the Washington, D.C., area, which may be why we keep seeing stories about this in the press.

And there are a few that really jumped out at us as having -- you know, smaller cities like Naples, Florida, that have sort of a disproportionate number of physicians doing this considering their populations size. Naples is a

town of 315,000 people, and they've got 16 physicians that ended up on our list.

Most of the physicians on our list for whom we had specialty information from, you know, one of the management firms or any of the sources that listed specialties, most were in primary care. We did find a few specialists, like endocrinologists and cardiologists, that were doing this, but overwhelmingly primary care.

And just looking at the addresses of the physicians on our list, most of them seemed to be either on their own or in a two-person practice. There are a few larger retainer physicians where we found up to seven at one address. So either they're completely solo practice, which was the norm in the folks that we actually talked to, or they're in a larger practice but the only retainer physician on our list at that address.

When we talked to both the sort of big-picture consultant folks and the individual physicians, we saw a pattern of there's really three different models within this retainer model. The first one we're calling fee for extra services, and this is really the most common and was the model used by the very first practice in Seattle. The

retainer fees explicitly paid for some extra services. Often that annual physical is one thing that folks point to as this is what your retainer fee is going to. And above and beyond those extra services that are explicitly stated, then the physician is continuing to bill insurance or Medicare separately for all of their office visits, or the patient directly if they're not accepting insurance.

The annual fee for this type of practice among the physicians that we interviewed -- and this is a small sample -- ranged from $600 annually to $4,200 annually. The GAO study found an even wider spread. There are some that charged tens of thousands of dollars. But the most common is $1,500.

So the second model -- this is less common, but the word from some of our interviewees is that it's growing -- is where this annual or monthly fee actually covers all of your costs for your physician visits. So you pay your fee to the physician, and then you never get billed for another office visit during that year from that physician. So you may still be paying for specialty care or for other medical services, but for your physician to whom you've paid a retainer, all of your visits are covered. And the

physician isn't billing insurance or Medicare. A lot of them have completely opted out of Medicare. And the fees for these practices, when we interviewed them, ranged from $1,500 to $5,400 annually. So a little higher than the other model, but the low end is actually sort of the norm for the fee for extra services.

Then we talked to a few physicians that were trying to create sort of a hybrid model where paying the retainer is more of an option within their practice. So you can remain with the physician and not pay the retainer, but you may get different services from that physician. In one practice we talked to, the patients who don't pay a retainer are much more likely to be seen by a physician assistant; whereas, the patients who pay the retainer fee are guaranteed to see their physician when they come in for a visit. So that was just one example that someone gave us of how they were trying to differentiate and offer something that people would be willing to pay extra for. So in this model, physicians tend to keep a lot more of their non-retainer patients.

But, in general, among the folks that we interviewed, they had really dropped their patient loads.

So most of the retainer physicians that we spoke with had at least 2,000 patients that they personally were responsible for before they switched to a retainer practice. And when we spoke to them after their switch, they had from 100 to 425 patients. So a big drop. A lot of them said they actually wished they had a few more. They were aiming more for, you know, the 400 to 600 range, but still a lot fewer than they had before. And that's very similar to what GAO found in 2005, a big drop.

We also tried to get a sense from the physicians that we interviewed of who was choosing to pay the retainer fee and whether they were seeing big demographic shifts in their patient load once they had made the shift. Some said not really, that it seemed to sort of be a very similar mix. When they did note that there had been shifts, we heard two repeated sort of sets of people. One was complex or sicker patients. For example, one physician thought that she had a lot more cancer patients, that her cancer patients were a higher proportion of her patient load, you know, and felt that she was really serving as sort of a care coordinator and advocate for those patients. And then another set which I think is more in some of the media accounts of these

practices are people -- you know, we kept hearing the phrase, "people for whom time is more important than money," that they're willing to shell out the money for that guarantee that they'll get in to see their physician when they want to and they'll get the extra time. We also asked about the share of their patient load that was Medicare and heard a real mix of anywhere from about 20 percent of the practice to 60 percent of the practice, and some specifically mentioned that they had Medicare beneficiaries whose children were paying their retainer fees as a way to get some extra care for their parents.

Most of the physicians that we spoke to really enjoyed their new practice after the transition to being in a retainer-style practice. They thought they had a lot more time to spend with patients. We kept hearing phrases like "This is the kind of doctor I envisioned myself being," "This is how I was taught to practice medicine." A lot of folks said that they had been really burnt out before they made the transition and that this was something that kept them in medical practice.

On the flip side, the hardest part that many, many mentioned was when you give out your cell phone number,

you're always on call, and some felt that they really couldn't even go on vacation because their patients expected them to be available when they wanted them.

I would say the hardest part of this study was trying to get a handle on what impact this all has directly on Medicare beneficiaries, because this is such a small number of physicians, and then Medicare beneficiaries are only a fraction of their patients. It's like searching for a needle in a haystack. But some physicians stated that they feel like they have more preventive care, better continuity of care, more services in general. Some were able to, you know, cite specific anecdotes where they thought they had improved patient outcomes.

One said, "This is a much better lifestyle for me, but I don't think the medical outcomes for my patients are necessarily better." And when we tried to speak with Medicare beneficiary counselors about this as a way to sort of talk to folks that talk to a lot of Medicare beneficiaries instead of trying to seek out the individual Medicare beneficiaries, they weren't seeing widespread access problems, but a couple did mention they were concerned about folks that they had spoken to who had

chronic illnesses or the children of folks with chronic illnesses who really found that decision when they were confronted with, "Are you going to pay the retainer and stick with your physician or are you going to switch to another physician?" folks that were in the middle of a chronic illness really found that a more challenging decision to make and thought that the change would be more disruptive for those beneficiaries than probably your average patient within that practice.

So that's an overview of what we found with our study, and I'd be happy to take questions.

MR. HACKBARTH: Thank you, Elizabeth.

Clarifying questions, round one.

MR. GEORGE MILLER: This was excellent. I enjoyed reading the chapter, so thank you very much. Do you have demographic information on the physicians in the database of 756, where they're from, what they look like, rural versus urban, and --

MS. HARGRAVE: We have addresses. They were overwhelmingly urban. I would say there were maybe 12 or 16 that weren't in a metropolitan statistical area, and they tended to be in resort towns.

MR. GEORGE MILLER: And how about demographic information?

MS. HARGRAVE: We don't have a lot of other demographics, because, you know, if you think about sort of the information that you might see in a physician directory, it's really the name, maybe the specialty, and the address.

MR. GEORGE MILLER: Okay, all right. And then just a follow-up to that same question, if you had more demographic information on the patients that they saw. Did they give you that information?

MS. HARGRAVE: We just don't.

DR. KANE: Was your sense that they incurred any additional costs to take care of these patients, like added a medical record or, you know, added a nurse practitioner or some way did they add any costs? I mean, I'm grossing for these people who have 100 to 400 patients. I mean, a hundred is 150K and 400 is 600K.

MS. HARGRAVE: Right.

DR. KANE: That's a gross. And I'm just wondering, was there anything that you took off for that? Because if you could get even a hundred patients, that's 400 visits a year, that's --

MS. HARGRAVE: The main thing is that the ones that are going -- so there are several companies that are set up to help transition physicians to this model and actually will take care of collecting the retainer fees from the patients.

And if you sign up with one of those companies as a physician, you commit -- you sign a contract with them for something like five years, and they get a third of the retainer fees. At least for one of them. I don't know if that's true for all of them. But, you know, a set-up like that. So the physician may not be getting all of that money, so that's one cost.

MR. HACKBARTH: And what is the company doing for its one-third?

[Laughter.]

MS. HARGRAVE: They do a lot marketing to get -- so if the physician doesn't get the 600 patients that they want just from their original panel, they'll go out and find them patients.

MR. HACKBARTH: So did you study that at all, Elizabeth, and how they do that marketing, how they target potential customers willing to pay?

MS. HARGRAVE: We didn't go into that level of detail, but we did meet with a few of the companies and sort of heard more about the -- they help physicians sort of walk through the transition and, you know, offer meetings with the patients and things like that. So there's sort of a whole set of services that they have up front. And then the ongoing services over that five years are really the marketing and the collecting of the retainer fees so the physician doesn't have to do that.

MR. HACKBARTH: It sounds like a good business to be in to me.

[Laughter.]

DR. KANE: If you already have [off microphone].

MR. KUHN: That enrollment business does sound good.

I've got a question. Did you look at or have any conversations with the Office of Inspector General about efforts that these organizations have to navigate in order to make sure they're compliant? You know, for example, as you said, the big selling point is the preventive wellness extravaganza that they're selling out there.

MS. HARGRAVE: Right.

MR. KUHN: But yet at the same time, there can't be a surcharge on any covered Medicare services. So what's the fine line that they have to walk when they deal with the Office of Inspector General?

MS. HARGRAVE: That's a really good question. I know Cristina has been talking --

MS. BOCCUTI: Why don't you mention your experience, and then I'll --

MS. HARGRAVE: So the Office of Inspector General put out a letter, I think it was in 2004, where they laid out -- it really has to be -- the retainer fee has to go for services that are not covered by Medicare.

So it can't just be that you're spending extra time. It has to be something like the physical that's specifically not covered by Medicare, except, of course, PPACA just added some benefits to Medicare that Cristina can talk about.

So that was -- OIG hasn't issued anything, any additional statements since that original letter where they laid out that bright line. And when we spoke to folks, we were speaking to them before PPACA had passed, and a few of the consultants said, you know, even if Medicare did add an

annual physical, we could always come up with something that we're offering that isn't covered by Medicare.

MR. KUHN: My guess is that every one of these folks that's operating one of these is going to have to go see their attorneys by the end of this year because of the new physical that's going to be in PPACA. The surcharge on this, I think everyone is going to have to reorganize themselves in some form or another.

MS. BOCCUTI: Yes, I think Elizabeth heard that, and we've also heard when we have talked with some other providers that there are some issues that are coming up, and one has to do with the annual preventive services that are now part of PPACA. Those haven't really totally been defined, so that's going to be coming up.

But also other things we've been hearing, too, are that practices might not be full-on retainer practices or concierge practices, but may be having additional charges for some things that aren't Medicare covered. So these are things that providers have been asking questions about. And you originally asked about the OIG and that report that they had with a clarification, and I think in some regards CMS may be looking into some clarification, may want to be

looking into clarifications regarding the upcoming preventive services.

MR. KUHN: So my guess is the same-day appointments, the 24/7 access, those kinds of things are probably going to become much more prominent, I would guess, in these than --

MS. BOCCUTI: Right, that's a gray area.

MS. HARGRAVE: But those are the kinds of things that OIG said that doesn't really count as non-covered, because the visit is still covered, right?

MR. KUHN: Right.

MS. HARGRAVE: Being able to get the visit when you want it isn't really enough.

DR. MARK MILLER: The second model wouldn't run afoul of that.

MS. HARGRAVE: Correct, because they're not billing Medicare.

DR. BERENSON: That's just where I was going. So there's no obligation if there are covered services that Medicare covers to actually bill Medicare? In other words, these docs don't have to opt out of Medicare? They can simply not bill for covered services and there's no problem?

MS. BOCCUTI: In the first model, they can --

DR. BERENSON: I'm sorry. In the second model.

MS. BOCCUTI: In the second model, I think as Elizabeth said, that's the most common situation where they -- physicians who have opted out of Medicare are more likely to be using the Model 2.

MS. HARGRAVE: And most of the ones that we talked to in that model have opted out.

DR. BERENSON: But they don't have to opt out of Medicare? That's my question. Do they have to opt out of Medicare, or are they --

MS. BOCCUTI: No, they don't, because then the patient -- if the physician has not opted out of Medicare, then the patient -- if the patient can get a bill, a claim to some regard, and then the patient could still submit it to Medicare if the physician was still enrolled in Medicare, whether they're a participating or a non-participating --

MS. HARGRAVE: But, in general, they're just not billing the patients for the individual --

DR. BERENSON: Aren't they then sort of routinely waiving cost sharing? And isn't that -- I mean, it doesn't seem --

MS. BOCCUTI: I think it's not as common of a model, and it's a confusing situation.

DR. BERENSON: Okay.

MS. HARGRAVE: I'll give you one example of -- the only physician that we talked to that was in that model that hadn't opted out, in addition to his practice, he was a hospice physician. So he hadn't opted out of Medicare because he wanted to continue participating with Medicare for the hospice work that he was doing. But for his patients, he wasn't billing them, he wasn't, you know, giving them anything that would allow them to go bill Medicare, so effectively was not working within that system but hadn't completely opted out. But he said that his lawyer kept telling him that he should opt out of Medicare to make it clear. But he hadn't yet.

MR. ARMSTRONG: Two quick questions. First, in the written report you mention four states where the question came up, the regulatory question: Are these really insurance plans and should they be regulated that way? You describe how they've been resolved. My question is: Has this come up even more recently in any additional states since we wrote this report?

MS. HARGRAVE: Not that I've seen, but I haven't looked for it in the last few months.

MR. ARMSTRONG: Okay. I ask only because we see that this is growing, and your report talks about, you know, significant growth. And I was not aware of it coming up anywhere else, but I wanted to ask if you knew.

Second, it sounds like you've had a chance to talk to a couple of the organizations that helped to organize these. I'm wondering if any of those interviews or if you know of any of these practices that have initiated or tried looking at studies on the impact overall of the per member/per month expense trends or population outcomes when they apply this model to primary care. Or have they expressed any interest in trying to understand the impact on that?

MS. HARGRAVE: I think MDVIP, which is the largest organization, has tried to do some of that. They haven't really risk-adjusted it, so it's hard to know -- I mean, they do claim that the overall medical costs for patients in their practices are lower because they're preventing hospitalizations. But it's hard to know because it's not really --

MR. HACKBARTH: How would they know?

MS. HARGRAVE: Right.

MR. HACKBARTH: They don't have access to the claims information. They don't know if the patient is self-referring to the specialist. They wouldn't know necessarily when the patient was admitted to the hospital.

MS. HARGRAVE: Exactly.

MR. HACKBARTH: It seems it would be very hard for them to do --

MS. BOCCUTI: We're not aware of independent research --

MS. HARGRAVE: No.

MS. BOCCUTI: -- that has taken that on, that question on.

MS. HARGRAVE: But the organizations that are helping -- to directly answer your question, the folks that are organizing these are trying to come up with ways to show that, but it's not clear.

MR. BUTLER: Just a quick technical observation, and MDVIP, the biggest one. It's interesting, if you pay your $1,500 -- I know this happened to somebody. If you pay your $1,500, they do aggressively want you in to do your

visit, in part because if you don't, it's not tax deductible. You cannot deduct the $1,500 unless you have shown that you got services for that. I know somebody who got audited that happened with.

So they actually promote to make sure that that occurs.

MS. HARGRAVE: So tax deductible as a medical expense?

MR. BUTLER: Well, if you're taking a medical deduction, you can't -- if you're just paying 1,500 bucks and there's nothing to show that you got medical care for that, it's not deductible from your taxes. So it's one of the reasons MDVIP actually, you know, encourages and they -- you know, they get in touch with you and say, "Come in and get your visit."

MR. HACKBARTH: It's so high -- it's so difficult to qualify for the medical expense deduction now. The thresholds are so high that --

DR. KANE: If you're working, the flexible spending may be -- does it qualify for flexible spending?

MR. HACKBARTH: Yes, that's an interesting question. I don't know.

DR. NAYLOR: A great report. I'm wondering about the intersection of this service and the evolving home health or medical homes where it's expected that those practices provide care coordination and access. So would primary care providers who are part of systems that have said we are medical homes and are receiving support either through a CMS demo or other be able to legitimately stand as a concierge -- excuse me, retainer doc?

MS. HARGRAVE: The thing that we're really using that -- the retainer to represent is that you're paying that extra amount for it. So to the extent that the extra payment to the physician for the medical home is --

DR. NAYLOR: For the same service [off microphone].

MS. HARGRAVE: For similar services, but not necessarily coming from the patient for that. I don't know whether they'd meet the definition.

MS. BOCCUTI: Well, I'll add to that. Last year when we were doing some focus groups and we were asking about access and we had physicians and talking about their acceptance of patients for Medicare and other insurance types, and then we were asking them about -- we had primary

care physicians in these focus groups, and we were -- they brought up the issue of concierge care. And I remember vividly one of the primary care physicians saying, "Really, this is a medical home, you know, and I wish we could be charging" -- you know, knowing that there are these fees and sort of creating kind of a comparison to if it were a medical home and you could get fees through that kind of venue without being considered concierge.

So I think people have made that sort of -- some people have made a parallel there, which is what I think you're getting at.

DR. CHERNEW: This is about Slide 9, which gives the numbers of people. That's actually not just Medicare people, right? Those numbers -- I just want to clarify. That's all people, the 100 to 400 people in their practice they want --

MS. HARGRAVE: Yes, right.

DR. CHERNEW: And is your sense that most of them are actually not Medicare beneficiaries?

MS. HARGRAVE: So it really varied among the people that we talked to. There was one practice that said they had about 60 percent Medicare beneficiaries, and

another was more like 20 percent, so it really varied. So some percentage of the 400, 600 patients is Medicare, but not all.

MR. HACKBARTH: There does seem to be this disconnect between the amount of publicity and the numbers, and I'm not sure what to make of that, although coverage doesn't always equate with, you know, the actual number of problems. In fact, we've seen some of that in our own research about Medicare beneficiaries having problems with access where there seems to be more coverage of it than our survey data might suggest.

But set that aside for a second. The potential revenue here, as Nancy and Bruce were pointing out, is really quite large, if you're talking, you know, 500 patients at a thousand bucks each, $500,000 in revenue for a practice in addition to your fee-for-service revenue. Those are amounts that are sufficiently large even if you share them with, you know, a company. That might cause people to think twice about the model, and even if you can only get 200 patients to do it.

And so this phenomenon is something that I think needs to be taken seriously. I guess my fear, my worst fear

-- and I don't know how realistic it is -- is that this is a harbinger of our approaching a tipping point where you have this huge price discontinuity between what people can get through this model and what they can get by continuing to practice in Medicare. And at some point this discontinuity is going to resolve itself, and it probably won't be in favor of people staying in Medicare. There's too much money to pass up. And you combine that with, as Bob was pointing out the other day, you know, we've got a large cohort -- Ron has made this point -- a large cohort of physicians nearing retirement, and the nightmare I have -- and, again, I don't know how realistic it is -- is that a couple of these things come together, and you could have a quite dramatic erosion in access in a very short period of time. So that's my nightmare.

It's a tricky question. If you're worried about that, what you do about it with the policy levers, you know, I've heard some people suggest that maybe the thing to do is to prohibit concierge practice for anybody who wants to be involved in Medicare, so you can't do the fee-plus model et al. and be in Medicare, although my fear about that is that you might be shooting yourself in the foot and making the

problem even worse and just drive people out of Medicare altogether and compound a developing access problem. So I think this is a very important phenomenon to try to understand better than we now do.

Let's open it up to other round two comments. That was mine.

DR. BORMAN: First a question, Elizabeth. Did you get any sense for numbers of individuals who might have closed their retainer-based practice? Because I think -- and I imagine that number might even be harder to come by.

MS. HARGRAVE: I think so. When we were doing our literature review, we did come across a few news stories of folks that hadn't been able to make it, and one of the 16 physicians that we spoke with was sort of not -- didn't have as many patients as he wanted and was really wondering whether the town he was in was large enough to really find enough patients willing to pay the retainer fee.

DR. BORMAN: And I think that that may speak a little bit, Glenn, to your concern, albeit it doesn't entirely mitigate it. This seems like something that is really going to have -- is going to be a very niche thing in some fairly sharply defined geographic locales. And that

doesn't necessarily make it okay, but it certainly, I think, will limit the market a bit. And I think as more and more people get in the market, more and more people will encounter this problem being able to sustain this kind of practice, and it will to some degree become self-defining.

I personally think that maybe one of the take-homes from this is the repetitive comment of people's enjoyment of their practice. And I think one of the things that tells us is that some of the conversations where we have talked about the medical home and primary care, whether it's provided by a physician or other qualified health care professionals, is that we need to make the provision of primary care services something that's professionally, personally rewarding and less hassled, that that counts for a lot, because these people, depending on how you do the math and what these companies are really getting, may or may not in the end be getting huge increments of their prior practice amounts, but what they are getting is presumably less hassle and more time. And those are two of the ways that you can reward physicians.

So I do think there is an important take-home message here for the bigger world that the things that can

be done to make primary care service provision more streamlined and more pleasurable for the provider to provide are -- that's a take-home message from here that will withstand all the other stuff.

I also think that the regulatory piece of this -- I mean, I certainly would be worried as hell about the IRS showing up at my door, or the OIG or somebody, and so I probably would turn tail and run on this pretty quickly, you know, once I got encouraged by my lawyer to do something because I'm basically a chicken and I don't look good in orange and white stripes. But, you know, I do think there are things that will self-limit this, but I think there is a take-home message.

DR. DEAN: Yeah, I had some of the same questions that Karen just raised. I wondered about the potential size of the population that would enroll in this, and I suspect it's relatively small and localized in certain areas. But the other interesting thing is, as I looked at this, I said, too, that's a medical home. And I'd be curious to have Scott comment on this because this is very similar to what I think Group Health did with your one clinic that got all the attention in Health Affairs. And I think the interesting

result of that is that, yes, the investment on the front end was higher, whether you call it a retainer or whatever, but the overall cost for those patients that were involved in this approach to care was significantly less. And so it would be interesting -- I don't know that this is the model we'd support, but the idea that by adding these additional services you both improve the experience of both provider and patient and save money at the same time is certainly a very appealing idea. Does that fit, Scott, with your experience?

MR. ARMSTRONG: So just briefly I would say to your point I have really, frankly, mixed feelings about this. On the one hand, we see these practices creating many of the elements of primary care that are the very elements I think we should be advancing. In our practice, we've created these very elements turbo-charged, you know, in 26 medical centers and demonstrated that we're driving better health outcomes, lower medical expense trends, and our primary care providers are as happy as these doctors are. They're probably not making as much money, but -- and so to your point, there's elements of this that are really exciting. I think my biggest concern and the reason, Glenn,

I would agree with you that we should be looking at this is that these are practices set up to achieve different goals, and I think many of the goals that we are responsible for aspiring to. They're not goals that overall are intended to lower the medical expense trends or improve the overall outcomes for populations of patients. And I think that's the closest I can get to the nutshell on what is my issue with this, despite the fact we've demonstrated these are, I think, really close to what the future of primary care ought to look like.

DR. DEAN: Yeah, I mean, I'm very troubled by the sort of elitism that goes along with this, and those things. But the core issues, I think there's something to be learned there.

MR. HACKBARTH: It would be interesting, actually, to delve into that, if possible, and it may be impossible because there's so much diversity among the retainer-based practices and what they do. But it does seem, as Scott says, that the initial goal is quite different. And, thus, many of the activities, I think, that Group Health Cooperative is doing in terms of team-based practice and the like are not necessarily found in a retainer practice, which

at least in some instances based on press coverage seems just to emphasize more ease of access or longer face-to-face appointments as opposed to active treatment of -- you know, active outreach and all the things that are inherent in the Group Health model.

So my basic point is I agree, you know, it would be interesting to see if we could do more of a comparison. Are these basically the same thing just by a different name? I think maybe not, but I'm not sure.

DR. DEAN: I think they're not completely [off microphone].

MR. HACKBARTH: Yeah.

DR. BAICKER: It seems as though we care about this issue for two primary reasons. One, there's an issue of equity across Medicare beneficiaries, and, two, there's an issue of access if the take-up of this by wealthier beneficiaries then crowds out availability of doctors to lower-income people. And they have different ramifications over the short run and the long run.

The equity issue, in some ways we don't spend a lot of time and energy worrying about rich people consuming more of stuff in general as long as we think low-income

people have an adequate, reasonable set of health care consumption available to them. So I worry about the availability of care for low-income people. If high-income want to go buy lots of extra services, I don't think we're in the business of stopping that. So whether it's a regulatory issue, are these providers extracting more money from the Medicare system than law entitles them to is a separate question. Assuming that that's okay, then I worry less about the inequities across income -- that happens for all sorts of goods, and we can't end income inequality through this program.

The issue of access seems like a short-run problem to me insofar as capacity doesn't adjust. So if you have a fixed number of providers and we're worried about low-income people being crowded out, I don't know then if this really morphs into an issue about access to primary care -- you know, capacity of primary care. Is this a workforce problem where there aren't enough physicians to meet the demands? Or is this really a payment issue that we should be worrying about high-income people consuming too much?

MR. KUHN: When I read this paper and when I listened to Elizabeth's presentation, my comments are quite

similar to what Karen was sharing earlier, and that is, this does really seem like a niche market at the present time, you know, when you look at the numbers that you put out there. If you look at the 756, if that's the total number -- and that number, I'm sure, could move a little bit -- that's only one-tenth of 1 percent of all physicians in this country, so it's very, very small. It's very much a niche market.

But as I kept reading the paper and listening to the conversations here, what I keep thinking about is that -- so it's hard for me to draw any conclusions, you know, when it's only one-tenth of 1 percent of the market. But I think the one conclusion I do come to is, like Karen said, that we ought to be figuring out what is it that people like about this and how do we begin to incorporate some of those features into the program overall as we think about the other payments out there. So I think if there is one take-away, I think Karen really nailed it, that I think that's it.

DR. BERENSON: Yeah, I agree. I see this as a sort of a canary in -- what is it? -- the mine, something or other --

PARTICIPANTS: Coal mine.

DR. BERENSON: Coal mine, that's what it is. That in and of itself I don't think it's a big deal, but as you sort of laid out earlier, this combined with other factors could -- we could hit a tipping point where docs opt to do any number of other things.

There's another model called the Ideal Medical Practice, which also not too many docs have signed up for. This is within insurance. They're not charging any subscriptions, but basically it's doctors with a very sophisticated electronic health record who have no staff and have much lower overhead, and that's how they get time with patients, so they don't have to see nearly as many patients a day. And we don't -- I think it would be important to sort of be relatively open-minded and try to get some empirical data on sort of the relative merits of going in various directions, sort of the team-based approach where the doctor -- everybody's practicing to the top of their license, and the doctor, the physician is really not seeing all patients all the time, to the other extreme where the doctor, only the doctor is seeing all the patients all the time. And my hunch is that both models are probably

producing better results than the status quo, which is the hamster on the treadmill phenomenon.

I think Group Health, if I had to pick, Group Health is doing it the right way, free up the doctor to have more time and also have a team. But I think we have -- in the specifics of how do we define a medical home, I think we are looking for outcomes more than we should be sort of defining here's what you have to have in place.

There's no question that a concierge practice, the Ideal Medical Practice, would fail NCQA, and yet they might be producing pretty good results. So it's another example of where we really need to just sort of look for what the outcome or outputs we want and be a little less prescriptive on exactly how you get there.

MS. BEHROOZI: Just briefly, I wanted to highlight a comment that you made on page 8 where you say that a couple of doctors mentioned that they review their patients' medications. And I wrote next to that, wait a minute. Isn't that basic medicine? I mean, since when is this the extra. And I don't even mean, you know, the extra that Medicare doesn't pay, but just the notion is kind of flipping the medical home discussion that people are having

about whether this kind of stuff really belongs in a medical home.

The flip side of that is that if you let -- if we let too much of this stuff become the extra or the upper-tier care, then what becomes basic care is really eroded and you really have the danger of becoming a two-tiered system. But we're not close to that yet. I realize that there are -- it's only 756 doctors. But that really struck me.

MR. BUTLER: So my own anecdotes. I know, I think, six of these primary care physicians, so I must know 1 percent of the total.

[Laughter.]

MR. BUTLER: And they all fit the same profile that the MDVIP -- about 2,000 patients, and they went to 600, and they've never been happier. And they would make the argument -- and I've seen some of this firsthand -- that, look, we were -- almost all these are private practitioners, so if you're already employed, they're not vacating employment to do this. These are successful, good internists who have been chasing the ancillary dollars and been very busy, whether they're doing bone density in their office or trying to get a piece of that ancillary or this to

make a little bit more for how hard they're working, they say enough. And this transition has actually changed their lives in many cases, and they do -- I know, I've seen it. They do spend time. They make phone calls that they don't charge for. They even make home visits. And, yes, I've seen them go over the medications to help manage the cost of it, not, you know -- and so $1,500 sounds like a lot -- and it is, and, you know, I'm irritated by it in the same way. But, you know, often people pay a lot more than that out-of-pocket. And so I've seen -- gee, you know, I was a real doubter, and believe me, have these on your staff, and now you have 1,400 patients without a primary care physician. It is a short-term problem. But it does shine some light on what makes a physician -- and they haven't, you know, backfilled and said now I'm going to see a lot more of others. They've taken on a different lifestyle and a different approach to their practice.

MR. HACKBARTH: That all makes sense to me, and I also wouldn't get too, too comfortable saying, well, it's going to be a niche product at $1,500. You know, markets are dynamic, and the price may come down to $1,250 or $1,000, and they'll start searching for what sucks enough

customers into the system. And then when that starts to happen and it affects the access for other people, then the willingness to pay will start to go up as people start to feel their access eroding because more and more people are going into this.

So where the equilibrating price is, I don't know. I wouldn't get too comfortable that we've seen sort of the dimensions of what the market for this are at this point in time. There could be a lot of adjustments on both the supply and demand sides. Now Mike will correct everything I said.

DR. NAYLOR: I just want to switch this to the beneficiaries' perspective, and I think beneficiaries should expect, all beneficiaries, really excellent primary care services. And, you know, we ought to figure out what are the policy levers to make sure that everybody has access to that. So I think that there are multiple models to achieving that, but I think that constantly focusing on the performance of the system to meet all beneficiaries' needs ought to be our goal. And I hope that we'll look toward all of the transformational policy drivers that achieve that for everybody. So to me, everybody deserves really excellent,

well-integrated, well-coordinated primary care services, and we ought to be figuring out how to make sure everybody gets it rather than focusing on the model or the providers of those per se in the current system. I think that there will be multiple providers and multiple systems providing this going forward.

DR. CHERNEW: I agree completely with that, and in the spirit of what Glenn said, I think we've recognized for a while that there was a concern about insufficient numbers of primary care physicians, and I think we've recognized through a number of actions that improving the fees that primary care physicians make would help alleviate that. And this is one way that I think at a minimum, looking at it from the outside, it disciplines the market to do that. And the big challenge is to make sure that we have enough chance to react should the Hackbarth nightmare come to pass, but I don't think there's anything inherently wrong with a world, if primary care is valuable and they can earn more providing better care and not doing a bunch of ancillaries to think that that gives us some idea of how we might achieve a longer-run goal of changing the distribution of what physicians are. And I actually think if you could really

make some of the money -- we shouldn't think of the set of physicians as just a fixed group of people, you know, X number of primary care physicians, and that's just all we have.

I think you'll see -- post Medicare you saw a bigger response in terms of physicians coming in and not coming to various places to satisfy the demands. I think it just gives us some idea of what you would expect would happen if the problems we identified earlier were, in fact, real. So I guess they were.

DR. CASTELLANOS: I have a lot to say. Mike, you taught me something. Patients -- and I wanted to jump in on Level 1, but I really couldn't because I didn't have any clarification.

I live in Fort Myers, which is right next to Naples, and Naples is a community of 300,000 people with about --

MS. HARGRAVE: Sixteen.

DR. CASTELLANOS: They have an excess number of this, and we have them in our community, too. And what I'd like to do is give you a physician perspective, and something that Mary started doing, a patient perspective.

As a specialist, I deal with a lot of these VIP patients, and quite honestly -- and I don't mean this to be critical -- they have unrealistic expectations. As soon as they come in the room, they want my cell phone number, and they want to know if I can call their brothers and their uncles and their neighbors and stuff like that. And I try to do this to every patient, but I usually don't give out my cell phone number. For the specialist, there's been some issues.

Now, as far as the primary care, I can tell you in my community there is an access problem, and especially in the wintertime when there's a tremendous influx of new patients coming in and snowbirds coming in.

And, Nancy, you said something about a year ago, and I think your parents live in Naples. You said, you know, there are spots in this world where there's access problems, and this is one of the spots. There is an access problem to primary care.

What I'd like to do is -- what I did is I talked to a lot of the doctors in our community about this, seeing this on the -- and I'd like to share an e-mail with you, whoever would like to have it. This is a group of

internists that Peter talked about, quality guys, older people, excellent physicians, don't have any ancillaries.

Can you put up Slide 11 just for a second?

You know, I spoke to them and I said, "What do you think?" They said, "Well, you know, Ron, I'm getting tired. With this SGR uncertainty, the proposed cuts, the unfunded mandates. You know, maybe it's time I should do something like this." And what they did -- and I'll share this with you, and it's not a scientific study, but they went ahead and looked at their patients and sent out a letter to their patients saying that we're thinking about going to this and we will have a retainer fee on a monthly basis. Now, it's not $1,500, but it was a figure of somewhere around $50 to $100 a month. And they said that 55 percent of their patients liked that idea so they could get access, so they could have the doctor's telephone number.

So when you're a 75-year-old male or female with lots of comorbidities, you're living in a home by yourself, your kids aren't there, you're frightened, you have a telephone access. You have care that you can depend on. So I think there is something where the beneficiary really looks at this.

Now, there's a couple other issues that I'd like to say. You know, I don't like the idea of concierge medicine. I think it's something that we should all be providing to every patient all the time. But it's unrealistic to expect every primary care doctor to do that, especially being the hamster on the treadmill. But I think this may be an elephant in the room because I think patients really want something like this. And if we're not going to provide that in our health care delivery system, then the patients are going to go out looking for it. And if we can't provide the things that a physician wants to be able to practice medicine the way he or she was trained, to have less stress, less burnout, and not have this SGR debacle and the proposed cuts as a threat, I think there may be something here.

You know, there's another group of people that you haven't looked at, and I see it in my specialty, and I'm note sure if Karen sees it in her specialty. But we have people that feel they're experts, and when you go there, they drop out of Medicare, and when they do this surgical procedure, you know, the sky's the limit. And this is really concierge medicine because they're doing this as a

specialist and as surgical -- I know a lot of the plastic guys do it, and I know some ENT guys that do it. But I think that's another group of people you haven't looked at as concierge medicine-type people.

My last and final comment is that we do need these comparison studies looking at cost, volume of services, and quality of service and, more important, access. Thank you.

MS. UCCELLO: Yeah, building on many comments, Kate's and others', thinking about this in terms of both the equity and the access, I think it's important to think about this not just in terms of the primary care but also what the ramifications are for the specialty care. And, you know, maybe we don't care if somebody has a lot of money and they want to buy some extra time with the primary care doc and get all these extra tests and that kind of stuff. Well, if that's how they want to spend their money, fine, and if there's no access issues that come down on the primary care side, fine.

But now what happens when all the test results come back that may not have been needed and there are false positives or whatever? What's the impact then when they go to the specialists? You know, what is that doing on the

cost side, what's that doing on the access side of the specialty docs? Just thinking about it on that side, too, I think is important.

MR. HACKBARTH: So there are different ways that you can look at this issue. One is through sort of a normative approach: Is this the way medicine ought to be practiced? Is it equitable for different classes of patients, et cetera? And that's important, legitimate, and a discussion worth having.

Another way of looking at it is sort of the way that Mike was describing. Look at this as -- about market signals. What is it signaling in terms of patient preferences, provider willingness to provide service at different prices?

I am interested in both conversations, but I'm especially interested in the latter conversation about what the market is signaling and, in particular, wish to avoid Medicare getting behind the curve and in a very abrupt and disruptive way finding that our price is even further out of line than we may have thought, and that access to primary care is going to be even worse than we had assumed for a variety of other reasons.

And so, you know, we have proposed and now Congress has adopted steps to help increase payment for primary care, but what this sets me to wondering is whether we are basically, you know, fiddling when things are about to get dramatically worse. That's not an assertion that I know that they will or I believe they will. But that's my fear, that we're behind the curve in terms of the policies that we're looking at.

That's my concluding thought on this.

DR. DEAN: To me the bottom line is that primary care has to be restructured, and I think that all these different models tell us that.

It reminds me, a couple years ago, the New England Journal brought together a panel of specialists and people with a special interest, and they did a session on restructuring primary care. And most of these same issues came out of those discussions. The one statistic I remember is Tom Bodenheimer from California had done the calculations, and he said if the average primary care doc with 2,000 patients in his panel did everything that was typically expected of him, he works 18 hours a day.

MR. HACKBARTH: Right.

DR. DEAN: And I think that sort of sums it up, where the burnout comes from, and it needs to change. I think we're seeing different models of how it might change, but it needs to change.

MR. HACKBARTH: Yeah. And I like the way you framed it in your earlier comments, Tom. If you put more money into primary care, some of it may go to increased take-home pay for the physician. Some of it may go into practice supports that make the job more doable than it seems today.

And, you know, the medical home model is in part at least based on the philosophy let's invest more in it, not necessarily to dramatically increase the take-home pay. I don't think that's what's happening at Group Health, but the resources are being invested to make the job more doable, sustainable, attractive to physicians in training.

You know, all of this conversation has set me to thinking that maybe we need to rethink what we've said about the medical home. When we talked about medical home, you know, a couple years ago now, it was, well, let's test and see if it saves money; you know, whether the hypothesis is true that if you invest in medical home there will be fewer

specialty referrals, fewer avoidable hospital admissions, et cetera.

Well, you know, that would be really nice. On the other hand, it may be that even if it increases money, you need to do it in order to make the job doable, to keep people in primary care practice, let alone attract new ones to it. And it may be the savings model, which is actually what's built into the reform law, as I understand it, let's do a pilot to see if it saves money. It may be the wrong way to think about the medical home project.

DR. BAICKER: Just to build on both what you were saying and what Mary was saying, it is a sad commentary that we're thinking of extra services as being able to talk to your physician within a couple of days of needed to, doesn't seem like it should be the bells and whistles. How this influx of money into primary care from a limited segment of the population affects the whole system in terms of prices being adequate to gain that kind of access I think is inherently tied up with entry into the profession.

For a long time, we sat around bemoaning the fact that there wasn't enough money in primary care, and now a bunch of money is coming into primary care, but it's coming

in a very funny form. And so how that extra money filters through into increased entry into it and, therefore, access for other patients and, therefore, the market equilibrating price so that people get the baseline services that we consider reasonable baseline can't be evaluated without evaluating the workforce entry issues, I think.

DR. MARK MILLER: I know we're out of time, but just a couple of things. Some of the comments on medical home sort of leave me with this thought, because, I mean, there are pieces here sort of concluding that this is necessarily -- and I think this came out in some of the exchange here. Medical home I think is kind of questionable. In some ways, it seems like you can just boil down those comments, and particularly your last comment, to well, then, maybe it just means more needs to be paid to primary care physicians. I mean, at least as a first step. And, you know, how much the medical home goes along with that is a second question.

MR. HACKBARTH: Well, the medical home does two things. One, more is paid, but it's also paid in a different way. To get the more, you don't have to do more visits and more services. It's paid as a per month payment

per patient, which allows you to build infrastructure with it as opposed to, you know, just chase it.

DR. MARK MILLER: And fair enough, but I think what these models do is they make that payment. They don't necessarily bring the rest of the infrastructure along with it. My only point is that the first lesson of this may be a payment lesson, which is sometimes what I hear on some of this exchange. And then it's a second question of whether the infrastructure is something that we want, and want in a certain way, team or individual physician, and is there a way to get that, or whether you can get some effect from the pay -- the change in pay, both either in level and form in and of itself. But it's just the kind of marrying those two things -- we should be very careful and not necessarily, in my opinion, treating this as a medical home.

And I had one other question for Ron, which was this: You talked about what your patients who came from these practices said. You know, they had higher demands and that type of thing. Did you find any greater coordination with the physician who sent them?

DR. CASTELLANOS: Yes, I did. He sometimes or she sometimes even came with the patient.

DR. MARK MILLER: Did what? [Off microphone.]

[Laughter.]

DR. CASTELLANOS: Came to the office for the office with the patient. The physician.

DR. MARK MILLER: I got to hear this again. You said --

[Laughter.]

DR. CASTELLANOS: He was really trying to figure out how to do it.

MS. HARGRAVE: That's something that we heard in our interviews, too, that it's a service that several of the people that we interviewed offered, that they will go to specialty visits with their patient.

MR. GEORGE MILLER: But, you know, we sit here and listen to this, and we laugh at something that's funny, but the market has figured out a way to do this right. I mean, if you read that slide there and why this is being done, the market has figured out that I need less patients, amount of money, and I can give better service. Instead of us figuring out how to do this, maybe we ought to listen to what the market says works right. And, again, what Tom just said I think says it best. It's the right amount of money

with the right amount of patients being able to give the right amount of care. And you don't have all the things in Slide 11, so maybe that's a lesson we learn.

Like his panel, I have a panel also. I live in a neighborhood where all of my neighbors are physicians, and I see them leaving, and they tell me all of the problems with the system in my driveway.

[Laughter.]

MR. GEORGE MILLER: And it's mostly these things. They're overworked, they've got too much to do. And Tom said if they did everything right according to what everybody requires, it's 18 hours a day. That's not practical. And maybe we ought to focus on what's right and try to design a system around that.

DR. BORMAN: Again, I support that there are important messages we take out of here. I want to come back to something Herb said, though. In the last wave of enthusiasm, you're making me real nervous about drawing sweeping, huge conclusions from 0.1 percent of people. And I just want to be real careful that we do this in a way to pull out what's important and what's appropriate. There's nothing here we've heard, there's nothing here about

relating to quality measures, about relating to outcome. I mean, not just the infrastructure, which you've appropriately highlighted, but the other thing -- and I know you don't mean to imply that, but I'd want to be real careful about readers of this or listeners to this, you know, be a little bit skeptical here that in our enthusiasm that we don't get carried away, that we work very hard to objectively identify what are some take-home things that we can make better about this, but that we just be a little bit careful. You know, I can see the headline now: "MedPAC endorses concierge medicine for all." Just be a little bit careful here.

MR. HACKBARTH: Thank you, Karen. That's a very important concluding comment for people in the audience. There is a shortage of facts. And thank you, Elizabeth, for bring at least some basic ones to bear, and we need more thoughtful analysis before we leap to any conclusions or any policy recommendations.

So thank you again, and let's move on to our next topic, which is clarifying Medicare's authority to apply least costly alternative policies, a topic we last talked about in the spring.

MS. RAY: Good afternoon. As a Commission, you have raised concerns about enhancing Medicare's ability to innovate. In 2009, the Commission raised concerns about the pace of Medicare's demonstrations. Most recently, in our June 2010 report to the Congress, Commissioners discussed that Medicare might be able to improve health care, quality, and efficiency if it were given broader authority to demonstrate and implement new delivery models. The Commission also voiced concerns about the level of resources allocated for the development of policy innovations.

As we push Medicare to be a more intelligent purchaser, Commissioners also raised concerns about Medicare's flexibility to use innovative purchasing policies. In the June 2010 report, Commissioners discussed several purchasing policies that have the potential to increase the value of the program that Medicare lacks clear authority to implement.

I am back here today to talk about one specific policy that we raised in the June 2010 report and that is called least costly alternative policies.

Under least costly alternative policies, or LCAs, payment for a group of clinically similar services is based

on the least costly item. LCA policies do not require any new or additional collection of pricing data. Medicare uses existing statutory payment formulas to set the payment rate of a group of clinically similar services.

When applying least costly alternative policies, it is necessary to assess the evidence on whether a service is clinically similar to one or more other services. By setting the rate based on the least costly item, least costly alternative policies have improved payment accuracy. This, in turn, has resulted in savings for beneficiaries, the 20 percent cost sharing for Part B services, as well as savings for taxpayers and the program.

Medicare's administrative contractors have applied least costly alternative policies for durable medical equipment items and Part B drugs in their geographic jurisdictions since the mid-1990s. In one instance, CMS implemented a least costly alternative-type policy nationally to pay for two biologics under the Hospital Outpatient Prospective Payment System in 2003.

We anticipate that opportunities to apply these policies will increase as more clinical information becomes available.

Your mailing materials included a case study about two drugs that treat advanced eye disease. There may be an opportunity to apply a least costly alternative policy in the future once a head-to-head NIH study that is comparing these two drugs is completed in 2012. Currently, researchers have estimated the difference in Medicare's payment rate per dose at $2,000 per dose for one drug versus $50 per dose for the other.

Medicare has applied least costly alternative policies based on the statute's "reasonable and necessary" provision that no payment may be made for any expense that is not reasonable and necessary for the diagnosis or treatment of an illness or injury. Recently, a beneficiary challenged the use of a least costly alternative policy to pay for a Part B inhalation drug. The U.S. District Court agreed with the plaintiff's argument that Medicare must follow the detailed statute in paying for Part B drugs. The court concluded that the Secretary exceeded his authority in applying least costly alternative under the reasonable and necessary authority.

Health and Human Services appealed this ruling and the Federal Appeals Court agreed with the lower court

decision, finding for the plaintiff. Since the appeals ruling, Medicare's contractors have formally withdrawn the least costly alternative policies for Part B drugs.

Therefore, we are here today for you to discuss a policy option of giving Medicare the authority to apply least costly alternative policies to Part A and Part B services. Using this clear statutory authority, CMS could develop a systematic process to consider and implement least costly alternative policies. Such a statutory change could be coupled with a requirement that the program evaluate opportunities for its application. For example, the statute might require that CMS assess the clinical similarity of existing services and two newly-covered services.

You might want to consider this option because in the past, CMS has always not been able to use new flexibility. Your mailing materials included a case study of a pricing flexibility called inherent reasonableness that CMS has used only once.

A policy option of giving Medicare authority to use least costly alternative policies could be linked to a policy option that ensures that a clear and transparent process be developed for applying these policies.

Characteristics of the process included being clear and transparent, permitting opportunities for public input and comment, identifying and defining groups of clinically similar services, ensuring access to the most costly service if it is medically necessary, and just as an aside, the current process does include this, and permitting a beneficiary to gain access to the most costly service if that is his or her preference. Again, the current process does include this feature.

I want to emphasize that this new flexibility is not intended to impede patient access to necessary care.

So this is an illustrative example of the steps to apply a least costly alternative policy, and in this illustrative example, we're looking at a new service.

And so first you would want to determine whether or not it falls into a Medicare benefit category, and if it does, is it reasonable and necessary. And if it is, then you would want to determine whether or not it's clinically similar to existing services. And then the rate for that service, if it was clinically similar to one or more existing services, would be set according to the statutory formulas, but based on the least costly item. Again, as I

mentioned previously, this would not require any new collection of pricing data.

So to implement this authority, the Secretary could use existing infrastructure developed under the coverage and payment processes or the Secretary could develop a new pathway or some combination of both. This slide summarizes some features of the current coverage and payment processes.

For example, on the coverage side, there is a specific opportunity on the national coverage side for stakeholders to make a request for an item or service or product to go through the national coverage process. On the payment side, that process is usually started by CMS, sometimes because of a Congressional mandate.

In terms of implementation, coverage policies are most frequently implemented locally, but also nationally, as well. By comparison, payment policies are usually implemented on a national basis.

In terms of transparency, both coverage and payment policies have opportunities for notice and comment. The difference is payment policies most frequently, of course, go through the Federal Register process. On the

coverage side, they go through an online process where either CMS or the contractors post draft policies online.

In terms of formal technical advice, that tends to be a little bit better developed on the coverage side. On the national coverage side, CMS can sponsor external technology assessment, sometimes through AHRQ, or seek advice on clinical topics through the Medicare Evidence Development and Coverage Advisory Committee. On the local coverage side, the Medicare contractors can -- are required to consult with the Carrier Advisory Groups, or now they're called the Contractor Advisory Groups.

On the payment side, this formal process for getting external technical advice is a little less developed. There is, however, on the hospital outpatient side the Advisory Panel on Ambulatory Payment Classification Groups.

So to close on this slide, again, the Secretary could build upon these processes or develop new processes or some combination of both.

So to summarize, least costly alternative policies have improved payment accuracy, and this in turn has resulted in savings for beneficiaries, taxpayers, and the

program. Their legal foundation, the Secretary's legal foundation to apply them is unclear, and future opportunities to apply them will increase as more clinical information becomes available. We seek comments about the policy options that we have discussed and any additional research that you'd like.

MR. HACKBARTH: Let's begin on this side with clarifying questions. Cori and then Ron.

MS. UCCELLO: Okay. I'm just a little confused on what kind of the options are. Is one option still to do this through the coverage determination process and another through the payment process, or is it everything through the payment process but using some of the coverage stuff?

MS. RAY: Well, I think even to back up from there would be if just looking at Slide Number 6, one way to go about this is to give the Secretary the authority to implement least costly alternative and then you could -- from there, you could leave it to the Secretary to decide the pathway to do that.

DR. MARK MILLER: Do you want me to pick up, Nancy? The way I would think about this is I think one thing that kind of came out in our conversations and one

thing that we want to put in front of you guys is that this authority is not without its controversy, okay, and I think the key thing if this authority is going to be clarified and pursued by the Medicare program is that a process is developed in order -- where certain principles are met, and I think that's the key slide, is sort of what is the process going to be where all stakeholders can feel that they had input and were treated well, had the ability to bring information, that the beneficiary has the ability, either because they're willing to pay more or because clinically it's been determined that they can get the drug.

What I think Nancy was doing with the end of the presentation was to say there's two existing processes that you can sort of help think about how things move through the agency, one on the coverage side, a little different characteristics, one on the payment side. I don't think she's saying, or we're saying you have to pick, but these are the characteristics you might blend, you might say, no, I want to put it on that path but I want to modify that path, you know, that type of thing. I think that's what Nancy's trying to get -- what we're trying to get across here. Does that even get close to your question?

MS. UCCELLO: I think so. So I'm not sure this follow-up question is relevant, but I'm still going to ask it. You know, with all the new comparative effectiveness initiatives and the restrictions on using the results from those to determine coverage, how does that then inform this question?

DR. MARK MILLER: I mean, the way I would answer it is that the coverage process will produce -- I mean, the new clinical effectiveness process will produce information that could inform this process.

In this instance -- Nancy, make sure this is correct -- we're talking about something that's determined to be covered. What we're really trying to figure out is whether it's clinically similar and hence goes to one price or the other. That's the way I have it organized in my mind.

A nod here would help me out a lot here.

MS. RAY: Yes.

DR. MARK MILLER: Okay.

MS. RAY: Yes.

MR. HACKBARTH: And just to follow up on that, so the language about on the prohibition of using comparative

effectiveness information is specific to the coverage process and not to the payment policy process.

MS. RAY: I think so. I would want to double-check that, but I think that is correct, and I think the --

MR. HACKBARTH: That is my recollection, as well.

MS. RAY: -- and my recollection is that the policy can't solely be based on the one study, that there needs to be other studies, but I would want to go back and double-check that.

MR. HACKBARTH: So does that help, Cori? Ron and then Mike.

DR. CASTELLANOS: I have two questions. One is on page 11, you talk about the clinical appropriateness, where you can get access to the more -- to these products if they're clinically appropriate, the more expensive drug. Maybe it's drawing a fair line, but on page 17 at the bottom of the material, you said Medicare coverage authority for beneficiaries to gain access to a more costly service, if that is his or her preference. So it's both clinical and preference?

MS. RAY: I guess I was talking about two different instances. In the first instance, so let's say

there are three widgets and they have been found to be clinically similar, but for people with, you know, purple ears, they just -- and that's one percent of the population, let's say -- they tend to do better with widget number one. There is -- my understanding is that the physician can go to the medical director of -- the contractor medical director to start that process going so the patient could get the more costly item and Medicare would pay for the more costly item and/or an appeals could always be done.

Now, the second case is that, you know what, I want widget number A no matter what and I am willing to pay for that, and that, I think, I was thinking that that could be accommodated through the advanced beneficiary notice, and that is through the coverage process.

DR. CASTELLANOS: So there are two processes?

MS. RAY: Yes.

DR. CASTELLANOS: Okay. Thank you. The next question is just -- probably it's just -- you know, in April, they took it away from the Part B drugs, but it still exists under DME. How is that worked under DME?

MS. RAY: That's a very good question. When I checked in August, those least costly alternative policies

for the DME items were still up in the database, in the coverage database, and we are in the process of trying to contact some of the DME contractors to exactly figure out how they are being applied.

DR. MARK MILLER: But there is some sense that perhaps the decision on the drugs had a rather chilling effect across the board, and that's what we're trying to sort out.

DR. CASTELLANOS: Thank you.

DR. CHERNEW: [Off microphone.] Ron asked my question.

MR. HACKBARTH: Other clarifying questions?

MR. BUTLER: I don't quite understand. Can you think of examples where it works the other way? Rather than something new being expensive and not necessarily producing a better result, but the other, something new that is cheaper that somebody is contesting that the existing thing is more effective and therefore we don't let go of the higher price of the existing product, even though the new product may be cheaper and produce the same result?

MS. RAY: Are you asking me, can I think of an example like that?

MR. BUTLER: Yes.

MS. RAY: Yes, I can.

MR. BUTLER: Okay, because your examples go the other way in here, in the --

MS. RAY: Under the DME fee schedule, the negative pressure wound therapy pumps, the payment is based on the original pump and that price is much -- at least according to an OIG report, that's a pretty recent report -- that price, that payment rate is much greater than what would be charged if payment was based on the newer negative pressure wound therapy pumps, yet Medicare is still paying based on the original one.

MR. BUTLER: So there is that case, too, in your write-up?

MS. RAY: Yes.

DR. BERENSON: I was very happy to see the text box and your brief comment about inherent reasonableness. I was at CMS when it got shut down when we had market prices showing that our fee schedule was much too high. But it seems to me it's not a subset of least costly alternative. It strikes me that it is a separable topic deserving -- I actually think it may have broader application and is

second-best to competitive bidding for DME, but is there a reason you sort of have it as -- or you sort of put it in here, and does that have to be that way?

DR. MARK MILLER: So what I think we should talk about here, Nancy, is kind of the back and forth, some of the back and forth we had on this when we were preparing this. At least one take-away from that conversation I got was that the infrastructure to execute inherent reasonableness in the agency was just a much heavier lift in order to kind of pull it off, and that was my --

MS. RAY: Yes.

DR. MARK MILLER: All right. Why don't you --

MS. RAY: I mean, I think in terms of implementing inherent reasonableness, I think the difficulty there is the collecting pricing data that is sufficient to meet the standards that CMS put into the final 2005 rule that they issued on this policy, and it is a different policy than least costly. Whereas least costly you're determining if items are clinically similar, with inherent reasonableness, I mean, it can be limited to one item and you're saying if data out there suggests that Medicare's payment rate is at least 15 percent off, then we can adjust the payment rate

either up or down by 15 percent. But I think there, the threshold is collecting the pricing data.

Now, as far as the decision to move forward on the least costly alternative policies and focusing on that and not inherent reasonableness, again, we just picked -- I mean, one of the reasons is that we discussed least costly alternative at length in the June 2010 report.

DR. MARK MILLER: The only thing I would add to that, I mean, one way to think about the least costly alternative is you know the two prices and the difficulty is trying to figure out the clinical effectiveness, which I don't think is a small lift in and of itself. The other way, you have to produce the pricing --

DR. BERENSON: Yes. All I'm saying is we should keep them separate and if we want to make a decision that we don't want to tackle inherent reasonableness, then I think that's fine. But I just don't want to lose it as -- I mean, it's its own topic, I guess is my only point.

DR. KANE: Are there any studies of the effective LCA, or I guess it's similar to reference pricing, on the likelihood of a newer lower cost item coming into the market? So I remember sitting on a doctoral committee for

someone who looked at drugs and that looked at countries with referencing pricing and said in countries with reference pricing, where the lowest price drug is the price all the drugs are paid for, they were less likely to have lower cost substitutes introduced. Now, I don't know if that's just that one study, or is that a common phenomenon? I guess what's the impact on the market and on future innovation? Has anybody looked at that even around these LCA or grouping types of pricing policies? Maybe nobody knows. I just wondered.

MS. RAY: I think the literature on the effective reference pricing done by other countries, I mean, I think it seems to be mixed, and I'm definitely not an expert on it. Some will say that it does have an impact on the market. Others will say that in terms of beneficiary access and outcomes, there is no problems. I guess I could look at the literature one more time and come back to you with, you know, a better answer to that.

MR. HACKBARTH: The thesis --

DR. KANE: The question is whether when you have a bundle of services with a reference pricing-type policy, that manufacturers of similar types of services, especially

if they have one already in the bundle, may not want to lower the overall reference price by bringing in a lower-cost equally clinically effective substitute, and that is the doctoral thesis I sat in on. That was a finding. But I don't know how universal it was or whether anybody had done a real analysis of this at a broader scale. Let's just say the widget manufacturers might actually have a cheaper deal they could get out, but they don't want to lower the overall reference price for all their other products because they're cannibalizing themselves.

MR. HACKBARTH: I guess what I'm stuck on is the other side of that. If you don't have it, then what's the incentive to come in with a lower cost product --

DR. KANE: That's another -- yes. Also, it would reduce the desire to even do that R&D.

MR. HACKBARTH: Right.

DR. KANE: I didn't know if anybody has studied the rate of innovation and whether it differs when there are products that are bundled like that as opposed to not.

MR. HACKBARTH: Yes. Jennie?

MS. HANSEN: This is separating out the two issues, I think, Bob saying that the reference, or, excuse

me, the inherent reasonableness is something that is separate from the other pricing aspect of it. Just especially with the new court case coming out, what might be the incentive to take this on at this point as an issue is more of a question. Why might we be more successful now to take this on as an issue? And then, separately, is there any access to information in commercial plans that have a decisional process that could be somehow understood as to how decisions get made along the way.

MR. HACKBARTH: The first part, if I understood your question correctly, the court case interprets current law and says, here is what the Secretary or cannot do within the current statute. What we would be recommending here is the Congress amend the statute to give the Secretary explicit authority to do X, Y, and Z, and then the court case, the current court case is moot. Do you want to address the second part?

MS. RAY: Right. Right. As far as use of least costly alternative by commercial plans, I would have to get back to you on that. To my -- I don't want to misspeak. I have not run across them, but I would want top get back to you.

DR. DEAN: [Off microphone.] -- the formularies are --

DR. BORMAN: In general, I support this line of inquiry. I think that the materials were nicely presented, both in written and in the slides. One could envision what people have already touched on, the interdigitation with comparative effectiveness. But also, you can kind of sort of almost SNF value-based purchasing lurking to some degree behind here and efficient provision of services and accurate pricing, so many things that the Commission is on record for, potentially take this under that umbrella. And so in our conversation about enabling CMS to do the job that's been assigned to it on behalf of the program, that there seems to be value in considering this. I think obviously there's a fair amount of sharks swimming here and we need to be pretty careful about being crisp about what is the question. As Bob has pointed out, there's different pieces here in terms of IR versus this, but I think there's value, too.

So my clarifying question, however, would be do we have some sense about the scope of this, and by that, here's why that occurred to me. The examples that we've seen

primarily are devices and drugs, and I can kind of envision how that rolls out. However, your slide just said new service, and in theory, that could be something other than a drug or a device. It could, in fact, be a procedure, for example. So do we need to do some thought about that, or do we need to just say we think that this relates to types of services being imaging, lab tests, drugs, as opposed to saying this would potentially apply across the program? Because I can think of an example just off the top of my head that might be open operation for arterial disease of the lower leg versus a catheter-based service, and while they can achieve the same short-term result, there are durability issues with the catheter-based.

And so then you've got to talk about what's the result over a multi-year time, and then how do you judge the equivalency of that in an LCA kind of setting.

So I guess my gut feeling is that this would have to be more restricted to things like devices, drugs, tasks, but I'm not sure and we might need to explore that as a sub-question if we go forward with this.

MS. RAY: And I just want to clarify just one point. The illustrative example where I started out with a

new service, again, it does not necessarily -- I mean, that was just an example. It could be an existing service, as well.

MR. HACKBARTH: So in this area, there's some history, legal history, legislative history. These are not new issues. If we are to recommend to Congress that Congress amend the statute to explicitly authorize these policies, it seems to me that we would do well to quite explicitly address the sort of issues that have come up in the past and that have been both a political, legislative barrier, and in some cases a legal barrier. And some of the issues that come to my mind are these.

One, people have argued that this is a bad idea because it will discourage innovation, sort of the point that Nancy raised. Now, other people might say, well, it won't discourage innovation. It will just refocus innovation on creating products that are lower cost and better. But that's sort of one type of issue, what is its effect on the innovation system.

A second issue that it seems to me has been implicit if not explicit is, well, this is illegitimate intrusion in market pricing. You know, the market is

setting prices for these things and here along comes the government and says, no, here is a different price, as opposed to the current system where basically we take what the price is that's being charged and we pay it. Frankly, that's an argument that I don't get in that it seems to me that there's not a functioning market here when people are basically setting the price and everybody's paying it without comparing it to other comparable products. That's what makes a market function, is that comparison of value and that doesn't happen at the patient level for a variety of reasons. It seems to me it's got to happen at the payer level. But that's another type of argument against this that is heard that I think needs to be taken head-on if we're going to be at all persuasive in doing this.

Then a third type of argument against it, well, is that the decisions will be made poorly. They won't be based on appropriate evidence, appropriate experts won't be involved, et cetera. And so there are sort of procedural responses to them, some of which Nancy began to outline in the paper.

And then sort of the fourth type of argument is, well, not all patients are the same and even if you do your

best good faith effort, say, oh, these are comparable products, for some specific categories of patients, those comparisons may not be relevant and so there needs to be a safety valve whereby the patient with a really unique set of needs and circumstances can get access to a different product.

There may be other arguments, as well, but my basic point is because of the history around this, if we want to be persuasive, I think we need to really bing, bing, bing, say here are the issues that have been raised and here's our sense of how you might respond directly to those issues.

So that's my round two kick-off comment. Let's proceed, other round two comments. Ron and then Mike.

DR. CASTELLANOS: I'd like to digress just a second to give you an experience that I had with LCA. My personal experience with LCA was with the Part B drugs for cancer of the prostate. I think I'm going to start out by saying I got a phone call from Mark Miller once saying, "Ron, is there a new treatment for cancer of the prostate?" And I said, holy, I didn't read USA Today. I guess I missed something. And I said, not that I'm aware of, Mark. Why?

And he says, "Because since we changed the LCA policy, there's been a 20 percent decrease in the use of that drug." And I said, holy, what's happening?

So I went back to our society and we tried to figure it out, and I think there are some answers, but not an answer good enough to say that it accounts for the whole 20 percent. Instead of giving it to a person all the time, we do it in a minute or pulsatile, and that's a new form of treatment and it's the appropriate thing to do. But that bothered me that 20 percent usage was dropped as soon as payment went down. That really bothered me.

I also said, you know, there's been a lot of screaming and a lot of fighting and teeth chomping over the cost, because what we were doing, we were getting paid a tremendous amount of money based on the average price, wholesale price. This wasn't something I established. This was a Medicare regulation. And I don't want to say it was insane, but we were getting paid unreasonably high for doing nothing. We do get paid appropriately now, and I think price accuracy has really made a difference in this drug.

So I can only say this, and it's not a very nice thing to say, is that when I was at a meeting after April 20

when the LCA policy for Part B drugs were removed, and that was announced at a urology meeting and there was a whole bunch of cheering, and there was only cheering for one reason, and I'll leave that up to you to figure that out.

So what I'm saying to you now is I think this can be a good policy if it's truly clinically equivalent in efficacy, and especially if the physician has the ability to say, I want another option, and the patient has an option of preference. So has it worked for Part B drugs for cancer of the prostate? You bet it has. We have payment accuracy and there hasn't been any really, real disruption of efficacy of care.

DR. CHERNEW: I'm curious as to the extent to which different aspects of bundling or other things that might be going on could help us get around some of this problem. So I don't see, for example, in the wound therapy one why you couldn't envision that it will pay a certain amount for wound therapy and let whoever is getting that have to make the choice, or we'll pay a certain amount of treatment of whatever it is.

It strikes me that many of the bundling things work, and I think my general sense is it's going to be

extremely difficult to move through to the system we want to get to if we try to, on a case-by-case basis, have a hearing about the equivalence of this versus that. And I understand that purple ears is a really good example because I haven't met many of the people, but there's always people that have various types of things explaining why in their case it's different and physicians have different opinions. Just the geographic variation literature shows you why it's so hard to go this route.

So while I'm generally supportive of this as a rule, I think that there's probably better ways to solve the problem, the basic problem, and one of the things that I would like to see happen in general is have potentially the beneficiary share in some of the savings if they choose the less expensive one. The way it works now is you just don't pay for the more expensive one, but the beneficiary doesn't get anything out of that. But if you set the price a little bit higher, the beneficiary chose the more -- they would have an incentive and you could see it working out.

So I think that there's -- least costly alternative is certainly sensible in a lot of the cases that are discussed. When you see some of these things, it's kind

of annoying. But I think if you really were going to think about how to set this up, you'd try and achieve the same goal through a broader, easier to work on an ongoing basis kind of strategy. That's my sense.

MS. BEHROOZI: This is the kind of thing that we do in our drug program, in particular. I think Karen's right that there's some lower-hanging fruit than others. And, of course, with Part D drugs, it's administered through plans, but at least in Part D drugs, there's some opportunity, I guess, for Medicare that should be pretty long-hanging, one of them you identified that's pretty glaring, Nancy.

I just want to distinguish it from a formulary, though, because in a formulary, you might have tiered copayments, and the problem for the payor is that even though the person at the highest tier might be paying a lot of money out of pocket, the payer is still exposed to all the difference between what might have otherwise been the reference price that they would pay and the, you know, outrageously priced other thing that the beneficiary has not all that strong a disincentive to purchase. They might be paying $50 for a non-preferred brand drug, but what the plan

ends up paying is $150 as opposed to the beneficiary paying $10 for the preferred and the plan only paying the other $40 or something like that. So I think that's really important to keep in mind.

And, Glenn, in your point about the market, it's really important for the one who is the payor to be an active purchaser in the market, because as you said, price is not an immutable thing. I mean, it's not just about whether manufacturers will develop lower-price products, Nancy, but they will lower their prices to get onto your reference price list. I mean, we had a circumstance, because what we do is pay the full price, there's no beneficiary cost sharing -- that's what exists at the reference pricing level -- but then people have to pay the entire difference if they want something else. And so having that strong an incentive, that strong a protection of beneficiaries and that strong a message to beneficiaries, this is the least costly clinically effective drug, manufacturers want to get there so that their product will be purchased.

And we had a circumstance where the popular brand name statin, which shall go unnamed, pretty much came down

to the level of the generic because they did not want to be closed out of this reference pricing structure that we had. And we actually lowered our drug spend -- not lowered our drug trend, we lowered our drug spend by a percent, '07 to '08, and this was one of our most -- our strongest tools.

I just want to say, then, in terms of the legitimacy of the process is key, and you've really focused on that, for us, it's transparency of decision making and the trustworthiness, of course, of the decision making, experts' independence, review, constant review, staying current all the time, and, of course, the right of appeal for the purple ear people and the ability for people to pay that extra out-of-pocket, the other $1,950 for the drug that will do the same thing if they want to. And then once they feel like all of that is available to them, certainly our experience was that then people felt like, okay, fine, so I'll just take the free drug. That's fine.

MR. HACKBARTH: So value-seeking purchasers, that's what makes markets work effectively, and so what Mike is suggesting is that one way to think about this is how do we engage others to be those value-seeking purchasers, whether it's providers who have to buy this product out of a

bundled payment, and we've seen some of that with the advent of DRGs for inpatient services.

DR. CHERNEW: [Off microphone.]

MR. HACKBARTH: Right. Right, where it can be patients who are rewarded for buying -- using the lower-cost product, or conversely penalized for using a higher-cost one. Or you can do it at the insurer level, and so -- but the one thing that's sort of non-negotiable is you've got to have value-seeking purchasers to make markets work and sometimes that basic point seems to be lost in debate.

Other round two comments? Bob?

DR. BERENSON: Well, in round two, I will revise and extend, or whatever the language is, my round one remarks about IR. I guess I'd want you to consider putting it not on an equal basis with LCA, but on a parallel basis rather than sort of just a text box that there's a sort of a separate discussion of IR.

And it seems to me that this could be a pretty valuable tool if, in fact, competitive bidding for DME sort of gets sidetracked again. It's sort of an alternative. And frankly, I don't know what's contemplated under competitive bidding for the markets that don't have

competitive bidding, whether maybe others know what happens. Do we use the bids that come in from the markets that bid to adjust the fee schedule for the remainder of the country, I guess would be my question, and it seems to me it's complementary to using the IR authority, or similar to the IR authority. We try to get marketplace information to identify services that are significantly overpriced.

I think it's worth at least laying out the argument for doing IR. If it turns out that it's too onerous to actually go through the about 12 bullets here that the agency would have to go through, at least we have identified another place where CMS doesn't have the discretionary administrative dollars to save mandatory dollar-side money and we could at least make that case. Or it could be that CMS didn't implement this because they no longer see that there's a lot of savings in it. I don't know. I just think we need to understand this a little more and give it a little bit more attention, is all.

DR. MARK MILLER: And I wouldn't characterize it as taking up LCAs because they're against, you know, taking up IR. This is just where we kind of went to first. And I think if we do take it up and look at it, one serious

portion of the time that we spend looking at it will be trying to figure out whether there's a more streamlined way to execute it, because I think there is some cumbersomeness to it.

But I just want to ask David, do you know the answer to the question on markets in DME that don't have competition?

MR. GLASS: [Off microphone.]

DR. MARK MILLER: He said he --

MR. GLASS: I don't think there is an answer yet, but I'm not sure.

MR. KUHN: I think they just use the standard gap-filling process that they have now for those products that are outside of those ten MSAs, is my guess.

Looking at the last bullet there in terms of the comments about policy options, let me just try to talk to two of them here for a moment. One is in the paper, you talked a little bit about LCA being done nationally and what process could be used for that, and a discussion was to use the NCD process. We could look at that further, and I think it's worth looking at further, although I do worry about clogging up the NCD process as part of that.

MS. RAY: I think that that is one concern about that, given the resources that they have right now and the fact that, I don't know, I guess maybe they do about a dozen NCDs a year or something like that.

MR. KUHN: Right. It's cumbersome and it's slow and I think it would slow the process down. You know, you could give the Secretary, allow him to consider cost as part of the NCD process to do it, but I think it would be cumbersome to do, so that would be an issue.

The other option, and I'm not wedded to this but I'm just tossing it out as something we might want to consider as we go forward, I think it was in the spring when we had Sean Tunis here talking about coverage with evidence development and the CED process, and if you remember that conversation with Sean, it basically was while there might not be enough evidence to go ahead and cover something, CMS would go ahead and cover it for now but then collect the evidence on a go-forward basis and then kind of defer a decision until later on. And that was kind of detailed in the June report.

So kind of picking up on that theme, for lack of a better term here, maybe call this evidence-based guided

payment and basically you could put some items into the LCA process now, create an LCA benchmark so all these items would go into that process at the current time and that if the different innovators that came up with the product were able to produce the evidence that they deserved a payment above the LCA benchmark, then they could move forward, because I think the process we're all kind of looking at right now is that there's a differentiation, and we've talked about how do we bring someone down. Maybe we ought to look at this differently and say, okay, we're going to all come in kind of at this space and if you want to be higher, produce the evidence to go higher as we go forward.

So again, I'm not sure I'm terribly wedded to that, but it's a different option to look at as we go forward.

MR. HACKBARTH: So what I hear you saying is basically shift the burden of proof.

MR. KUHN: Exactly.

MR. HACKBARTH: Right now, the burden of proof is on CMS to prove equivalency, as it were, and you would say it's on the sponsor of the new product to show it's different.

MR. KUHN: Exactly. That would be the big difference here. So that might be another policy option we might want to consider or to look at a little bit more as we go forward.

MR. HACKBARTH: [Off microphone.] Round two? Any others? Thank you, Nancy.

The last session today is a report on the recent growth in hospital observation care. Dan, you can take down your Elizabeth sign. Yeah, there you go, so nobody calls you Elizabeth.

MR. GAUMER: Good afternoon. Okay. In recent months, the growth in hospital observation services has become more widely documented in the media, and many of these stories have tied the trend in the growth of observation care to an increase in Medicare beneficiaries' financial liabilities.

CMS has been active on this in the last few months as well. They've scheduled an open door forum, which they had in August. They've sent letters to hospital advocates with concerns about the growth, and they've also commissioned some research on the subject, which is due out later in the fall, I believe.

Some have contended that the Medicare RAC program, which is the Recovery Audit Contractor program, has had some influence on the observation care growth. However, at this point in time, we haven't had clear documentation of this increase, with the extent of it, and also whether or not the RACs have been tied to the increase.

MedPAC has reported on observation care growth in the 2010 March report, and at that point, we showed significant growth from '07 to '08 and at that time, you all expressed or some of you expressed some interest in the subject. And as a result of the interest and, therefore, the growing awareness in the subject, we've put some information together and we'd like to get your ideas and your opinions on the subject.

I'm going to very quickly provide a little background information and then I'm going to walk you through the results of three of our research questions, and as usual, at the end, I'd be happy to take your questions and Dan's going to also assist with taking questions as well.

CMS defines observation care as a well-defined set of specific clinically appropriate services which include

ongoing short-term treatment, assessment, and re-assessment that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients, or if they're able to be discharged from the hospital.

Generally, observation care is an outpatient service and generally thought of as a lower intensity service. Hospitals may choose to systematically manage their observation patients as a part of an observation unit, or they may not. When they are managed by a unit, this may occur in a separate department with specifically devoted staff.

In cases where patients are not managed through an observation unit, the patient is generally placed in any available bed and managed by their admitting physician.

Most recent data available on this from 2003 indicates that about 29 percent of U.S. hospitals have observation units or were expected to start observation units very shortly. However, we're trying to get a little bit more current than '03. The best anecdotal information we can put together suggests that observation units have become more common since 2003.

The decision a physician faces of whether to admit a patient to inpatient care or treat the patient in observation is defined by two independent sets of CMS criteria. Medicare defines coverable observation care as that which is reasonable and necessary, eight hours or longer, and ordered by a physician. Medicare also advises providers that the decision to discharge a patient from observation or admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. CMS adds that only in exceptional cases should observation cases spend more than 48 hours.

On the inpatient side, CMS suggests that physicians should consider a variety of clinical and resource-related factors in making their decision. They suggest physicians should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis.

Hospitals are reimbursed a single payment per stay covering all observation hours and the associated emergency department and clinic visit. Observation cases originating in the ER are generally considered higher severity than clinic cases and yield a higher reimbursement rate.

Observation rates are significantly lower than inpatient rates. For example, after adjusting for the wage index, a patient presenting in the ER with chest pain and served on an observation patient basis would yield a $720 payment, and the same patient served on the inpatient side would yield a $7,600 payment.

However, it's important to note here that if a beneficiary is admitted as an inpatient following their observation stay, they have no out-of-pocket liability for the individual tests and procedures they incurred as an outpatient. But if the beneficiary is discharged directly from observation care, they are liable for the co-insurance tied to each individual outpatient service.

Experts have noted various economic benefits for providers resulting from observation care and observation units such as maximizing inpatient unit capacity, reducing the number of unreimbursed or denied inpatient claims, and reducing staffing costs.

As I alluded to a moment ago, observation care alters the beneficiaries' financial liabilities in two ways. First, as outpatients, beneficiaries in observation care pay a 20 percent copayment for their actual observation

services. And on top of that, if there are other services on the outpatient side that they incur, they pay roughly 20 to 40 percent of those -- of that care as co-insurance. In contrast, on the inpatient side, the beneficiary pays a fixed deductible of approximately $1,000.

Second, because observation time is not counted towards the three-day prior hospitalization rule used to trigger the skilled nursing facility coverage, it is possible that an increase in observation volume will result in fewer beneficiaries qualifying for SNF coverage, and therefore leave more beneficiaries to pay the full cost of their SNF care.

DR. MARK MILLER: Hey, Zach, just before you go on, and I can't remember if we put this somewhere else in the presentation, the $720 is what they get for the observation, but they can bill on an outpatient basis for other services provided? Am I correct?

MR. GAUMER: That's correct, yeah.

DR. MARK MILLER: Okay. And I can't remember if we organized that somewhere else, but I think it's important that it get said somewhere.

MR. GAUMER: Okay. It will come up again.

DR. MARK MILLER: I apologize.

MR. GAUMER: No, no, but we did touch on it here.

So moving on to our findings. The number of Medicare claims for outpatient observation care grew rapidly from 2006 to 2008, growing from approximately 900,000 claims to 1.1 million claims. Given changes in Medicare enrollment over this period, this equates to roughly a 26 percent increase in the claims per thousand beneficiaries. In contrast, during the same time period, the number of all Medicare outpatient claims per beneficiary grew about 4.5 percent.

In addition, the number of observation hours grew even faster than raw claims, at 37 percent per thousand beneficiaries. More rapid growth in observation hours suggests that growth in the length of observation claims has grown.

Overall, from 2006 to 2008, the average length of observation claim increased from 26 to 28 hours. However, growth in observation claims differed across the distribution of claim length. Claims of 48 hours or more increased over 70 percent. This rapid growth resulted in

the longest category of claims growing as a share of claims, also.

In 2006, claims of 48 hours or more accounted for 8 percent of all claims, and in 2008, they accounted for approximately 12 percent of all claims. Just in contrast, non-reimbursable claims, those one to seven hours in length, declined 2.5 percent during the same time period and declined to a level of 7 percent of all claims.

The conditions associated with observation claims are often cardiac-related and generally consistent from year to year. Chest pain accounted for, by far, the largest share of claims at 21 percent in 2008.

The next most common was heart disease at less than 5 percent. Among the 15 most common observation conditions, 7 were cardiac-related and 14 were also on the top 15 list in 2006. The fastest growing conditions were syncope, vertigo, and claims with unclassified condition codes. In contrast, the fastest growing conditions for claims 48 hours or more were non-cardiac pain-related conditions.

Before I explain our second finding, I'll give a little bit of background on the Medicare RAC program, so

we're kind of going back to the background here for a second.

Under the Medicare RAC program, CMS contracts with a set of auditors on a contingency fee basis to retrospectively detect and correct past over or under payments for any providers participating in the Medicare program. The RAC program began as a demonstration program limited to just a few states.

In March 2005, auditors began reviewing the claims of all providers in three states -- California, Florida, and New York. The demonstration was expanded to three other states in 2007 just before it ended, and then finally the program was expanded nationwide as a permanent program in 2010, January of 2010.

The demonstration ultimately recovered approximately $900 million and 85 percent of that was from inpatient hospitals. Some have hypothesized that Medicare's RAC program spurred hospitals to increase their use in observation care. The presence of the RAC demonstration in only a handful of states from '06 to '08, provided us with a natural experiment to test the RAC observation growth hypothesis.

Therefore, a comparison of observation utilization in hospitals in California, Florida, and New York versus hospitals in all other states should, therefore, allow us to identify the impact of the RAC demonstration.

Second finding. Overall, data from hospitals in the three RAC states suggest that the Medicare RAC program may have had a modest affect on observation growth between 2006 and 2008, but that there were other factors present. First, we found that hospitals in the three RAC states had consistently lower levels of observation utilization. The number of observation claims was consistently 11 to 12 claims per thousand beneficiaries lower than hospitals in RAC states -- I'm sorry -- at hospitals in RAC states than at hospitals in non-RAC states. And the same trend existed in the context of observation hours.

In light of the lower levels, the utilization of observation claims grew slightly more rapidly at hospitals in RAC states, increasing by eight claims per thousand beneficiaries versus seven claims per thousand beneficiaries in non-RAC states.

Just as we observed on the national level, growth in observation claims differed across the distribution of

claim length at both hospitals in RAC and non-RAC states, and claims of 48 hours or more grew most rapidly. Growth appeared faster at hospitals in RAC states as the number of claims increased 88 percent from 2006 to 2008, and that's just within the largest category, the 48-plus hours.

However, when comparing the growth rates of RAC and non-RAC states, it's important to recall that the growth rate of RAC states is based on lower levels of utilization. But the main point here is that these long claims grew rapidly nationally in both RAC and non-RAC states.

In addition, claims of 48 hours or more grew as a share of all observation claims in both RAC and non-RAC states, and they accounted for a somewhat larger share in RAC states. From '06 to '08, claims of 48 hours or more increased from 12 to 16 percent of all claims at hospitals in RAC states, growing 4 percentage points. In contrast, at hospitals in non-RAC states, claims of 48 hours or more increased 3 percentage points from 8 to 11 percent.

Adding to our finding that observation care increases were not limited to hospitals in RAC states, we observed that hospitals in these states were no more likely to have rapid growth in observation claims than other

hospitals. For example, the 706 hospitals in the three RAC states accounted for approximately 19 percent of all hospitals nationally. But in contrast, after ranking all U.S. hospitals by their growth rate in observation claims, we found that hospitals in the RAC states accounted for 20 percent of hospitals with the most rapid observation growth rates. Therefore, hospitals in RAC states did not appear to be driving growth nationally.

The story was slightly a bit different in the three RAC states because a disproportionate share of hospitals accounted for the majority of observation claims. So specifically within California, Florida, and New York collectively, approximately 30 percent of hospitals accounted for 55 percent of all observation claims in 2008, and 90 percent of the increase in the number of observation claims from 2006 to 2008.

Some have also hypothesized that the increase in observation claims resulted from a conscious effort by hospitals to reduce short inpatient stays. We observed evidence of this on the national level and to a slightly greater degree in RAC states. Nationally from 2006 to 2008, the number of one-day inpatient stays declined from

approximately 49 one-day inpatient stays per thousand beneficiaries to approximately 46 one-day stays. A similar decline occurred at hospitals in RAC states, except that in absolute terms, we observed the decline in one-day inpatient claims was approximately one claim greater per thousand beneficiaries in the RAC states.

In addition, statistical tests of the correlation between the change in the number of observation claims and the change in the number of one-day stays displayed a light to moderate correlation. This correlation was present on a national level and slightly stronger for hospitals in RAC states. Evidence suggests that observation growth is the result of a broader national trend in increased scrutiny of short stays and that Medicare's RAC program is not the only payer exerting pressure on providers to limit short inpatient stays. Anecdotal information suggests that private payers are also exerting pressure on hospitals to avoid short inpatient stays. In addition, all-payer hospital data displayed a comparable national growth rate in observation care from '06 to '08.

Looking at that all-payer data on a state level, we found that Medicare-specific observation growth rates was

not always higher than the all-payer observation growth rate. For example, in New York, the Medicare-specific observation growth rate was higher than the all-payer growth rate. And in California, the Medicare-specific growth rate was lower than the all-payer growth rate. This inconsistency existed across all the states and suggests that other payers or other factors beyond the RACs may be influencing observation growth.

A recent study in the American Journal of Medical Quality also suggests that efforts by both Medicare and private payers to more closely monitor short inpatient stays as the impetus to initiate a new hospital observation unit. In this case, the authors concluded that after six months, their new hospital observation unit had achieved its primary objective to decrease the number of unreimbursed admissions. This unit also increased the number of the hospital's observation claims by 72 percent in that six-month period, decreased the average length of inpatient stays, and decreased the number of facility-wide readmissions.

Finally, at a CMS-hosted forum on observation care in late August, hospital participants suggested that a variety of relatively recent regulatory changes made to

outpatient reimbursement policy and admission and observation criteria may have contributed to the growth in observation care.

In recent news reports, and also at CMS's forum, a number of cases were cited asserting that Medicare beneficiaries' financial liabilities have increased as a result of being served as observation patients. You've probably read one of these recently yourself, but the common theme of these stories is that beneficiaries end up being surprised with large bills for outpatient co-insurance or very large bills for SNF care that they thought Medicare would be covering.

As I described earlier, outpatient observation carries different liabilities for beneficiaries. Rather than paying the inpatient deductible of $1,000, beneficiaries pay outpatient co-insurance which may vary significantly depending on the scope of services, tests, or procedures provided to the beneficiary while they were in outpatient care.

The more likely source of greater liability for the beneficiary stems from their not qualifying for SNF coverage, because their time in observation does not count

towards the SNF three-day prior hospitalization rule. Anecdotally, it appears that beneficiary liability has increased as observation volume has increased.

However, a quantitative analysis of the complete outpatient out-of-pocket costs of observation patients would assist in our understanding the specific impact for beneficiaries.

In conclusion, we've observed a clear growth in observation care. This growth may partly reflect hospitals coping with greater public and private payer scrutiny of short inpatient stays. Hospitals may be attempting to reduce the financial risk of inpatient claim denials by choosing to treat certain Medicare beneficiaries as outpatient observation cases.

Although this trend does not appear to have a dramatic impact on the overall Medicare spending, there appears to be the potential for this trend to increase beneficiary liability in some instances involving SNF care.

We're very interested in gathering your ideas and opinions and we'd be happy to answer any questions.

MR. HACKBARTH: Thank you, Zach. Let's see. I think we're starting on this side this time, so Round 1

clarifying questions, Tom and then George, and Nancy and Herb.

DR. DEAN: Thank you. This is interesting because we do a lot of this. I'm curious. In the individual groups, is there much variation between individual hospitals?

In other words, I'm curious, if some of this is sort of a local approach to the decision-making because it's an area that's caused a lot of confusion for us as physicians as to what's covered and what's not covered, and every time I ask about it, I seem to get a different answer. And so, this is a model that we've resorted to, but I'm curious if it varies much from one medical community to another.

MR. GAUMER: We dove down a bit in the RAC states and looked at a subsample of about 225 hospitals and there was a significant degree of variation, I guess, for that top quartile of hospitals in those RAC states. But I haven't really looked beyond those three RAC states to dive down a lot more. But I guess I'd also reference that across states, on a state level, there seems to be some wide variation as well. So I would assume that probably yes.

MR. GEORGE MILLER: Also very good work and I certainly enjoyed reading the chapter. A couple of things that came out at me, and I'll just ask if you did any study. Is there a correlation between the same time period you did this study and the perceived increase in volume in ERs around the United States?

Do you know or did you look at that study and see if there's a correlation between increased volume and the increase in observation?

MR. GAUMER: I did not look at that increase, but we can look at it.

MR. GEORGE MILLER: Yeah, and this is just my own intuition that that may be a part of the problem, also. And then one of the challenges is what Tom just said. There's a different criteria for Medicaid observation status versus Medicare observation status, and that's some of the confusion. I know physicians always ask that. I'm trying to remember the diagnosis. You can put a patient in observation status for one thing, but can't do it for the other, and I'm sorry, I don't remember that.

But could you look at that, also, and see where that conflict may drive it?

And then finally, you mentioned in your paper about the denials. My sense is that denials may be a strong driver of this issue. Do you know the magnitude of denials over the last three years as well, both for Medicare and the private care -- private payers, I'm sorry.

MR. GAUMER: I can give you a very broad sense of what happened as a result of the RAC demonstration, but in terms of private side or private insurer denials, I don't have any sense of that. But I've got one slide about the RAC program, there were roughly a billion dollars in overpayments which are essentially denials, and 85 percent of that was for inpatient hospitals, and I think the majority of that $830 million we're looking at inpatient admission-type stuff. So I can get better information for you, but I think largely that's what we're looking at.

MR. GEORGE MILLER: Yeah, I'll come back in round 2.

MS. KANE: Yeah, I'm just trying to understand how the observation unit is accredited with a decrease in readmissions since they weren't admissions to begin with if they were observation units. So does that just mean that they didn't treat them well in the observation unit and then

they were discharged and then they came back in? That only counted as an admission rather than a readmission?

MR. GEORGE MILLER: No, they were an observation; then they became an admission.

MS. KANE: But, I mean, so how did you avoid the readmission? How do you get a --

DR. CHERNEW: [Off microphone].

MS. KANE: Yes, but how did you reduce the readmission? How would it reduce the readmission rate?

DR. CHERNEW: [Off microphone].

MS. KANE: Oh, so the second time around?

MR. GEORGE MILLER: Right, right.

MS. KANE: Okay.

MR. KUHN: Just a quick question. On Slide 6 when you look at the percent of change from '06 to '08, did the Medicare pricing change much during that same time frame as well?

MR. GAUMER: I'm going to look to Dan on this one. He's our outpatient expert.

DR. ZABINSKI: Let's see. There was a big change, I want to say, from '07 to '08 in just, I don't know, how the whole thing was defined. In '07, hospitals could get

specific separate payments for observation services. Had to meet a fair number of criteria, but they could. In '08, CMS essentially packaged all observation care. There's a special category with, say you have an ER visit along with some observation care, where there's a combined payment for the two.

And that resulted in a higher payment than what the observation care was the previous year, but it's a combined payment. It's a really different animal in '08 compared with '07 and earlier.

DR. BERENSON: I wanted to pursue what Mark was getting at earlier, which is for a typical observation day for chest pain, does the $720 cover the sort of hotel functions, the bed and the nurse, or does it also include the oxygen, the cardiac monitor, the IV access, all of that stuff? Or are they billed separately?

DR. ZABINSKI: Again, that really depends. It's going to include the nurse, any -- you know, if you have a separately paid -- you know, some drugs in the outpatient payment system are separately paid, some are not. If it's a separately paid drug that gets administered, that's going to add to the payment. If it's a packaged drug, that's not

separately paid. It depends what you're talking about. Like an MRI. If you get an MRI along with it, that's going to add to the cost. That's going to be separately paid.

DR. BERENSON: So do we know if, sort of, what the range of outpatient claims amounts are? I mean are we in fact paying lots to some hospitals for observation more than the pro rata share of what they would have gotten on an inpatient DRG? Do we know that?

MR. GAUMER: We did not do that as a part of this analysis, but as we were going along with our analysis we realized that we need to do this.

There is some work going on, on this. You know. I noted CMS is doing some work. I think they've contracted with a consultancy to get some of this done, and I think they're going to get at that. So if they can't get it, maybe we'll do it too and get back to you.

MR. ARMSTRONG: As a barely recovered hospital administrator, maybe still recovering, and someone who's looking at the health care system a little bit more broadly, I just would affirm we're seeing that this trend is happening, and I think it's a result of more than just Medicare policy.

Two questions, and I don't know that they're answerable, but building on what George had said. This analysis seems to bring to it a point of view that says observation use is an alternative to inpatient use, and I think it's possible it's actually an alternative to other uses of other parts of the ambulatory care system as well and that it could be a trend driven by lack of well managed outpatient care, lack of access to primary care, higher volumes of emergency room visits to begin with. I don't know for sure, but I just think it's a question that's worth asking about.

And then second, when I look at these trends, I think one question I would raise as to whether this is good or bad would be any information we'd have about the health or quality implications of being two to three days in an observation status unit versus two to three days in an inpatient bed. Infection rates or other information like that, I don't know if those are analyses that are even possible, but it's certainly a question that comes to my mind.

MR. GAUMER: We did a literature search to snoop around for some of that, and there really wasn't a lot out

there. So we're still looking, and hopefully someone will come out with something soon. So I'll have to get back to you on that as well.

MS. BEHROOZI: Just on the anecdotal reports of patients being surprised by SNF, SNF stays not being covered, I wonder if you have looked or if it's possible to look at on the impact on payable SNF claims by Medicare.

MR. GAUMER: No, not yet, but we want to do that as well. So I would love to get back to you on that.

MR. BUTLER: So two quick ones: One, I assume the people that are surprised on the 20 percent co-pay are those, as I referenced in the last session, that don't have, the 10 percent that don't have any supplemental, that are paying out-of-pocket. So it's probably a small percentage of the population that is actually paying that co-pay, right?

MR. GAUMER: I believe that's correct.

MR. BUTLER: Depending on the supplemental plan, but in general.

MR. GAUMER: Yes, I think that's true.

MR. BUTLER: The second thing is more technical. The big growth in the 48th hour and beyond, you know, I

thought there was some restriction even in being able to bill or being credited for anything beyond 48 hours that was somehow, that was fixed, and so part of this increase is not maybe a real increase but a documentation issue in what's going through the system. Is that true?

MR. GAUMER: There are two points, I think, to make in response to that. The language about the criteria of observation care, on that slide, I'll go back to it.

I was essentially -- the text I was speaking was essentially reading the policy that Medicare has on this, where it says the hospitals should not exceed, or only in exceptional circumstances should the observation exceed, 48 hours. So there's no hard, fast rule specifically.

But I've heard through the course of this that a lot of hospital billing systems are set up to truncate to 48 hours, and so when they submit a claim it comes in at 48 hours no matter what. It could have been 72 or 49; it comes in at 48.

So you see that in the claims data. You see a spike at 48, and that's why we decided to look at the trends in terms of 48 or greater -- because we think that a lot of the 48-hour claims are actually somewhat longer.

MR. BUTLER: Yes, I know that's what we were doing. Then there's no difference in the payment to us.

MR. GAUMER: Right.

MR. BUTLER: Except for additional ancillaries that would be ordered in those additional hours.

MR. HACKBARTH: Can I follow up on Peter's first question? So for the 20 percent co-insurance on the additional services, typically, most beneficiaries are going to have supplemental coverage of some form to help cover those. However, on the SNF care, so if they're deemed ineligible for SNF care because they didn't meet the three-day hospitalization requirement, that would not be typically covered by the supplemental coverage because it's an uncovered service.

MR. GAUMER: That is correct.

DR. MARK MILLER: And just on the point of how much you get paid, the way I understood it when we talked about it is if you're in less than eight hours you don't even get the observation payment.

MR. GAUMER: Right.

DR. MARK MILLER: If you're over eight hours you get the observation payment, the 720 or whatever it was, and

then nothing else, no matter how long, but you can bill for the ancillaries. And I think that's what you're saying, right?

MR. GAUMER: Yes. No, that's good.

DR. NAYLOR: So I really applaud the focus on observation days and on both the quality issues as well as the beneficiaries' liability issues. I think this is really important.

Can you comment on, and it probably was in this great report, but the percentage of people who are subsequently hospitalized following observations versus discharged and if you know anything about the differences -- you mentioned it in the report -- on staffing in observation units, although people can go throughout the hospitals, but versus the traditional inpatient?

MR. GAUMER: Okay. This is kind of a tricky data issue, so I'm going to try not to get too far into the weeds on it. But generally it can be hard to follow, the observation claim, into the inpatient side of the data world. Okay.

But luckily, looking at hospital cost reports, there is some good information there on the all-payer

universe. So we're looking at Medicare, private, everybody that's coming through the hospital, and generally on that level, across the nation, about 16 percent of all observation cases get admitted.

Just based upon my own opinion, I'm going to guess that it's comparable for Medicare. That's kind of what I've heard when I ask some experts what they've thought. But I would love to try and get some more detail from that inpatient data.

I just need more time to do it, so I'll try to do it.

DR. MARK MILLER: Anything on staffing?

MR. GAUMER: I'm sorry?

DR. MARK MILLER: The second question on staffing, differences in staffing.

MR. GAUMER: Ah, yes. The observation units, what I've read on the observation unit is that devoted staff, people that are devoted, they are physicians, hospitalists often and nursing staff that are devoted specifically to the observation unit, and that observation unit can exist in its own room or it can exist kind of in a virtual sense throughout the hospital.

Generalizing again, hospitals that don't have the observation units often will rely on the staff of the unit, the inpatient unit or even the ER, where the patient gets placed. So the admitting physician will be tracking that patient, and the staff devoted to that bed, wherever it may be, will be responsible for the hourly care or the monitoring.

MR. HACKBARTH: Any other clarifying questions?

DR. CASTELLANOS: On Page 14, you suggested the forum suggested regulatory changes that may have had an influence. What are those regulatory changes that were suggested?

MR. GAUMER: These are some of the things that Dan was referring to.

DR. CASTELLANOS: Okay.

MR. GAUMER: So policy changes in outpatient policy, and then at this forum folks were also citing changes to the observation criteria as well as the inpatient criteria.

And I think just to give you a taste for what was being said, I think in terms of the observation and inpatient criteria I think folks were saying that generally

these criteria were being made more difficult to interpret generally, whether that meant more strict, less strict, more difficult to interpret.

DR. CASTELLANOS: That heads off my next question. On Page 4, you mention that a lot of the providers are using guidelines from QIOs, trade associations and private consultants.

And I guess my question really is to what extent are the hospitals using this software, the black box, specifically maybe InterQUAL from McKesson?

MR. GAUMER: I've heard that roughly 80 or 85 percent of hospitals are using InterQUAL from McKesson. The articles I've read have not given much information about what's contained in that software, but that it's used pretty widely across the hospital industry.

You know at the same time hospitals are using other consultancies. It sounds like some choose to use the QIOs. It sounds like a lot of hospitals are coming up with their own admitting criteria, probably all. I don't really know, but there's a lot of evidence out there. Sorry. There are a lot of criteria out there to read that are written by QIOs, consultancies, hospitals, even physician

groups and such. So there's a lot of information out there, a lot of different ideas.

DR. CASTELLANOS: I'll follow up with that question in level two.

MR. GAUMER: Okay.

MR. HACKBARTH: Okay, round two. Oh, I'm sorry.

MS. UCCELLO: Just a quick question, 16 percent overall observation stays get admitted. Does that vary by the length of observation stay?

MR. GAUMER: I don't know the answer to that.

DR. CASTELLANOS: Round two.

DR. BORMAN: I think that clearly the use has gone up. I think this is extraordinarily difficult to dissect, and you guys have made a really great run at it. There are just a lot of moving parts that have gone on here, and I'm not sure that in the end we'll know the answer, and in the end I'm not sure we need to know the answer. I think maybe we need to understand sort of the pieces that have fed into it.

I personally believe one of the biggest nuggets here is disparate use of terminology or the same terms meaning different things. For example, observation services

provided by physicians, according to CPT definitions, are something that you would think marry up to a hospital, considering an event, an episode of care of a patient being an observation service, but that's not necessarily so at all. And that leads to enormous confusion.

And then, as the other practicing physicians at the table can attest to, you regularly get these calls about recoding your admission and doing different things in order to optimize performance for the hospital side, yet that may or may not be consistent with how you bill on the physician side for observation. So there's an enormous morass in here that I think would be very difficult to tease out.

I think the more important trends are it's going up. Are the things that we're moving into doing with this, are they safe? Are they appropriate? Do they bring value to the beneficiary?

Should we be doing something different? Is there a way that we want to do observation?

What is the value? Should there be more strictures around it?

As opposed to necessarily trying to drain a swamp here, that I think will be very difficult. For example, if

you extend this out to 48 hours, you can start to get a lot of operations that may or may not be appropriate performed on a totally ambulatory basis because now you've basically converted it into a 36-hour admission.

So I think there are just a lot of things here. We need to ask ourselves what is our purpose in looking at this. And if it's to dig into the details, we have a wonderful analytic staff. I have no doubt they can do it. If they can't, nobody else can.

But if the object is to say is there something here about policy, are we incenting the right things, then maybe we need to frame our questions more clearly to that end.

MR. HACKBARTH: Good point and good question, so let me ask Mark to respond to that.

As I recall, the genesis of this was that I think George and Peter, maybe Herb, had raised the question about what's going on with observation days and a lot of people had associated it with the RAC program.

So initially, I think we were just trying to respond to that Commission request: What do the data indicate?

But now you've framed sort of the next question. Okay, we've begun some data analysis. What's the end point on this? Where are we ultimately headed with this conversation?

DR. MARK MILLER: And that's exactly right in terms of it, and I think this is not unusual for us, to kind of muck around a bit in the data and try and see if there's something here.

For myself, I think it's relatively clear that there is at least one beneficiary angle that has come out of this, and maybe more, but certainly one.

On the payment side, I mean, and this is a long way around of I'm not sure. On the payment side, there's at least two more pieces of information that I want before I start to think of is there a payment policy objective here. One is I want to see what the other billings are going on around the observation stay. If I can't do that, then I'm a little unsure what I'm to do.

And I'm also kind of curious about how many of these do turn into the inpatient setting. I know we have a general number, but I'm curious about that. So we are obviously mucking around with the data.

The exact next step for policy and payment are unclear to me, and I have a couple ideas and a couple things I want to see. On the bene side, I think there are at least a couple things that we may have things to say about.

DR. BORMAN: I personally think the beneficiary side is the clear thing out of what you've shown us so far, where we need to be deeply interested in that piece I think, and then the point of is there a bundle of services around here that's not being captured as a bundle and that would be appropriately captured as a bundle. Those are the two things that I think potentially jump out.

And then maybe is there a safety/quality issue here that we may not be equipped to speak to necessarily, but we may at least uncover and ask someone else to take it forward.

MR. HACKBARTH: Let me just pick up on the beneficiary aspect of this and invite people to react during a round two. It doesn't seem right to me to hold the beneficiary responsible and potentially have them handed the entire bill for a SNF stay after they've been three days in an observation unit. If they are three days in the hospital, whether it's classified for payment purposes as an

inpatient stay or as an observation stay seems to me ought to be irrelevant for whether the beneficiary is covered for an ensuing SNF stay. To leave them holding the bag just doesn't seem right. So I invite anybody to explain why that's wrong-headed.

Let's see. So, Tom.

DR. DEAN: I would, first of all, just certainly reinforce what Karen just said about the confusion that surrounds this whole issue. It's a constant source of confusion for us.

In response to Peter's question, I think there are some things that are not paid for by supplement policies, even for those people who have them. The one that we get the most flack about is drugs -- that as I understand it, when a patient is admitted for observation, they can bring their own medications and they can supply their own medications, except the problem is they'll bring in a bottle with half a dozen different kinds of pills in it and there is simply no way that the hospital staff can verify what those are. So they use hospital supplies, and then they get billed at hospital charges. You know the $5 aspirin and all that sort of stuff.

And I don't know. I hadn't encountered this before, but I suspect that maybe supplement policies don't cover that, if there is a rule that they could bring their own. I'm guessing because I know it has come up quite a bit, and people will object to the idea of their being admitted to observation for things like that. I suspect it may cover for other things, at least I'd say that's the one that we've gotten the most objections about.

The three-day stay issue, I guess it's hard for me to comprehend. That comes up also a lot in our situation, and we watch it very carefully, that I can't believe that a hospital staff would try to admit somebody to skilled care after three days of observation. Maybe they do, but I know that that's sort of a very basic requirement although, to get more basic about it, there's a lot of question about that requirement in general. But that's beyond the scope of our discussion.

And I guess finally, and this might be off the topic a little bit, but I'm wondering about the other regulatory things. We went through a big turmoil this last year about the physician supervision issue, and I don't know whether that has come up in your discussion or not. That

was where CMS said that for a patient that was admitted for observation for a wide variety of services, including simple IV therapy if I admitted somebody that was dehydrated, the physician had to be in the hospital all the time they were receiving that service or else it would not be paid for. It created a great stir, and finally CMS backed off on that requirement.

My understanding was that they were seriously looking at reinstituting that, and it was completely illogical because if I had admitted that patient there was not a problem. Yet, in our situation at least, it's the same staff, the same beds, same nurses, everything. But if they were on observation, the nurses were not allowed to supervise; you had to have a physician there. On the other hand, if they were on observation, the physician had to be there, completely nonsense.

And finally, CMS backed off because they got this huge pushback, but my understanding is that they're still contemplating applying that requirement. I don't know. Do you guys?

DR. ZABINSKI: On this most recent outpatient rule, they've sort of made clear that I think they're going

to do what you said they decided to do, sort of back off on it, the requirement that the physician be there all the time. At the beginning, if I recall, it's like at the beginning the physician has to be there just at the start of it. Then after that staff can handle it.

DR. DEAN: I just wondered if that was part of CMS pushback to try to stem this trend. I don't know. I mean it's not a logical response.

MR. HACKBARTH: Are we able to determine how frequently patients go to SNF care after observation care?

DR. ZABINSKI: I haven't been a part of doing that yet, but my basic understanding is that we can link those two things. So I'm hopeful.

DR. BAICKER: I think this is a really interesting fact pattern, strongly suggesting that is a case where the financial incentives are changing labeling in a way that doesn't map to real changes in care, and I'd be very interested to see more drilling down on the scenarios in which it most affects provider reimbursement and the scenarios in which it most affects beneficiary out-of-pocket liability, and how those correlate. So you could look at observation care after an initial admission versus not after

an initial admission, to get a the readmission incentive and map the specific provider incentives for that observation care to how much of the cost is then really getting displaced onto patients who are then paying for skilled nursing facility care that they wouldn't have to otherwise.

I'm sure there are lots of other cases, but it's much more frequently that the incentives are more aligned. This seems like a direct displacement that we don't see that often and that we should be particularly concerned about the financial incentives it creates for the providers.

MR. GEORGE MILLER: Yes, I was going to say something similar.

And I agree with you, Glenn, that in this particular issue, for the beneficiaries who come to a hospital but may be in observation status, they really don't know that. They're there in the hospital to be cared for. They should not suffer financially because of that quirk. From a policy standpoint, we could fix this.

So, of the conclusions, I would strongly suggest that we come up with something that would deal with this issue very specifically while we look at all the other issues that have been raised around the table. But this is

something from my perspective, from a policy standpoint, we should be able to fix relatively easily and very quickly because it is unfair. It's just absolutely unfair.

MS. HANSEN: I can only concur with what's been already said.

I guess I do have one question that intrigues me. That is if in fact, now with this 30-day readmission kind of under the bright lights, how much this will possibly change over time because people, systems will not want this on their record to be a real, true readmission, but an interim stabilization opportunity and have this be reimbursed at least at this level, again with the punitive potential issues onto the beneficiary. But just as a point of notation, since 2008, we now have the 30-day readmission component side of it. So I wondered if that's something just to be attuned to as a workaround. You know. Not to get reported in that way. So that's something, that light should be shone on this early just so that it doesn't become a mechanism to deal with this differently. Yes, yes.

MR. GAUMER: Okay. That sounds good.

Mark, do you want to say more about the readmissions? I don't know.

Okay. I thought you were looking at me.

MR. HACKBARTH: Well, you would think that all other things being equal, with a focus on readmissions and the link and payment to readmissions that this would become more of an issue in the future, rather than less.

MR. GAUMER: Yes.

MS. HANSEN: Just, I said that I also concurred with the policy discussion changes on behalf of the beneficiary. I wonder if even some interim kinds of things, so that people upon admission are just notified formally that this is the case because what happens with some people who are quite ill and perhaps need the SNF a little bit later. I mean they are the ones who are most surprised. If there is any kind of way to kind of let people know this is going to be one of their responsibilities until we get the policy fixed.

MR. HACKBARTH: Let's see. Anybody else on this side?

MR. ARMSTRONG: Just briefly, I want to concur with many of the recommendations made.

Just one additional point would be, and this perhaps comes because I'm new to the Commission, but it

seems as if what we're observing is a system. Different interventions create different kinds of results, and we can't always predict what they are. I mean the volume of in-the-office provider ancillaries, they're kind of all over the place. And it feels a little like whack-a-mole where you knock it down one place, then it pops up somewhere else, but it's always moving around.

Anyway, it's just provocative to me to imagine how we pay attention to how the whole system is working and every once in a while just check in on are we seeing blips that we either predicted or didn't predict because of some of the policy changes that we've made in the past, rather than responding, staying kind of a step ahead or at least co-equal with some of those changes.

MR. BUTLER: Okay, a couple of comments. Is it a quick technical fix to say if you stay longer than 72 hours that's the same as a 3-day stay and therefore you qualify for the 3-day stay? That would be another way for the SNF. That would be a very simple technical fix.

DR. MARK MILLER: Well again -- and I'm not proposing this. I mean you could also just say that observation days count, whether it's one or two.

MR. BUTLER: Right.

DR. MARK MILLER: I mean you're sort of saying if three occur, then they count.

MR. BUTLER: Or if you had one day on observation and two days as an inpatient, yes.

DR. MARK MILLER: Right. I mean those are the kinds of things, yes.

MR. BUTLER: Right, because I think that probably is the biggest liability. But, okay.

So more general comments, we haven't really said it that clearly, but the difference between being an inpatient and an outpatient is going to really get blurred here rapidly. We have some cases, for example, that we do as an outpatient that we're required to bill as an inpatient. There's no outpatient code.

Now you want to save some money? You know, force it into? We have joint replacements that go out the same day. We have to bill them as inpatients. They don't ever get in a bed. Figure that one out.

So this blurring is tricky, and it's going to only get trickier I think.

Second is --

MR. HACKBARTH: On that example, Peter, it's because joint replacement isn't on the list.

MR. BUTLER: Right, it's not an outpatient billable code. So go figure, right?

Okay. You talk about your lowest cost alternative, and I give you an idea.

Okay. So where was I?

I think in general the hospitals, first of all, are not doing observation days in any way for positive financial results. They don't look at these things and say these are profitable. They're avoiding not getting paid on the inpatient side.

And I think the difference between RAC and non-RAC is we're all getting ready for RAC whether it's there or not. We're all getting ready for readmissions, whether there or not. We all have confusing admission criteria that are being deployed, and it's across all payers.

So I think those collective things are saying we better err on the side of making these observations, which in general I'm told, as we look at our data, are actually more expensive. Unlike what you speculated in the paper, it's actually more expensive, especially if it's on the

unit. You have to be more attentive to the vitals and the checking-up than you would if they were inpatient. So it's not like a cheaper first day if you have it an observation. So that's just one thought.

And then the last, maybe more important one is here we're building, going to open a new facility with a huge ER that has 60 rooms in part because we see medicine moving towards the emergency room in order to manage these very things. We will have observation rooms, so that we think as a congestive heart failure comes in or as a chest pain comes in we have both the ancillaries and the staff to handle it as the continuum care much better there than having the elderly go in a unit, get disoriented, stay several days and come out worse than when they came in.

So as I think Scott was pointing out, I think it's an important part of the continuum. In general, these are good things if done in the right way, but certainly they shouldn't be -- the beneficiary can't be liable as a result.

DR. CHERNEW: I only wanted to say that while I agree that this issue about beneficiary liability is an important one and seems quite unfair we have had discussions about churning from nursing homes, where people are going

into the inpatient stay when they shouldn't. So a solution that just makes the observation qualify them for a higher SNF payment may not be one we want to jump on until we know more of exactly what's going on and how to deal with other types of issues around the broad spectrum of caring for certain types of patients.

DR. CASTELLANOS: I want to get back to that black box thing. You know, it bothers me because what that black box is doing, or the InterQUAL is doing, is making admission based on financial considerations. CMS is asking me as an admitting physician to consider the medical predictability of some adverse thing happening, the severity of the symptoms, et cetera, but yet the black box which is used by, what, 85 to 90 percent of the hospitals is predominantly making these decisions.

As Karen very eloquently said, even if I admit the patient, I get something from the hospital saying we want you to change the status. And sometimes they change the status, and it's another clarification without my notification. They get one of the hospitalists or another doctor, even though I'm the admitting doctor, to change the status. So that bothers me quite a bit.

The second issue is the beneficiary side and Tom is absolutely correct. This three-day admit doesn't make any sense. And we heard this morning that some of the MA programs don't require that and directly put the patient into a SNF if he or she requires SNF. To me, I don't know where you get that three-day decision.

I've had patients, and I can give you clinical issues -- an 84-year-old frail lady, no family, no nothing, with a fractured pelvis, and that's all she had. She had a little blood in the urine, and that's how I got involved. Yet, she couldn't go home. She has a fractured pelvis. She went to a SNF for eight weeks and had thousands and thousands of dollars a bill, and it's just not fair.

The last thing is something I was reading on this, and I'm just asking you if you could look into it -- the Oregon health plan policy. They don't ask the hospitals to make a level on care determination, but instead the Oregon health policy pays hospitals for outpatient services if less than 24 hours and pays inpatient rates for anything above 24 hours.

I'm just wondering. I don't know anything about the Oregon health plan. But if they can do it and have good

statistics and good results, it's maybe something we should look into.

DR. MARK MILLER: Ron, on your first point, I wasn't quite sure what, on the InterQUAL.

DR. CASTELLANOS: Yes.

DR. MARK MILLER: What was the complaint?

DR. CASTELLANOS: I guess my problem is it's a black box making the determinations, and at one time -- I'll level it.

At one time, I think Medicaid didn't use this. They didn't allow these types of softwares to make these decisions. They do it now.

And I know when we talked --

DR. MARK MILLER: See, Ron, this is why I wanted -- I'm not sure this is a Medicare policy. That's what kind of threw me when you made it.

DR. CASTELLANOS: Well, it's not a Medicare policy now, but it was now, and now it's been reversed. And we talked a little bit about this when we talked about the groupers last year.

I guess what I'm saying, Mark, is that these determinations are predominantly dictated and done perhaps

with physician concurrence, but without looking at some of the clinical indication that I think are very important.

MR. KUHN: One of the areas that could be looked at here, that might be worth checking out, is that when there is ultimately a denial and then they have to go through this extensive appeal process, then these kinds of tools, these decision support tools you're talking about, Ron, come into play here.

Maybe one of the ways we can get a better understanding of this as we come back to this issue is have MedPAC staff talk to some of the Medicare Administrative Contractors, the MAC Medical Directors, because they deal with this issue day-in and day-out.

They're out there advising providers and probably one of the best sources of information we could probably get on this. So that might be the place to delve into what you're talking about there.

DR. CASTELLANOS: Thank you.

MR. HACKBARTH: And the 3-day requirement, 3-day hospitalization requirement for SNF eligibility, boy, that's been around as long as I can remember, going at least back into the early eighties, late seventies, if not before. And

I don't know who thought that was a good idea and what the rationale was.

MR. BUTLER: I think it goes right back to the beginning.

DR. BERENSON: To try to prevent it from being a long-term care benefit, yes.

DR. STUART: It's worth noting that that was repealed by the Medicare Catastrophic Coverage Act, and there was a period of time when non-hospital-related SNF care was covered. So there is some and there has been some research around that. So if that's something that you wanted to bring back, there is a small literature about that.

DR. CASTELLANOS: There was discussion this morning that the MA programs, some of them don't require that. So that policy is in effect today by some MA programs.

DR. MARK MILLER: Right, but also those programs often have prior auth and that type of thing, can have limitations on benefits as well.

DR. CASTELLANOS: I just think it's something that's been around for a long, long, long time, to me

doesn't make sense from a clinician viewpoint and may be something we should look at.

DR. BERENSON: If I could just add, the listening meeting on ACOs that I went to, there was some discussion that ACOs might be able to waive the three-day stay just like an MA plan. If there's an integrated group doing active management, perhaps that's something they would want to do.

MS. HANSEN: And just to point out that the PACE projects don't have that limitation either. So it seems like there are all different little pockets around it.

MR. HACKBARTH: Yes. Okay. We are at the end of today. All that remains is -- and thank you, Zach and Dan, well done.

All that remains is the public comment period, and let me briefly remind you of the ground rules for the public comment period. Please limit your comments to no more than two minutes. When you see this red light come back on, that will signify that your two minutes are up. And please begin by introducing yourself and the organization that you represent.

MS. TOMAR: Is this on?

MR. HACKBARTH: Yes.

MS. TOMAR: I'm Barbara Tomar. I'm with the College of Emergency Physicians, and I'd just like to make a couple of comments about observation and the discussion we just had.

First, I think one of the drivers for the increase in observation use happened when the Medicare outpatient program switched from a limitation of only three conditions and diagnoses that were eligible for Medicare payment for observation to an unlimited number. That happened in 2008. So that was one area where utilization started to go up.

Secondly, I really want to make sure that you understand there's a real differentiation between the dedicated observation units and then people who are in observation status on inpatient floors. A lot of our members who are emergency physicians also run an observation unit, and it's also staffed by the emergency department, nurses and other clinical and ancillary staff. And there are a lot of rules in Medicare under observation about what you have to do and the timing. The average length of stay in those units is 15 hours, and only 1 percent of patients in some of the studies that have been published have ever

stayed more than 48 hours. So I just think that's important. There are really two distinct types of units.

The other thing I just wanted to mention was with regard to the three-day stay rule. We have long been on the public record as wanting to support counting time in observations toward the three-day stay. That rule is in the original Medicare law from 1965, and I think probably some of you are aware that there was a challenge to that in the courts. It winded its way up to the federal district court, and in 2008 they denied the plaintiff's request to count observation. But it is something that could be done administratively. Thank you.

MR. LINDE: Keith Linde, AARP.

I just wanted to drive home the point that was made over here a little earlier about the drug costs in the outpatient setting. Part B, as you know, only covers non-self-administered drugs. If you have Part D, it doesn't work so well, and even though you have Medigap the Medigap doesn't cover Part D drugs. If you have Part D, you have to go through your pharmacy. The Part D providers don't cover it. So it's a problem even if you have supplemental coverage.

Admittedly, the SNF denial as non-coverage is a much bigger financial liability issue than the drugs. But those $5 aspirins in the outpatient setting can really balloon and snowball, and it's something that would affect all observation stays, not just the ones that go to SNFs. We've been getting letters, complaints from our members about this issue. They're concerned about it.

Thank you.

MS. MCELRATH: Sharon McElrath of the AMA.

In terms of the black box I think one of the things that changed, that's also relevant, is that CMS did have a rule, going back to they had some edits that were also from McKesson called the Cox (phonetic) edits that said they weren't going to use the black box edits. They were going to use CCI edits which are ones that are vetted within the physician community before they take effect.

What happened with this, as I understand it, was that CMS sent out something to the QIOs who were doing medical review in the hospitals and saying, well, now you can use the commercial software. So first the QIOs were using it. Well, the QIOs at least had a rule that said before you deny something it has to be reviewed by a

physician of the same specialty. So maybe there weren't so many problems that people were seeing then.

Well then CMS transferred that function to the contractors. So it predates the RACs.

And as people have said, it's the whole thing of you know you're going to reviewed, you're going to get denied. So facing that and knowing that those people were all using InterQUAL then, and InterQUAL made it much easier for the hospitals then to use them. So one of the reasons that the hospitals all took up the InterQUAL, as we understand it, is because that's what the other people were using, because Medicare changed its policy regarding commercial software.

MR. HACKBARTH: Okay, we are adjourned for today and reconvene at 9:00 a.m. tomorrow.

[Whereupon, at 5:23 p.m., the meeting was recessed, to reconvene at 9:00 a.m., Tuesday, September 14, 2010.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Tuesday, September 14, 2010
9:00 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, JD, Chair
ROBERT BERENSON, MD, FACP, Vice Chair
SCOTT ARMSTRONG, MBA
KATHERINE BAICKER, PhD
MITRA BEHROOZI, JD
KAREN R. BORMAN, MD
PETER W. BUTLER, MHSA
RONALD D. CASTELLANOS, MD
MICHAEL CHERNEW, PhD
THOMAS M. DEAN, MD
JENNIE CHIN HANSEN, RN, MSN, FAAN
NANCY M. KANE, DBA
HERB B. KUHN
GEORGE N. MILLER, JR., MHSA
MARY NAYLOR, PhD, RN, FAAN
BRUCE STUART, PhD
CORI UCCELLO, FSA, MAAA, MPP

AGENDA PAGE

P R O C E E D I N G S [9:00 a.m.]

MR. HACKBARTH: Okay. Let's get started. It is time for us to begin. Good morning.

So our first session this morning is on addressing the growth in ancillary services in physician offices. Ariel?

MR. WINTER: Good morning. I want to begin by thanking Dan Zabinski and Kevin Hayes for their help with this presentation.

In this year's June report, we discuss the in-office ancillary services exception to the Stark Law, the growth of ancillary services in physicians' offices, and potential strategies to address this growth. We do not make any recommendations in this report.

In today's session, we will start off by presenting some data comparing the growth of ancillary services in physicians' offices with the growth in hospital outpatient departments. This analysis was requested by some Commissioners. We will also briefly review the policy options we described in the June report and assess whether you are interested in developing any of these into recommendations for a future report.

We've included background material in your paper, but I'm going to briefly highlight some key points. First, the physician self-referral law, also known the Stark Law, prohibits physicians from referring Medicare or Medicaid patients for certain designated health services to a provider with which the physician has a financial relationship.

However, the law generally allows physicians to provide most of these services, such as lab tests, imaging, physical therapy, and radiation therapy in their offices, and this is known as the in-office ancillary services exception.

This slide highlights some of the key potential benefits and concerns about physicians performing ancillary services in their offices. Proponents point out that the exception enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit. This could improve patient convenience, their adherence to treatment recommendations, as well as coordination of care. And there's also an argument that this expands access to care.

However, additional capacity for services like

imaging could lead to a higher volume. In addition, physicians who invest in equipment for their offices have a financial incentive to order additional services and several studies, including work done by the Commission, provide evidence of a relationship between self-referral and higher volume.

Over the last several years, there's been an increase in imaging, lab tests, physical therapy, and radiation therapy provided in physicians' offices. As described in the June report, ancillaries, particularly diagnostic imaging, account for a significant share of Part B revenue for several specialties.

In a proposed rule issued in 2007, CMS asked for comment on whether certain ancillary services should no longer qualify for the in-office exception such as services that are not needed at the time of an office visit to help physicians with diagnosis or treatment. To date, CMS has not taken further action on this.

Some Commissioners have asked us to compare trends in the growth of ancillary services and hospital outpatient departments with the growth under the physician fee-schedule, and the next few slides present these results.

This table shows the average annual change in the number of services per fee-for-service beneficiary from 2003 to 2008. The bottom line is that for all three categories we examined, diagnostic imaging, outpatient therapy, and radiation therapy, the number of services has grown faster in physician fee-schedule settings than in outpatient departments and other settings.

I want to point out that outpatient therapy includes physical therapy, occupational therapy, and speech/language pathology services.

Although not shown on this slide, the average annual payments for diagnostic imaging have actually grown faster in outpatient departments than in physician fee-schedule settings. And this runs counter to the trend we've seen for growth in the number of imaging services.

The reason for this is that physician fee-schedule payments for imaging fell by about 12 percent in 2007, due in large part to a provision in the Deficit Reduction Act that capped fee-schedule rates for the technical component of imaging studies at the level of the outpatient rate. This provision primarily affected MRI and CT codes. During 2008, physician fee-schedule payments for imaging began

growing again.

This chart shows cumulative growth in the number of imaging services per beneficiary for outpatient departments and physician fee-schedule services from 2003 through 2008. And the hospital outpatient services are indicated by the green line and fee-schedule services by the red line.

The first point to highlight is the steep reduction in the number of imaging services in outpatient departments in 2008, which was primarily due to a policy change that packaged many outpatient department imaging services with their related procedures. In other words, some imaging services were no longer paid separately from their associated procedures.

The second point is that even though physician fee-schedule payments for imaging fell by about 12 percent during 2007, the number of services continued growing during this year.

The third point is that the DRA payment reductions to fee-schedule imaging payments have sparked concerns that CT and MRI studies will migrate from physicians' offices to outpatient departments. In fact, from 2007 to 2008, the

number of CT studies grew faster in physician fee-schedule settings than in outpatient departments, and the number of MRI scans grew at comparable rates in both settings. These data are not on the chart.

Another concern is that the trend of hospitals purchasing physician practices has led to an increase in the number of imaging studies referred to hospitals by physicians. Unfortunately, we are unable to test this hypothesis because we are not able to identify if physicians are employed by hospitals using Medicare claims data.

This chart compares the cumulative growth of MRI and CT services to all physician services. It differs in a couple of ways from the prior chart. First, it focuses exclusively on physician fee-schedule services, whereas the prior chart included both fee-schedule and outpatient department services.

Second, it measures changes in both the number and intensity or complexity of services. The prior chart only showed changes in the number of services. And it shows growth in 2009 based on an AMA analysis that was presented at the April RUC meeting. We've added the AMA numbers here to give you a sense of how things have changed in 2009.

There are a couple of differences I want to point out between our numbers and the AMA numbers. The AMA uses a file from CMS with about 90 percent of physician claims from 2009. For our analyses we used files from CMS with 100 percent of claims and we will get the 2009 file in about a month or so. So we haven't yet done our own analysis of 2009 claims. And second, AMA uses a different method than we do to calculate changes in the intensity of services.

The chart shows the rapid increase in MRI and CT scans from 2003 to 2006, following by a deceleration in the rate of growth since then. According to our analysis, MRI and CT services grew by 2 percent in 2008 versus 3.6 percent growth in all physician services. The AMA numbers for 2009 are very similar.

It's important to point out that although growth in MRI and CT has slowed down in recent years, these slower growth rates were preceded by several years of rapid growth, and over time, the volume of physician services has shifted from evaluation and management and other services towards imaging. There are reasons to be concerned that some of this increased use of imaging may not be appropriate.

This slide lists the options that we described in

the June report to address concerns about the growth of in-office ancillary services, and for the sake of the presentation, we've separated radiation therapy and outpatient therapy from diagnostic tests.

These strategies could be considered individually or in combination and each one has strengths and weaknesses. Before we delve into these options, it's important to point out that physician self-referral creates incentives to increase volume under Medicare's current fee-for-service payment system which rewards higher volume.

Under a different model, however, in which providers received a fixed payment for a group of beneficiaries or for an episode of care, they would not be able to generate additional revenue by ordering more services. Therefore, the preferred long-term approach to addressing self-referral is to develop payment systems that reward providers for constraining volume growth while improving quality.

But because it will take several years to establish new payment models and delivery systems, you may want to consider interim approaches to addressing self-referral.

Improving payment accuracy is another strategy for addressing the growth of self-referral, but because there is separate work going on in this area, we have not listed it separately on this slide.

Before and after the publication of the June report, we met with several provider groups to learn about their perspectives on this topic and to solicit their input on policy approaches. We've also received letters from many organizations, and many of these groups are noted on this slide. Most of the groups raised significant objections to the options that we discussed in the June report. However, some organizations have supported tighter limits on self-referral, namely groups representing physical therapists, radiologists, radiation oncologists, pathologists, and clinical labs.

The first approach we described in the June report was to exclude outpatient therapy and radiation therapy from the in-office exception. And this was based on the rationale that physician investment in these services may influence clinical decisions about the treatment of patients.

In addition, therapeutic services are generally

not ancillary to an office visit because they involve multiple sessions and are rarely initiated on the same day as a visit. However, this change would limit clinically integrated groups that treat a wide variety of cancers using a range of modalities, including radiation therapy and chemotherapy.

For example, a medical oncologist would no longer be able to refer patients to a radiation oncologist who is in the same group for radiation therapy. Therefore, we developed another option that would limit the in-office ancillary exception to physician practices that are clinically integrated.

What we're trying to do here is balance the risks of higher volume associated with self-referral with the potential benefits of a clinically-integrated practice which is comprehensive and coordinated care.

A key issue would be how to define clinical integration, and here we propose two possible criteria. The first one, which was described in the June report, would require that each physician in the group provide a substantial share of his or her services, such as 90 percent, through the group. The goal of this rule is to

increase the likelihood that the physicians in the practice interact with each other frequently, share information about patients, and follow the same clinical pathways.

Currently, groups can contract with or employ specialists on a part-time basis to perform and supervise ancillary services. For example, a group can contract with a radiologist one or two days a week to supervise or perform -- supervise and interpret imaging studies. Such arrangements would no longer be permitted under this requirement.

The second potential criteria, which we've developed since the June report, would require the group to have Electronic health record technology and to use it for specific functions such as tracking patients with certain conditions, using clinical decision support tools, transmitting information across settings, and using computerized order entry.

The required EHR functions could be based on the meaningful use criteria that physicians must meet in order to receive an incentive payment for adopting EHRs. The goal of this criterion is to increase quality of care, improved care coordination, and reduce the necessary use of services.

We do recognize that this would be a fairly high bar for many groups to meet. However, physician groups that met both of these criteria would be well-positioned to participate in ACOs and to receive bundled payments.

An important question under this approach is whether a clinical integration requirement should apply only to therapeutic services or should it also be applied to diagnostic tests. On the one hand, requiring practices that provide any type of ancillary service in their offices to meet these tests of clinical integration could improve care coordination, quality, and adherence to clinical guidelines.

On the other hand, many small groups that provide imaging or clinical lab tests in their offices may find it difficult to meet these standards.

Finally, it's important to point out that even clinically-integrated groups have an incentive to drive up volume under the current fee-for-service payment structure. So eventually, the payment systems would need to be changed to hold providers accountable for costs and quality.

The next three options focus specifically on diagnostic tests. Under the approach on this slide, tests that are not usually provided on the same day as an office

visit would be excluded from the in-office exception. One of the primary justifications for the exception is that it enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit.

For our June report, we found wide variation in how frequently different types of tests are furnished on the same day as an office visit. For example, the rate at which imaging services are provided on the same day as a visit range from about 50 percent for standard imaging, like plain X-rays, to 26 percent for ultrasound to 10 percent for advanced imaging.

Under this approach, CMS would calculate the percent of the time that each type of test was performed on the same day as a visit, and then set a threshold for how frequently tests would need to be provided on the same day in order to qualify for the exception. For example, the threshold could be 50 percent. Tests that fall below the threshold would not be covered by the exception and therefore, physicians would no longer be able to order and perform these tests in their offices. CMS could rebase this threshold every few years to account for changes in technology and practice.

The next strategy is to reduce payment rates for tests that are performed by self-referring physicians. Studies by the Commission and other researchers have found that physicians who furnish imaging services in their offices refer patients for more imaging than other physicians.

In addition, research by OIG has found that patients of physicians who own clinical labs received more lab tests than all Medicare beneficiaries, on average. The objective of this approach is to recapture some of the additional Medicare spending that is associated with self-referral of diagnostic tests.

A key question would be how to determine the size of the payment reduction. This could be based on empirical estimates of the effect of self-referral on volume, or taking into account activities that are duplicated when tests are ordered and performed by the same physician, or it could be based on the normative standard based on a policy judgment.

Under the approach on this slide, Medicare would require some physicians who both order and perform advanced imaging studies to participate in a prior authorization

program. The focus would be on self-referring physicians who order many more advanced imaging services for a given condition than their peers.

Many private plans have been using prior authorization programs to control the growth of high-cost imaging and to ensure its appropriate use. These programs are based on appropriateness criteria developed by specialty societies, literature reviews, and clinician panels. The main benefit of this approach is that it would target inappropriate use rather than prohibiting self-referral, but this proposal does raise multiple concerns and questions. For example, the administrative costs of running such a program could be quite high, and there would also be administrative burdens on physicians who participate.

There are also questions about whether the guidelines that these programs use are based on sound evidence. And there's also a lack of independent evidence that these programs have a long-term impact on spending.

The strategy on this slide relies on changing the payment system by combining multiple services into larger units of payment, a concept known as packaging or bundling. Packaging refers to combining a primary independent service

with its associated ancillary services into a single payment unit, and it generally refers to services provided during a single encounter by a single provider. Under bundling, services provided during multiple encounters are combined into a single payment.

Either approach could create incentives to use ancillary services more efficiently. However, there would need to be a great deal of analytic work to identify and price cohesive bundles of services and to address situations in which multiple providers furnish services within a bundle. So this probably represents a longer-term policy direction.

This slide illustrates one potential path for combining multiple strategies. Congress or CMS could exclude a set of services from the in-office ancillary exception unless a physician group met criteria for clinical integration, or the group is part of an accountable care organization, or the services provided were part of a bundled payment which creates incentives for efficiency.

So to sum up, we've described several options to address concerns related to the growth of in-office ancillary services. We'd like to get your feedback on

whether you'd like us to develop any of these strategies into future recommendations. And, of course, we'd be happy to take any questions.

MR. HACKBARTH: Okay, thank you. Let's begin with our Round 1 clarifying questions. I see hands on this side.

MS. UCCELLO: In terms of the same day or the non-same day imaging tests, you alluded to this. Are there access problems that that helps address? Like, are there long waiting times at stand-alone facilities or this helps people get around or not?

MR. WINTER: Are you referring to limiting the exception so that physician groups can no longer perform certain tests --

MS. UCCELLO: Just currently --

MR. WINTER: -- or are you referring to the general environment?

MS. UCCELLO: Yes.

MR. WINTER: Okay. We have not -- I'm not aware of access concerns with regards to imaging generally. There have been some studies about mammography specifically by GAO which have not found widespread access problems. They found some sort of localized issues in rural areas. I'm not aware

of evidence that there are access problems in regards to advanced imaging like nuclear medicine, MRI, CT, or ultrasound, but we can look at the literature again and see what that shows.

DR. CASTELLANOS: Good presentation. Really appreciate it. I'm going to clarify, a little bit more clarified. I think we need to do something to control utilization. There's just no question. My point on Slide 7, maybe you could go to it, is that I think we've already done some under the various issues on imaging.

Now, I agree, your slide shows this, but there's some other data that shows that all imaging, not just MRI and CT, has definitely decreased down 2 percent last year to 3.3 percent, while physicians' all services were up to 4.6.

I just want to clarify that point, that I think we have done a lot already through a number of issues, the DRA, et cetera, to show that all imaging has decreased. I agree that MRI and CAT scan is part of all imaging, but if you look at the whole package, I think you really see that it has decreased compared to all physician services.

MR. WINTER: And for the 2008, I don't have the AMA numbers for all imaging. They didn't report that for

2009. I will look at that in the coming months. For 2008, we found that imaging across the board, looking at both volume and intensity, grew at 3.3 percent, and all physician services grew at 3.6 percent. However, there were some categories within imaging that grew faster than 3.6 percent, like echocardiography and CT studies.

DR. CHERNEW: You mentioned a little bit about site of care. How much is the difference in the total amount that's paid for one of these services if it's done in the physician office or if it's done in an outpatient department?

MR. WINTER: Imaging specifically or across the board?

DR. CHERNEW: Well, for the type of services you're talking about.

MR. WINTER: Okay.

DR. CHERNEW: So in other words, if we pushed everything, for example, out of the physician office into the outpatient department, would we be paying more per unit service, because now they're getting a different -- or are we paying less?

MR. WINTER: Okay. So for imaging, under the fee-

schedule, they used to be able to get paid more than the outpatient department. The DRA put a cap in and said, "You can't get paid more under the fee-schedule for the technical component." However, you can still get paid more in the outpatient department. So there are definitely imaging codes that are -- where the outpatient rates are higher than the fee-schedule rates for the technical component, and we can do some more work to quantify that.

DR. CHERNEW: Is it significantly higher?

MR. WINTER: It could be. I'd have to go back and look at the data. For the professional component, it's the same regardless of setting. The next thing would be outpatient therapy. By statute, the payment rates are the same across settings, outpatient, physician office, SNF, wherever, as long as it's paid separately.

Radiation therapy. I want to go back and look at those payment rates. When I looked at it three or four years ago, there were examples of codes that were paid more under the physician fee-schedule than in the outpatient department, but that might have changed in recent years so I want to go back and look at that again.

DR. NAYLOR: So this was a terrific overview of

the issue and I wanted to clarify Page 11. The definition of clinical integration, you mentioned that you cannot link physicians to the increasing number of physicians that are now being employed by hospitals or health systems.

So does this definition, if a physician moves into a large practice as part of a health system, isn't it easier for the physician to meet these criteria? Because they're much more likely to have electronic health records than physicians not as part of -- who are not employed by hospitals or health systems.

So I just thought it might be easier for them to meet these two expectations around being able to say, "90 percent of my practice is part of a group and I also have that record." So I was just wondering if there's a way to -- well, is that an issue?

MR. WINTER: Well, to the extent that they are going to be in a larger practice when they're employed by a hospital, I would expect they're more likely to be able to meet those criteria because they're more likely -- the physicians are more likely to be fully employed by the practice, more likely to have EHR technology. I think the literature says that, but I'm not -- I'd have to go back and

look and consult with my colleagues, like John Richardson.

One thing to point out, though, is that there was a recent study that looked at adoption of EHR technology by hospitals and found that only about 2 percent currently use the functions that are required to get incentive payments under the meaningful incentive -- under the incentive payment program so that very few hospitals actually currently comply with the meaningful use criteria.

So I'm not sure that just because you're part of a hospital it means that you would comply with the meaningful use criteria. But again, you may want a more flexible standard if you decide to adopt an EHR technology criteria for the in-office exception. You may not want to go all the way to where the department has gone with regards to meaningful use criteria.

DR. NAYLOR: I'll just follow up then, if a physician refers then to services within that health system, it seems that this could create a great incentive for them to do that, and if we can't track it, we won't know. Is that essentially right? We can't track the physicians' use of services within a system?

MR. WINTER: Right, not using claims data, right.

We certainly can't tell whether they're employed by the hospital.

MR. HACKBARTH: Clarifying questions?

MR. BUTLER: So same topic. My understanding, based on the material, is that there currently is a 75 percent threshold for this clinical integration and we're looking at maybe it should be 90 percent, is one way to look at this recommendation, right?

MR. WINTER: Right. And then the 75 percent test, just to clarify, that applies only to members of the group, so owners or employees. It doesn't apply to independent contractors.

MR. BUTLER: Independent contractors are excluded?

MR. WINTER: Right.

MR. BUTLER: So this is still something that I remember Jay talking about a little bit of this option, but I think to the average person, even to some of us, clinical integration doesn't -- you know, it's just such a nebulous term. And so, help me a little bit about bringing that to life and what it means. I understand that I think if you have a multi-specialty group practice of 70 doctors in a building and there are a bunch of ancillaries and that's

where they provide their care, they probably meet the test because that's where they have their practice. Right?

So give me an example where you would not likely meet that 90 or 75th percentile. Give me a couple of examples. That would help me.

MR. WINTER: Okay. So if you're a practice and you provide some imaging services and you do them one or two days a week and you bring in a radiologist, contract with a radiologist to come in and supervise and interpret the studies, you bill for the professional component and the technical component, and the other days when the radiologist isn't there, you don't perform this, you don't perform the studies, so you schedule all your patients on those one or two days.

Or this could also apply to pathology services where you bring in a pathologist a couple days a week to read the slides. Those kinds of arrangements would not comply with this proposal.

Another example could be if you're performing radiation therapy services as part of a multi-specialty practice and you contract with different radiation oncologists to come in different days of the week to oversee

what's going on, then that kind of arrangement would also not comply. But based on our discussions with physician groups and organizations, it seems that in most cases where multi-specialty groups are providing radiation therapy, they employ the radiation oncologist full-time because the sessions are done five days a week generally.

MR. BUTLER: The differentiator really is their use of independent contractors more than anything because you're likely, as that physician, to be in that office more than 90 percent of your time. It's just how you are using the other specialties to support the radiologist or the radiation oncologist? Is that the key differentiator?

MR. WINTER: Right, right.

MR. BUTLER: Okay.

DR. MARK MILLER: That's right. And the arrangements, you were saying it would not comply with this policy, but under the current 75 it does comply, just to be clear on that.

And just to follow up one other thing, it's true that you can't necessarily track, if they become part of the system and start making referral -- back to Mary's question -- but if it moves to the hospital side, it then gets paid

under the outpatient payment system?

MR. WINTER: Correct. If the service is provided in a hospital outpatient department, that's true. But if they're providing the services --

DR. MARK MILLER: It will remain in the office?

MR. WINTER: -- in the physician office, that's billed under the fee-schedule. So we don't know if that revenue eventually flows to the hospital because the hospital owns the practice.

MR. HACKBARTH: Let me --

DR. CHERNEW: My understanding was, if the hospital bought the practice and the practice met some criteria, it could qualify as then being part of the hospital outpatient department.

MR. WINTER: And that's a good point. So if it meets the provider-based standards, then it can qualify as an outpatient department and bill as an outpatient department. But those standards include financial integration, administrative integration, I think the same billing so I think the hospital has to do the billing.

DR. CHERNEW: [Off microphone].

MR. WINTER: Proximity, they can be off-campus and

meet those criteria. So there are different rules if you're on campus than off campus. I'm describing the off-campus criteria.

MR. HACKBARTH: They have to be under the hospital's license in some way?

MR. WINTER: That's right, its licensure, shared licensure.

MR. HACKBARTH: Could I just follow up on Peter's question? So one of the options that we're looking at is saying, well, you're allowed to self-refer only if you are in a clinically integrated group. Got that. Now, under the existing law, there is a definition of the group. Remind me what the function of the existing group definition is. It's not defining the boundaries of the exemption. What purpose does it play?

MR. WINTER: So physician groups have greater flexibility to provide in-office ancillary services than solo physicians, so they can use a centralized building, like a centralized lab facility. They can contract with a different physician to supervise the test or perform the test. So there's much more flexibility, and -- does that answer your question, or --

DR. BERENSON: I want to follow up where Ron was going on Slides 6 and 7 because I think it's pretty interesting, what the response was to a significant pay cut. It seems to me there's a natural experiment here that adds to the literature of behavioral response and I just want to understand that I understand this.

It seems that when we reduce significantly the prices paid, the fees paid for advanced imaging, in fact, we had a moderation of the growth. Growth rates dropped rather than -- at least some of the literature would suggest you get a behavioral offset to increase volume. You actually had a moderation of the volume growth, is that basically right?

MR. WINTER: [Nodding affirmatively.]

DR. BERENSON: Okay. And do we have -- and it looks like the services that were not subject to the caps didn't go up to make up the difference. I mean, they also moderated, is that a way to --

MR. WINTER: It's a little more complicated than that. GAO looked specifically at this question of the services that were affected by the cap and those that weren't and they found that services affected by the cap

grew at a rate -- and they were just looking at technical component and global services and not professional component -- those grew at a rate of 7.4 percent between '07 and '08, and services that were not affected by the cap grew at a much slower rate of two percent. So they actually found that the rate of growth was faster, but they didn't track the trend. They didn't show what the trend was in the prior year for those codes, and so it could actually have been higher and come down but still be higher than the other codes.

DR. BERENSON: But doesn't that finding suggest that the advanced imaging services grew pretty fast still after the cut? I mean, that was the 7.4 percent, you are saying?

MR. WINTER: Right. Right. And the advanced imaging services that were affected were mainly MRI codes in that year, some CT codes, but also nuclear medicine codes. And so this slide doesn't show the nuclear medicine.

DR. BERENSON: And what's really going on, I assume, is, well, at least anecdotally I heard that there was the DRA sort of caps sort of froze the purchase of new machines by a lot of practices that otherwise might have

done so, so you didn't have the influx of new volume from new sources. But the places with existing equipment perhaps increased their volume in response. Do we know --

MR. HACKBARTH: [Off microphone.]

DR. BERENSON: Yes. Is there any sort of information that sort of teases that out a little bit?

MR. WINTER: We don't have information from claims data because we don't know how long the practices owned the machine. We could use claims data to identify when a practice began billing for something and then we could presume, well, they bought the machine then. But a practice that was billing all along, we can't tell, well, did they replace the machine in this year or they're using the same machine with the older technology because they didn't want to go out and buy a new one. So it's a little bit complicated.

The other thing to point out is that the changes in the capital markets made it more difficult to finance acquisition of these machines around the same time, so that might also have dampened the demand for new equipment.

DR. BERENSON: But I guess to summarize, then, at least a significant pay cut, fee cut that generated revenue

savings to the program wasn't offset by a significant behavioral volume increase, and if anything, there might have been a volume decrease. Is that basically the summary?

MR. WINTER: I think it's fair to say that played a role.

DR. BERENSON: Okay. Thanks.

MR. KUHN: Ariel, two quick questions. On Slide 3, where you talk about one of the reasons or one of the rationales for the in-office ancillary exception was the convenience of the service, same day service has been one of the reasons that has been given, do we have from the claims data a pretty good sense of how many of those services are being provided the same day and how many of them on subsequent days? For example, someone comes in to see their physician. The physician says, I need to get an image of this. Go across the hall and see my assistant, or go across the hall and see the assistant, and he or she says, well, we'll schedule you a week from Tuesday. Come back then. So I'm curious, do we have a pretty good sense of what's going on the same day and how much of this is being perpetuated in subsequent visits to the physician office?

MR. WINTER: We have a sense of how frequently

tests and physical therapy services are done in the same day as a related office visit. In terms of tracking what happens down the line, like how many visits do they get after the test, we haven't done that analysis. But we presented results in our June report showing that for many of these kinds of services, they are provided less than 50 percent of the time in the office. I mean, the standard imaging, like plain X-rays, were the highest at 50 percent.

MR. KUHN: Okay. Thank you. And the second question I have is not part of the presentation you made, but I am just curious if you can give me an update on this. I don't know, four or five years ago, MedPAC as one of the chapters in one of the reports did a pretty exhaustive look in terms of kind of the safety issues related to imaging and physician offices and talked about the lack of regulation, lack of accreditation practices and physician office.

Can you give us an update kind of where -- what has changed since that chapter and kind of where we are in terms of kind of the safety side of this kind of technology in the physician office?

MR. WINTER: Sure. So we recommended that the Secretary develop quality standards for both the technical

component of imaging, which is actually performing the test, acquiring the image, and for the professional component, that is the work of the physician interpreting the results. We recommended this for all imaging services across the board, but we prioritized that these should be done first for advanced imaging and services that are growing more rapidly and are higher cost.

In 2008 in MIPPA, the Congress required mandatory accreditation for advanced imaging services, namely MRI, CT, and nuclear medicine studies, for the technical component only. So it doesn't apply to the professional component. And it was limited to those three types of services, and PET is a -- as well as PET, which is a subcategory of nuclear medicine. It did not apply to ultrasound or standard imaging. CMS is in the process of implementing those standards right now. They have selected three accreditation organizations that providers can go and get accredited from, and if they're not accredited after, you know, within a couple of years, they won't be able to bill the program anymore for the technical component.

So I would say our recommendations have been implemented in part. What's still out there are -- or

what's still lacking are standards for ultrasound and other kinds of imaging on the technical component side, and what's also lacking are standards for the professional component, with the exception of mammography, which was covered through MQSA.

DR. KANE: Yes. I had a question on Slide 6. That dramatic drop that you mentioned at the same in 2008 there was a bundling of the imaging services with other things. Does that mean that when they got bundled that you can no longer capture the use of imaging, or that they just didn't use imaging in that bundled service? Are you just -- what is that? Is that a measure of a reduction in the use of imaging or is it the fact that you can no longer capture the imaging part of the bundled service?

MR. WINTER: So I think that the hospital would still bill for a packaged service. I'm looking to see if Dan is here to nod his head, but I -- is that right, Dan?

DR. ZABINSKI: What?

MR. WINTER: Is that right? Okay.

DR. MARK MILLER: So why don't you come up here, Dan.

DR. KANE: You can get back to me if you want to.

MR. WINTER: So come on down. So they're probably still billing for it, but if they are, we're not capturing that in the data stream. We're just capturing -- those services are not reflected because now they are being paid as part of the independent procedure.

DR. ZABINSKI: The cost of the thing is reflected in the payment rate for the primary procedure.

DR. MARK MILLER: So in other words --

DR. ZABINSKI: It is not an explicit separate payment --

DR. MARK MILLER: -- of her two choices, the second choice was does this mean that the actual volume has fallen, or is it more difficult to count separately because it's part of a bundle, and I think this is --

DR. ZABINSKI: It's more difficult to count.

DR. KANE: Okay. So we just --

DR. ZABINSKI: I don't know if it's gone up or down --

DR. MARK MILLER: Right, because it's now part of a bundle.

DR. ZABINSKI: Right.

DR. KANE: That's just a little bit misleading, I

think, if the incentive -- or I think we need to just clarify that that drop does not necessarily mean a drop in volume. It just means we just may not be capturing it because it's now in a bundle --

DR. MARK MILLER: Well, just to --

DR. KANE: -- or we may, but we don't know or something.

DR. MARK MILLER: I thought Ariel actually tried to make that point when he put the slide up, and I'm actually glad you brought this up because there's real mixed questions about physician's office versus the hospital. But, I mean, one point is to the extent that if it does convert to an outpatient payment system, you also have greater opportunity to start paying on a bundled basis. But it doesn't mean that everything goes under the outpatient. But he did try to point that out as he went through it, that this was something of an anomaly on the OPD side.

DR. KANE: Yes. I just wasn't sure what that green line was capturing.

So I have one other question. On Slide 11, the possible criteria of requiring a group to have EHR technology and use it for specific purposes, I guess this is

just the whole meaningful use notion. How does one audit how someone is using their EHR technology? And I'm just wondering, is that a feasible and enforceable criteria for deciding whether or not you can bill for something?

MR. WINTER: Right. I'm not clear how that -- what their auditing standards are for verifying that hospitals or physicians are using those functions. I'm looking to see if John is here, more help. Is he there? There he is. John, is there anything more to say about that?

MR. RICHARDSON: [Off microphone.]

MR. WINTER: We'll have to look into that and we'll get back to you.

DR. STUART: I think we can all agree that there is a strong financial incentive for provision of these ancillary services, given the current fee-for-service structure. My question is, is there a literature on the marginal value that these services provide and is that marginal value different in outpatient settings as opposed to physician settings. And I can think of a couple of areas.

If the provision is truly unnecessary, then you

would expect to see higher rates of negative results on tests. You would probably also see some duplicative tests and you would almost certainly see higher intensity tests than might be recommended by guidelines.

So is there a literature that supports this, because if there is, you might have another approach altogether, which would focus on what the tests are showing and there might be penalties if you exceeded some threshold rates.

MR. WINTER: I'm not aware of a literature that looks at sort of duplicate studies, negative results, negative findings, comparing self-referral settings versus other settings. There may be a literature that looks at this like within hospitals, where there's generally more clinical data that you can capture to address these questions.

There's one study I can think of off the top of my head which looked at the intensity of services referred by self-referring physicians versus non-self-referring physicians and it was radiography services and they found that physicians who owned the equipment used in their offices tended to refer more of the high-intensity kinds of

radiography services, and I can get you the specific results for that. And I'll look into the broader question, as well.

MR. HACKBARTH: Round one clarifying questions? George?

MR. GEORGE MILLER: Yes. On Slide 9, you had mentioned consultation with stakeholders. I was curious what feedback you received particularly from the physical therapists about ownership of those services by any number of physicians, particularly orthopedics, and what feedback they gave you. I have some anecdotal information. I'm just curious what you received.

MR. WINTER: So the feedback we've gotten is very strong support for removing outpatient therapy, physical therapy services from the in-office exception. Their concern is that -- that they've expressed to us is that physicians -- referring physicians are getting into this area and buying up therapy practices and encouraging therapists -- or telling therapists that if you don't join me, I'm going to stop referring to you.

MR. GEORGE MILLER: Right. Right.

MR. WINTER: So there's some -- they're feeling -- and again, this is their view, I'm not validating this --

MR. GEORGE MILLER: No, I understand. Right.

MR. WINTER: -- they're feeling pressure to join up with or be acquired by physician practices.

MR. GEORGE MILLER: Okay. And then the follow-up, is there then literature to support increased use of physical therapy services to somewhat justify that, that anecdotal feeling, because I've heard the same thing from a couple of physical therapy groups.

MR. WINTER: There's some older literature from the early and mid-'90s which shows that when physicians provide therapy in their offices, they are more likely to use it for musculoskeletal conditions. There was a study by Swedlow based on California Workers' Compensation data which showed that and another study which had a similar finding, I think by Jean Mitchell. I'm not aware of recent studies, though, since the '90s.

DR. BAICKER: I'm guessing in the round two discussion, we'll dive more deeply into thinking about quality of care and the productivity of this use in terms of producing outcomes, so I wonder as a precursor to that how much do we know about whether these types of physicians are different from others and whether the patients they serve

are different from others, and I'm getting at that to think about if we are going to try to gauge the marginal productivity by looking at outcomes, are we comparing apples and oranges? Are the types of physicians that have the capacity to do this in-house in different types of areas, serving different income, ethnicity, age patients so that we're not going to be able to compare, or is this a pretty heterogeneous slide of the population of physicians and patients who practice this most heavily?

MR. WINTER: So from the claims data, we can tell that there are certain specialties more than others that are getting into this area, which we described in our June report. Ones that are specialties that derive a lot of their revenue from ancillary services, particularly imaging, include cardiology and vascular surgery and orthopedic surgery and a couple of others, including internal medicine, by the way, so it's not simply specialists.

In terms of the geographic distribution, we have not looked at that with claims data, but HSC has done several site visits and I think they've found that in certain areas more than others, this kind of what they've termed entrepreneurial activity is more prominent, and maybe

Bob can speak to that. I can't offhand. Examples that come to mind might be Miami or maybe Phoenix.

In terms of the impact on -- in terms of demographic characteristics of their patients, I'm not aware of research that's looked at that. It would be a little bit difficult. You could try to do with the information from the Medicare denominator file that we have information on demographic characteristics and try to link that to patients of physicians who were seen by these practices, but that research, I don't think any research has been done in that area yet.

DR. MARK MILLER: I would have thought you would have said just one other thing, which is what you and Jeff did, I think it was in the June report, I can't remember which report it was in, you know, all the literature showed that ownership has higher volume. What these guys did is they tried to organize the claims data by episode so that you had some control for similarity of patients and disease staging, and I'm not saying perfectly risk adjusted, but some attempt, and to reexamine that literature and say, are you finding it, and you found five to 100 percent differences in rates depending on what modality. So they

basically confirmed it with an attempt to control on differences at least among patients. But I think the biggest thing that we're probably stymied on is the demographics of the physician, which are definitely pointing to --

MR. WINTER: Yes, and I'm glad Mark raised that. We also controlled for different markets where the physicians were located and for physician specialty, so we tried to adjust for as many factors as we could.

The other thing I wanted to mention is that with regard to specialty hospitals, which is a different but related situation, they do tend to locate more in higher-income areas. They tend to serve different kinds of patients than general hospitals. So there's some literature there.

DR. DEAN: There's another set of procedures that I've been concerned about, and I wonder if it's included in this. That's the screening procedures that are offered directly to the public that in turn presumably generate other procedures. The one I'm thinking about is the coronary calcium screening that either both hospitals and physician groups tend to offer, usually at some ridiculous

low price, $50 for a CT scan and then you usually get several other things with it. That whole practice has been criticized both by some professional organizations as well as the Preventive Services Task Force, both because it amounts in a fair amount of radiation exposure and there's a lot of concern about where it leads in terms of a number of other procedures that most likely were not indicated in the first place. I suspect that those data would not show up in this analysis, is that right, or --

MR. WINTER: I mean, if they're not covered by Medicare, they wouldn't show up, no.

DR. DEAN: Well, they might -- the initial thing would not be covered by Medicare. The second round of tests may well be, and I don't know how you'd get at that, but I was assuming none of that would show up here.

MR. WINTER: No.

DR. DEAN: And I'm not sure how widespread it is, but I think it's fairly widespread.

MR. WINTER: To the extent there are follow-up tests that are covered by Medicare and paid by Medicare, yes, we capture those in our data. But we can't relate those to an initial screening test that wasn't covered.

DR. DEAN: Okay.

MR. HACKBARTH: I'm going to engage in some bundling here and bundling a round one clarifying question with a round two comment.

DR. BERENSON: That's packaging.

MR. HACKBARTH: That's packaging? Well, I don't know. That's right. Okay. I'm going to package, not bundle, and I want to offer the round two comment to give people an opportunity to react when their turn comes.

So the clarifying question, I just want to make sure I understand the implications of two of the options that you've described, first, the option prohibiting from referring for their own therapy services and then the option prohibiting from referring for imaging services not provided the same day, probably a lot of MRI and CT.

So, as you know, I used to run a large group, a multi-specialty group with in-house imaging, in-house therapy services, and the like, two-thirds capitated, one-third fee-for-service, in the one-third fee-for-service a lot of Medicare patients. So as I understand the prohibition on referring for therapy, a group like that could not refer to its own therapists and could not use its

own MRI and CT under the other option, even though it has built this practice, organized this practice in a way that is guided by the fact that it's a largely capitated group. It tends to be very value-focused. It would be flatly prohibited from self-referral under these two options.

MR. WINTER: Under the option where you carved out radiation therapy and outpatient therapy --

MR. HACKBARTH: Yes.

MR. WINTER: -- and under the option where you carved out tests that were not done on the same day, frequently done on the same day, that's correct.

MR. HACKBARTH: Yes. Okay. So I find that troubling, a troubling implication of that kind of approach. Obviously, the option which would say that there's an exemption for clinically integrated groups would help my former colleagues. As Peter says, the definition of clinically integrated, it's easy when applied to Harvard Vanguard. It may not be as clear in other circumstances and start to raise some tricky issues that I'm not sure I fully understand.

Among the options that you laid out, there are three that strike me as more targeted and then, therefore,

perhaps more appealing. One is the idea of packaging wherever that's feasible, and Karen, I think this is an idea that has, in the past, you've mentioned, made some sense. There's a lot that goes on in the surgical world and maybe there's an opportunity to expand our efforts of packaging and dealing with some of these issues. It wouldn't be a comprehensive solution, I imagine, but conceptually, that seems to me worth pursuing further.

Similarly, another targeted approach would be targeted prior authorization, and Ron, this is something I think you've mentioned in the past. You've said to me multiple times, let's focus on the appropriateness of what's being done for the patient. So if, in fact, we can target prior authorization to people who have a demonstrably odd pattern and then look at their specific services and focus on whether they're appropriate or not, that seems like a targeted approach that at least merits some further exploration.

A third approach that interests me -- and just be clear, I'm not endorsing any of these because I'm sure they raise complicated issues, but these are the ones that strike me as worth pursuing further -- is the notion of reducing

the payment rates for self-referred services based on the principle that we're paying twice for some activities. They don't need to be duplicated when there's a self-referral situation. And this is an idea that we've enforced in other contexts. You know, the same thinking underlies the reduced payment for imaging of contiguous body parts. The same principle exists in surgery when there are two procedures done. You don't get paid the full rate for both of them. And so this is an idea that I think is consistent with past MedPAC, past Medicare policy that makes sense. There isn't duplication of all of these activities and some reduction in payment seems conceptually appropriate.

So those three approaches all strike me as more targeted. I'm a little reluctant about the more sweeping approaches because I think there could be some collateral damage, as it were.

My starting point on all of this is that the problem is not self-referral per se. The toxic combination is self-referral combined with fee-for-service payment, often combined with mispricing of the services. It's when you get the three of those together that you have the risk of abuse, and so I don't like anything that sort of across

the board will slow efforts to organize care delivery, bring services under one roof. That strikes me as counter to other things we're trying to accomplish. Let's see if we can do more targeted things to get at the real problem, is my thinking. So I invite people to react to that.

So let's proceed to round two, starting over here, Cori and then Ron.

MS. UCCELLO: I'll just react to this targeting prior authorization. It seems to me that at the very least, providing information to providers on where they stand in terms of ordering tests generally is useful, even if it's not ultimately used on the payment side. I think somewhat of a risk in that is -- I don't know if this was in Atul Gawande's article or what, but when physicians are seeing, well, I'm below average or I'm average -- well, I'm above average but I'm doing it correctly, or I'm below average and I'm doing it correctly, I mean, there's not necessarily a lot of information -- you don't know necessarily what to do with that information when you get it. But I think thinking along those lines is appropriate.

MR. HACKBARTH: And one of the things that we've recommended in the past, Cori, is confidential feedback to

physicians on an episode basis, how their patterns of care compared to their peers within the same market. As you know, CMS is in the process of rolling out that sort of an effort.

MS. UCCELLO: And a question regarding -- back to you, Glenn -- on the packaging and reducing payment rates. In terms of timing, Ariel said that the packaging or bundling was maybe more of a long-term approach. Is reducing payment rates a bridge to that or would that also take a while to implement that kind of strategy?

MR. WINTER: Well, let me just clarify a bit. Packaging is probably -- it could be done on a shorter-term basis if you're talking about services provided in the same encounter by the same clinician or hospital, and so CMS in a single year implemented a new packaging policy for many types of imaging services because they tend to be provided by the hospital when they do the independent procedure, like ultrasound guidance as part of a surgical procedure. Those things are provided together by the same provider. It's fairly easy to combine them into a single unit.

You could think about applying that on the physician fee schedule side, but because of the way

physician services are valued through the RUC process, which can take some time, you have to -- you could come up with a comprehensive code that included, you know, multiple discrete services, but that would have to, I think, go through the CPT panel and then the RUC would have to assign a value to that code. And this has happened recently for nuclear cardiology codes and I think for echocardiography codes. And so there's precedent for this, but I think it's a slower process on the physician fee schedule side by the nature of how that works.

But there is also a faster way to do it, which is CMS could say we're applying an across-the-board 50 percent reduction on multiple imaging studies done on contiguous body parts, which they did in response to one of our recommendations. So there is a faster track for that, as well.

You were asking about reducing the payment rates for tests done by self-referred physicians. If Congress were to make a policy judgment like they have for services provided by primary care physicians -- primary care services provided by primary care practitioners and were to say, we're going to reduce these payment rates by five percent or

ten percent across the board, well, that can be done relatively quickly.

The kind of process or idea that Glenn has latched onto, which is going through sort of code by code and looking at activities that are duplicated when the ordering and the performing physician are the same person, that could take some more time, because again, that is using the RUC for that process, unless you wanted to bypass the RUC and have CMS do it on its own. Generally, they like to go through the RUC.

MR. HACKBARTH: Ariel, I would note that in the case of, say, contiguous body parts, there was not an effort to go through all of the activities, and it was, you know, a simple reduction. I think the same thing is true in terms of the payment for surgical procedures. They don't try to work out all of the elements. It's a simple reduction of some percent.

MR. WINTER: Well, actually on the imagine side, they did go through an exercise where they tried to take into account the duplicative activities that are not done for the subsequent imaging service, and they came up with a range of something like -- around 50 percent. They decided

to phase it in. They stopped at 25. And then Congress came in and said, "You have to move it to 50." So it ultimately was Congress' judgment to set it to 50.

MR. HACKBARTH: Okay.

DR. CASTELLANOS: First of all, just to disclaim, I want to make sure everybody understands. I belong to a very large clinically integrated cancer group, including medical oncologists, radiation oncologists, surgical. I do not own a machine, and I have no stock in that company. So I just wanted to clarify from a disclaimer point.

Glenn, I'd like to respond to a couple of comments you made. I'm also troubled by some of the issues that have been brought up, and one of the issues is the effect on the beneficiary. There's no question that site of service, there's cost differences in site of service, and there's copayment differences in site of service. There's no question there's a convenience and care coordination. But this should not be bundled into a thing where we do it for that reason because doctors make money. We do it because it's a convenience, it's a good service to the patient, there's quality.

Now, appropriateness, and I really want to get to

that a little bit. I totally agree with you, and, Cori, it kind of gets back to your -- about prior authorization. My personal feeling is that we do need feedback, and with prior notification there is definite feedback to ever physician. In other words, if you notify them that I want to do a CT scan, they're going to say fine, but they're going to give you feedback by saying it's not appropriate and maybe you ought to think of this as a different alternative.

We had a presentation on this, oh, two years ago, and I can bring that material back. But it's less invasive. It's cost-effective. Prior authorization, maybe we need to go to that on outliers who don't pay attention. But we've always stressed feedback to the physician, and sometimes feedback, not publicly but personally. And I think if we need to go to something, I think prior notification would be the first step, and then if we need to, to the people that are outliers that haven't paid attention, maybe prior authorization.

As far as inappropriate care, Glenn, you and I have talked many a time on this, and it's my feeling that we stress inappropriate this, inappropriate this, inappropriate this. And I remember Bob Reischauer -- and I think we all

do. I remember him for a lot of reasons. But I remember one statement he said. It really doesn't make a difference where you do the study, whether it's in the hospital, in the clinic, or where, as long as it's appropriate.

Where I'm going with this is that we had a group of cardiologists here, American College of Cardiology, and she made an excellent presentation on guidelines and issues of that. And I think we were all very impressed with that. I think it's fair to say -- I went back to my society talking about guidelines and appropriateness and all that, and I think it's fair to say I had a lot of resistance. A lot of the urologists were on my side, but a vast majority were not interested, and it appeared that maybe the society didn't take it as seriously as at least I thought it should.

What can we do about that? Well, I think we can do something. You know, when we talked about poor-performing hospitals, we talked about getting them help where they can increase the qualities and the issues that they deal with. Well, I think we can use that same approach with poor-performing medical societies or societies, actually going to them and letting them know what we feel is very important from a patient viewpoint, what's appropriate,

et cetera, you know, because I think we need to stress appropriateness, because I think there's a lot of us physicians that really want to do the right thing, but sometimes perhaps we don't because of practice patterns. For a lot of reasons we do something that's inappropriate that we don't even recognize we're doing. So I think if we can stress appropriateness in the approach on ancillaries, I think we'd be much better off.

Now, Glenn, you also talked about making the price right, and I agree with you. When there's outrageous reimbursement, we ought to make an issue there. And I think we talked a little bit about that yesterday or at least I tried to on the LCA issue with Part B drugs. It became -- we finally got the reimbursement correctly, and it really hasn't disrupted the care of the patient. So I think we need to work on that also.

Thank you.

DR. CHERNEW: I think it's clear that all of these are imperfect, and usually when we get these recommendations, we get a more complete analysis of, like, how effective we think it will be, what are the costs. And so I think to really do what we're doing, that's sort of the

next step to think through so we can begin to weigh the pros and the cons.

My general instinct, I think, is much the way you said, Glenn, which is, you know, we don't want to do any harm in preventing us from getting the system where we want because we've put various rules in. And I tend to be hesitant to put in a lot of rules that have sort of arbitrary administrative barriers to the way people organize. It somehow reminds me of -- I apologize for this little folksy kid's reference, but for the sort of Brer Rabbit and Tar Baby story where first Brer Rabbit hits the Tar Baby in the face and gets stuck, so then he realizes the problem and he hits it with his other hand and it gets stuck. Then his feet are in the Tar Baby, and everything is just all mucked up because he keeps creating problems, then trying to fix them with some other fix. And I think that's what often happens here. First, we don't want you to do it in the office, but that's not working. So then we want to change it so you can only do it if you're in an integrated group. But now we want you to be in a big ACO, so we make an exception for that. And now we're going to have to layer on some extra monitoring, and before you know it, you're

mucked up in this incredibly complicated administrative system to try and solve a problem that undoubtedly is a problem, but you might have solved by going a little bit slower and trying to get the incentives and sort of the payment right.

So my general view is, although I recognize the problem, I'm worried by a number of these, particularly the ones that make sort of arbitrary definitions of things, you know, that we think hard about doing that because there's industries that figure out how to get around -- just listening to your answer to the question about you can be an outpatient department if you're licensed the same and within a certain area and you've integrated your -- you know, all those sort of administrative rules become enormously complicated, and trying to get a better payment system strikes me as maybe a little longer run. But from my view, that's preferable than to try and do some of these other things.

DR. NAYLOR: So I want to totally agree with Mike's perspective. I think that the goal of our system is integration, is integration for people, and the evidence is showing that, you know, if we target populations and provide

them with immediate access to a team of players where a team, for example, could -- a physical therapist could help an individual who comes in with back pain and prevent -- immediate access, and prevent the use of costly tests. And that was part of an earlier chapter here, that we don't want to create systems that will not allow for the targeting of the right population to have immediate access to the right set of services that might be not in your language but the least costly alternative and add more value and achieve better integration for the person.

So I think we have, you know, this notion of thinking about how we'll get to bundling or packaging makes a great deal of sense, thinking about how we'll target makes a great deal of sense, and certainly thinking about how we'll pay for value maybe through the right kind of both quality incentives packaged with the right kind of financial incentives I think is right.

I also think that this issue of quality does deserve a great deal more attention. I am concerned that we're focused on technical competence in the light of evidence about the critical importance of professional competence in combination with technical competence.

MR. BUTLER: So I feel like this is fruit that has been ripening for about two years, and this is the year we are going to pick some of it, I hope. I agree that we ought to pick -- make recommendations that are realistic, doable, sellable, and advance us some, not stretch too far. I think that's consistent with what we've been hearing. So I have some combination of, Mike and Glenn, your two comments, and I'd like to go to Slide 18 to clear more specifically so that if we're going to look at more data to understand, I think there may be some things that we might take off the table in terms of options as we dig deeper. And I'll just tell you my own preferences.

On the left-hand side, the exclude from in-office exception for the therapy, I don't think that's going to be realistic to say simply you can't own one of these pieces of equipment in radiation or you can't have physical therapy. I'm most concerned about the radiation being used inappropriately. I'm just not sure the ownership thing is the vehicle to get there. So I don't see that as a realistic option.

Just to cover the other half of not pursue further, I really don't like the same-day thing. It seems

kind of -- you know, to pursue that further as an option and how you would really do that, I just don't see that as a fruitful way to go. We could say, you know, if it's not done on the same day -- if it's done on the same day, you get paid. If it's not done on the same day, you don't get paid. That's not realistic. So I don't see a lot of value in pursuing that.

Then when you get to the bottom half now on both sides, I do think there are opportunities. I like the clinical integration option on both the therapy and the diagnosis, and if only we move it above the 75th and begin to be -- maybe not go to the 90th, and I don't really like the IT piece. It seems a little gimmicky. But definitely we could strengthen above the 75th to some level that could further define what clinical integration means. I think that's worth pursuing.

I'm a little less clear on the payment rates, but I definitely think that the bundling, which is part of rate setting on both sides, is a fruitful thing to look at as a package of services that are coordinated for a price as opposed to taking just individual payment rates and trying to kind of incentivize that. I'm not as optimistic about

that.

Then, finally, on pre-authorization, certainly at a threshold, because we've seen an imaging at work in the private sector, why not apply something in Medicare. And I'm not sure why that shouldn't also be on the left-hand side of the chart, too, in terms of authorization on the treatment, not just the diagnostic side. So that if you had pre-authorization for physical therapy or radiation in some fashion above what's done now, I think it could be in both columns.

MS. BEHROOZI: I agree with a lot of what Peter said, and actually you had said, Glenn, also. Everywhere it says exclude or even reduce payments, you run the risk of throwing out the baby with the bath water, where, you know, there are good providers who -- you know, whether we're talking Vanguard or individual physicians or whatever -- who are trying to do the right thing, and, you know, why we would want to make it difficult for them or their patients or reduce payments when, you know, they're doing the right thing. You know, it seems to constrain our ability to do what we really want to do, which is to address the misalignment of incentives, or whatever you want to call it.

I think that one of the things that I really focused on in your paper, Ariel, was not just the number of MRIs. I mean, you know, okay, it's inconvenient to have to go for an MRI and, you know, lie there in the machine or whatever. They're making it more convenient, stand-up MRI or whatever. But you highlighted an example of physicians who were paid more generously, blah, blah, blah, for chemotherapy drugs, prescribed more costly chemotherapy regimes for certain types of cancer patients. Not only can that have a dramatic economic impact on the beneficiary, but maybe they're getting a regimen of treatment, chemotherapy, that's a lot more than inconvenient, that maybe isn't the best thing, isn't necessary at this point. And I don't think that payment levers really are sufficient to address what has become kind of ingrained -- with some people they may not particularly realize the way the incentives are working on them, or maybe they are trying to game the system, those outliers. But I just don't know that the payment levers are enough to really get at those incentives. And it reminds me of the conversation yesterday when we were talking about the three-day stays and the observation -- a three-day stay in the hospital being required for SNF

payment and the observation days not being counted. And people were talking about MA plans, well, they don't require the three-day stays, and everybody's response right away was, well, they've got prior authorization and other management techniques.

Maybe that's one of those things we're supposed to be learning from the private sector that we need more management techniques than just these rules about payment that people learn ways around or adapt themselves to. And so in support of prior authorization and prior notification -- not that none of the rest of it is appropriate. By the way, with bundling, we also -- with those people who tend to be somewhat, you know, not so positively influenced by payment levers with bundling as we've discussed in other contexts. There's the risk of stinting, that people won't get the regimens of care that they need or the diagnostic tests that they ought to have, right? So it's not that we shouldn't go to bundling, but it won't really work unless you have robust quality measurement and enforcement and all of that, and we're a long way from that.

So whether it's an interim step or something we build in forever, I would support prior notification and

prior authorization. I think maybe it's for -- I don't know at what level, you know, how many standard deviations or whatever, it's appropriate to all somebody an outlier, at, you know, the 90th percentile and above or 80th percentile and above. I think they absolutely should have prior authorization. I think we're far enough down the road. And like I said, concern about the dramatic impact on beneficiaries, I think we really do need to intervene. Perhaps prior notification for, like, the 60th to 80th or 60th to 90th percentile would be a good thing, not just for those physicians who find themselves in those bands at that time, but a sentinel effect for everyone.

And just, you know, to clarify a couple of points, prior authorization, it's not an anonymous bureaucrat or, you know, a computer program or whatever. There are clinicians who answer the phone and talk with the clinicians. When you're talking about prior authorization, one of the concerns you raise in the paper was timeliness. We are in a lot of cases talking about things not provided on the same day anyway, so there's plenty of time. And you can get instant answers on prior authorization and prior notification, and that's what we find using PA and prior

notification for diagnostic radiology we do now.

MR. ARMSTRONG: Let me just make three points, and I'll try not to be too redundant.

First, Glenn, I would just say I thought your expression or your frustration in your description of three areas to focus on captured very well my point of view as well. And the idea of targeted bundling, targeted prior authorization, and reducing payment rates for self-referred services I think are a nice combination of approaches for us to evaluate.

By the way, I would just say I'm not uncomfortable with prior authorization. I think it's less about approving procedures and more about creating a kind of transparency around what is it that we're doing and why. And I think with that spirit we could approach that idea.

The second point I would make is that I love the reference to Brer Rabbit, and it's sort of my version of the Whack-a-Mole, and this is, you know, a perfect example of where you try to affect the system in one place, it sometimes predictably, often unpredictably, pops up somewhere else.

And I think one of the risks in all this, which is

my third point, is that we talk about cost, we talk about utilization, and we throw in a concern from time to time about quality and quality of the procedures and so forth. But it's been so difficult -- and I don't know how we get there, but I will try to repeat this as we go forward through the next couple of years -- so difficult to connect these choices around policy, and payment in particular, to overall health outcomes for the populations that we serve. And I don't presume that just because utilization rates are going up for MRIs that that's necessarily bad if it improves the health and ultimately drives lower expense trends for the populations that we're serving. But so far in this dialogue it's very difficult for us to make those connections, and I think that's a point of view that I hope we can hang onto as we go forward with some of these discussions.

MR. HACKBARTH: Could I just pick up on what Scott said? As I recall the episode analysis that Mark referred to earlier, you know, one of the things that we tried to look at is, well, if you have increased utilization of the MRI, does it result in lower episode costs? And the answer there was no.

DR. BERENSON: I'm not going to disagree with a consensus that I think is emerging here. I'm conflicted on this topic because when it's done right, having the ability to self-refer in a practice I think is a very positive thing for patients for the practice. I mean, I can imagine -- well, I recently interviewed a primary care practice who brings in a colorectal surgeon weekly to do colonoscopies. That's partly to raise revenues and partly it's an underprovided service. It seems to me that's a good thing. Having a physical therapist down the hall I think can be a very positive thing. An orthopedist working with a physical therapist I think can be a very positive thing. It's being abused, and that's the problem here. So I'm sympathetic with not just the broad sweeping approaches but seeing if we can be a little more targeted.

Let me just say a couple of things. I think the results of the payment limits on MRIs and CTs and PETs give confidence around the use of payment policy in this area, and I think we can -- it's conceivable that just sort of identifying the duplicative activities that shouldn't be double paid might get us where we want to be, but it may be we want to go even further if that doesn't get us there,

such that the payment here doesn't become a very profitable business line, but it covers your costs and maybe gives you a little margin, but I think we should look at how to accomplish that. That would be my goal for organizations that are going to be self-referring.

I'm sympathetic to a clinical integration exemption, but, again, one of my recent interviews with an absolutely integrated multi-specialty group practice of a hundred-plus doctors, the executive director of it told me that the way they did very well through this past decade was by bringing in advanced imaging and billing the hell out of it. That's what they were doing. They brought in other services as well, and so even though I think they were probably a great practice, they were abusing this fee-for-service system. And yet I don't want to -- because I think when it's done right, it is something that should be encouraged. I am trying to figure out how to do this in a clinical -- so prior authorization I'm attracted to. In the imaging area, there are actual organizations -- I know Mass General is one that does their own, they have their own software with their clinical algorithms, and it may be that we could do -- I mean, to me a true integrated organization

is not only clinically integrated but administratively sophisticated. And it may be we could set up a delegation opportunity for those organizations if they can adopt themselves. It's not enough in my mind to just have a good EHR. I mean, they've got to be using it to address the appropriateness issue that Ron raises.

So it could be that the prior authorization is there as the default and that there's an opportunity for an organization to sort of demonstrate that they can manage utilization and not abuse the fee-for-service system, and how exactly we work that out I'm not sure. I'm not endorsing the Mass General model or anything, but I believe at least in clinical imaging the technology does exist for organizations themselves to essentially police.

I'm a little more skeptical that we really know what the impacts are going to be of packaging and bundling, like the concern about stinting that Mitra raises, but I think we should explore that. And I think it's easier with lab tests and things like that than an MRI. My hunch is that you would -- just like DRGs has one payment if you do the surgery and a different payment if you don't do the surgery, my sense is we would wind up with one payment if

you do the MRI and another payment if you don't do the MRI. We've got to -- because a single payment isn't going to do the trick, I think. So I think there are some tricky issues there, but it's absolutely worth pursuing.

MR. KUHN: On the issue of prior authorization, just a couple thoughts as we begin to think about development of that as a policy option.

First of all, on the Medicare program, on the fee-for-service side, prior authorization, to my knowledge, is not used anywhere in the program except in the area of fraud. And so for a management tool, this would be very groundbreaking in terms of the Medicare program where you would introduce prior authorization for the very first time.

The second thing that we really need to think pretty hard about on that one is the impact on the beneficiaries. Beneficiaries have never really been told now when they go into a physician's office. And so, you know, think of the conversation a physician would have with their beneficiary that said, "Well, I think you ought to have this test, but Medicare, the government, says no." That could start a whole set of conversations. Plus I think we need to think pretty hard about what is then the appeal

rights of the beneficiary to appeal that decision by the prior authorization organization that's out there. And does this go all the way to an ALJ? Or, you know, what is the process here? So if we're going to go down to prior authorization, I think we need to think pretty hard about the impact on beneficiaries and understand specifically the appeal process that's out there.

The second issue in terms of the pairing and packaging, I was at CMS when we did both of those. I'm a big fan of both. I think they make a lot of sense. On the pairing, I think there were 11 families of imaging services that we were able to deal with the contiguous body parts, and on the packaging in '08, I thought that was a good initiative to move forward.

Two thoughts on that, though. First, I think, if I remember right -- and we can look at this, Ariel, to make sure this is correct -- CMS pretty much exhausted all the easy ones to do. I think what's left is going to be pretty tough, and so I don't know how much more gain there is there. So that would be worth looking at.

The other thing on the policy side we're going to have to think about is what do you do if you do make these

changes. Under current law right now, it's budget neutral, so all those dollars go back into the outpatient payment system. Or do we want to make recommendations that the Medicare program harvests those savings for deficit reduction or whatever the case may be? So, again, that's one that we'll have to think about.

The third area I would point to is one that Tom Dean actually raised yesterday, and it was interesting. I was listening to Ariel's presentation, and it just kind of dawned on me. If you remember, yesterday Tom was talking a little bit about a provision in the current outpatient rule that's going to require direct supervision for a whole series of outpatient procedures that are out there. If you think about in a physician office, particularly for therapy services, there's not direct supervision. So one of the things as we think through this policy, would there be an unintended consequence with a current regulation that's going through the process right now, would that have the effect of moving site-of-service changes for outpatient therapy services to move from the outpatient to the physician office because of that direct supervision?

So as we continue to think about these policies,

let's also look at what's going on with the active consideration of that outpatient rule right now and would that have the impact of a site-of-service shift that we could see in the future.

DR. NAYLOR: I'm listening to everybody, and I'm kind of going over that list, and sort of checks and then scratches off of the different feasibility of the different options up there. One of my concerns is what's the burden on CMS and the various administrative overhead and what's the kind of cost/benefit of -- you know, what will it cost to implement that policy versus the Tar Baby approach, the problem of getting, you know, stuck and having to get deeper and deeper in the muck? So it would be helpful -- and I don't fully appreciate what it would cost or what the benefits are of a prior authorization program, but also the potential for a very nasty interaction with the beneficiary doesn't appeal to me, although sometimes it's the doctor you're really trying to get to, but they can get at you through the patient. So I think that is something you have to be nervous about.

About the only thing up there that I think fits right in with what we do normally is reducing payment rates

for tests based on the fact that there's overlap, you know, that they're repeating -- they don't need to talk to themselves and get acquainted with the patient again. I mean, that one, as long as it's not too hard to do, I think should happen. But I'm kind of worried about diverting a whole lot of attention to the short-term -- kind of where you guys were, to the short-term fixes for things that could -- will probably be fixed ultimately by this whole issue of bundling and ACOs and medical homes. I mean, one hopes that over -- there should be a lot more effort put into the longer-term solution than into the sort of short-term stopgap. You know, it's obviously a trade-off, but I'd favor doing less now in the short term in order to do more in the long term.

Then my last thought is on the outpatient therapy. I mean, radiation therapy is one thing. That's a big piece of equipment, and I can't imagine people giving radiation therapy unnecessarily, but it's kind of scary to think about, but maybe they do and that's really where you do need appropriateness screens. But on the physical therapy and the OT and all that, I don't really think there's huge synergies to having it be in a doctor's office. And as I

understand it, the profession doesn't either -- at least the professional association doesn't either. And I guess I'm wondering why that's grown so much. It really has grown a lot in the last few years, and maybe that's the one place where there's just no real reason to have it owned by a doctor. You know, there's no reason a physician can't work with other physical therapy practices in their community and say, you know, I'm an orthopod, here's the things I like to see happen with my knee replacements. But I just don't se any value, really, to having a physician own a physical therapy practice myself. I guess I'd like to know more about what the APTA has said about that. I know they haven't been happy with physician-owned practices and the volume that that's generated. So maybe that's the only one maybe we should just automatically exclude unless there's some really good reason for physician ownership.

DR. STUART: Well, first off, I'm going to add my vote to my peers in saying, yes, the Hippocratic Oath is right. The first thing we should do is not do any harm. And what I hear is all of the ways that we might do some harm in terms of unintended consequences. But it comes back to the issue of we're not sure what we're buying here. And

I'm reminded of the conversations that we had around the home health care benefit in the sense that it -- in one sense it's almost the same when we're talking about therapies. We're not sure what these therapies are actually doing for the patient, and this is what prompted my first-round question about what do we know about what we're buying here and whether that differs from the services in another setting.

In the home health area, we had a number of conversations about pay for performance and about outcome measures that we could tie to payment. And I would think here that that's something at least that we should be adding to the list. I don't know how much we know about this, but we have learned about the productivity of therapies in terms of reducing physical functioning -- or improving physical functioning, rather, and so that's a way we might go. We've already talked about some areas that seem fairly well established. MRIs for lower back pain is a no-no. There are some things that clearly ought to be done that I think we might at least think about developing a list for -- if not pay for performance, you know, some offshoot of PQRI, something that focuses on outcomes in terms of what we're

actually buying here.

MS. HANSEN: Well, first of all, I'd say that colleagues on the other side of the table here have pretty well expressed the key points, and I also would probably condition my comments also relative to the background that I bring since I lived under full capitation for 25 years, had collocated services from physician services to dental services to make it, again, easier for the beneficiary who would be frail, just to make their life better, but we didn't have financial incentives to create more services. In fact, just as an anecdote about being cautious about standards of care, I still remember actually going toe to toe with the State of California over the standard of expectation of an air contrast barium enema for a woman who was 63 pounds and 93 years old and just saying that that's not something we would do because that isn't necessarily quality practice, even though it was on the books at the time.

So it brings me back to the whole comment that several of you have brought up about quality, and I think it was raised initially by Herb and then also by Kate and others of you on the other side. If we could really have

that as part of the context, I think about access, value, and quality, especially with the whole question of the amount of radium that people are exposed to sometimes overusing CT scans as a frequency as compared to sometimes routine X-rays. So if we could just begin to bring some of that literature in, coupled with the work that we did back in 2008, that would be great.

Thank you.

MR. GEORGE MILLER: I agree with Jennie that most of what I've been thinking has been said already, so I do want to echo that, you know, I think part of our responsibility is to look out for the beneficiary to make sure there's quality and value and access.

I am drawn to the statement made in the reading that you shared, though, that we are concerned about the mispricing of services because of the fee schedule and the fact there's inequity in the payment system and somehow we have to address that. But then I'm reminded with Michael's example that we've got to be careful in how we try to fix that, whether it's through prior authorization, which has some appeal, or bundling, as you mentioned, Glenn, which I think has some appeal.

I think that the problem is we do have abuse in the system, abuses because of the fee-for-service system. We just don't know where that abuse is specifically and how to address it. So I certainly would like to see more studies so we can be very, very definitive. But the current fee-for-service system does create an opportunity to generate additional revenue, not necessarily because of quality but because you can generate more revenue. So I'd certainly like to see that addressed before we make decisions on what's the best course of action to take.

MR. HACKBARTH: Okay. We are about 10 minutes over time. This is not the last time we're going to talk about this topic, so if you can really keep your comments focused, I'd appreciate it.

DR. BAICKER: That's a lot of pressure to say something important.

MR. HACKBARTH: Yeah, right. That's exactly how it was intended, Kate.

[Laughter.]

DR. BAICKER: I'm rattled now.

In thinking about the incentives that we're creating, I agree with everyone that the goal is to foster

appropriate use of care, and we should in some respects be neutral about where that's delivered. We don't really care if it's appropriate and we want to create incentives ideally such that the provider is choosing to provide the service if and only if it's appropriate. And the challenge there is, you know, that clearly highlights the advantage of eliminating overlapping payments. If it's more lucrative for a provider because he or she is getting double paid for essentially the same thinking, we want to eliminate that.

The challenge is that there's no bright line of appropriate versus inappropriate, and what we struggle with is surely there aren't a lot of providers saying, well, radiation here is not warranted at all, but I could make some money so let's do it. I don't think anyone's doing that. I think there's a very gradual diminishment of appropriateness, and people are drawing the line in different places. And that's really hard to price appropriately because it's so subtle and continuous, and our pricing is not continuous.

So as a first step to thinking about that, I would love to see more information on appropriateness as measured by differences in patient characteristics either pre-

existing utilization in health or other predictors of the probability of a patient getting this particular service and how that -- given his or her existing characteristics, and how that varies across providers who have an ownership stake and who don't have an ownership stake. And if you see a big gradation in the appropriateness of the patient on a continuous scale across these different settings, then that's a flag that we have an even bigger problem in terms of incrementally too much being done versus the incentives being small enough that it's an issue of overpayment but not an issue of changing inappropriateness.

As a side note, the intriguing thing about the targeted prior authorization is -- I think it would have a very strong psychological effect not just on the marginal services of those physicians who are subject to the prior authorization, but on physicians who don't want to suddenly fall into the bucket requiring prior authorization, that interactions with private sector research partners suggest to me that those incentives can be just as strong as the financial ones. You don't want to be labeled as the overuser who has to call Medicare every time you want to do something, and that might provide some social stigma that

could be very productive in terms of modulating provider behavior.

[Off microphone] There, I'm done.

MR. HACKBARTH: And it was important. Thank you.

DR. DEAN: I agree with everything that's been said.

[Laughter.]

DR. BORMAN: The way I would think about this a little bit is that we've got three things going on: we've got increasing volume, we've got the issue of the influence of ownership, and we've got the problem of appropriateness. It would appear to me that on just purely the volume side, we've kind of done some of the payment -- pulled some of the payment levers, and I'm a little concerned that we don't know yet the entire fallout of that as evident by the data we don't have and the things we can't tease out. So I'm a little more reluctant to say doing more of that before we know those answers is a good thing.

In terms of the conflict of interest piece, frankly, I think in the end that these things, Glenn, as you point out, kind of hit everybody and that our work on conflict of interest and disclosure in the end is probably

the more fruitful place that we're going to get to deal with some of that ownership overlap issue. I think payment can be helpful in that and can be a secondary lever, but I think we need to recognize that for what it is as a piece of the conflict of interest, the whole big issue.

So that sort of leaves us with the appropriateness piece, and that's where I guess I would deviate a little bit from the enthusiasm for prior authorization, and I'll come back to why in just a minute. But I first would suggest sort of the Nick Wolter idea that we need to look at in terms of target high volume, high use, high cost. Pick out the five things that cost Medicare the most and figure out where in each of those there's one of these kind of challenges and try and deal with those in a very targeted way, and that may mean packaging in one place and some other modality in another. But let's do it in a way that's driven at the things that -- the conditions that cost Medicare the most, because then we have an opportunity to combine appropriateness and cost, maybe.

My personal concern with prior authorization relates to my own experience when laparoscopic cholecystectomy was a new procedure, and our North Texas

Medicare intermediary actually instituted a prior authorization program, and we had to call Austin. It was not staffed 24 hours a day, so if you needed to do a cholecystectomy for acute cholecystitis at 2:00 in the morning, there wasn't anybody to talk to, it was a little bit of a problem.

There were also issues that the person we were talking to, other than the persons that Mitra describes in terms of being peers and knowledgeable people, appeared to be at best a high school dropout a fair amount of the time. And we all fairly quickly learned that there were a couple of buzz words that you could say that would make the person on the other end of the phone sort of short-stop the conversation and say yes. And when they analyzed the program, something like 95 percent or more were being approved, and it really was not very helpful.

So I would just caution that prior authorization has to be done in a very carefully crafted way to get the kind of outcomes that you want; otherwise, it's very easy to get to a wrong place. So I would just say before we necessarily say that's a great thing, maybe look at the high-volume, high-cost diseases and say is that a technique

we could apply to those.

MR. HACKBARTH: Okay. Thank you, Ariel.

As we shift --

[Recording equipment failure, Mr. Hackbarth's comment was not recorded - approximately two minutes.]

MR. HACKBARTH: -- just part of the weighing that needs to be done.

Okay, David, lead the way on accountability for DME, home health and hospice.

MR. GLASS: Thank you.

In this presentation, we'll pull together some findings from our work on geographic variation and from our sector-specific analyses related to accountability for three services: DME which is shorthand for Durable Medical Equipment, orthotics, prosthetics and supplies; home health and hospice. Today is an introductory discussion. If the Commission wishes to consider specific recommendations, those would probably be developed in detail in the specific sectors.

So why are we looking at these three sectors?

And let me say that first of all we are not disparaging these sectors. They could all be of tremendous

benefit to beneficiaries, and they play an important role in the Medicare program. So we're in no way minimizing their importance.

They also may not be the only services we should look into in this way. For example, we're just beginning to investigate Part D, and there may be similar concerns there.

But today we're looking at these three sectors for the following reasons: First of all, they share some characteristics that contribute to vulnerability for fraud, abuse and overuse, and we'll get into those shortly. They show patterns of aberrant service use. And in high use areas, these services do not appear to substitute for other services, or, more technically, they're all positively correlated with the use of remaining services.

So our hypothesis is that greater accountability could decrease inappropriate use and slow Medicare spending growth.

So let's look at some of the characteristics. First of all, physicians prescribe, but others generally deliver the care in these areas. For example, a physician prescribes a home health episode. Nurses, therapists, home health aides deliver the care. The physician does not have

to be involved. It does not require continuous physician involvement or any of the physician's time. Hospice can have more physician involvement depending on the circumstances.

They also require little capital investment in facilities. So entry is not constrained by the need to raise large amounts of capital as would be necessary for a hospital or other facility.

Services in these sectors are delivered at the patient's home for the most part, not at a facility, with some exceptions for hospice. In the extreme, DME suppliers at one point could operate from a post office box. They now need 200 square feet of storage area and a business address that one could visit during business hours, but still very limited capital is needed for entry.

On the cost-sharing side, DME has 20 percent cost-sharing although supplemental insurance often covers it, which is why the ads on TV always start out "If you have Medicare, this is of no cost to you." There is no cost-sharing for home health, and hospice has very little. Specifically, patients who receive respite care are liable for 5 percent co-insurance, and hospices may choose to

charge co-insurance on drugs not to exceed 5 percent or $5 per drug.

The point is that these services generally do not need physicians' time, so they aren't constrained by the supply of physicians. Their supply is not constrained by a need for capital, and beneficiaries have little incentive not to use the service. Taken together, these characteristics may make these sectors vulnerable to overuse.

One interesting thing is we found in our work on geographic variation that spending on these services can change the pattern of overall spending, and this is somewhat surprising because they are a small share of spending overall, only 14 percent taken all together. But they can be as high as 24 percent of spending in the top 10 MSAs with high spending in these 3 services, and we also have noticed that they increase relative service use most noticeably in high use areas. For example, Odessa, Texas, the MSA there is 18 percent above average in service use with these services, but it's really only about average if you just look at all other services.

So we can look at this graphically on the next

slide. To get oriented, this graph shows the percent of beneficiaries on the Y axis who live in MSAs, with the relative service use shown on the X axis.

The yellow bars are total service use, which is all Medicare spending adjusted for prices, special payments and beneficiary health status. This is similar to what we reported last December, except we're here just looking at one year of data, 2006.

In the right-hand detail, the 3 bars, 15 percent above the average have about over 5 percent of the population in them.

DR. STUART: The green bars?

MR. GLASS: I'm sorry? The yellow bars.

DR. STUART: The green bars?

MR. GLASS: Yes. Well, here they are, as if by magic.

[Laughter.]

MR. GLASS: So on the green bars, we've removed DME. We've removed DME, home health and hospice from the total and looked at the distribution of service use for all the remaining services, again price and risk-adjusted.

The distribution pulls in toward the middle with

over 50 percent of the beneficiaries now living in an MSA, with use within 5 percent of the national average. For example, the last green bar, which represents per capita service use for beneficiaries in Miami, is just over 125 percent of the national average. Including all the services, it was nearly 140 percent which is the yellow bar at 135 plus. Altogether, only 3 percent of the population is now over 15 percent greater than the national average.

We're looking at the extreme values because we're concerned with overuse, fraud and abuse. What this is saying is that spending on these services is exacerbating regional differences, particularly at the high end of service use.

When we look at variation for these services individually, we see some startling patterns. So these data are price, but not risk, adjusted because we did not want to assume that the HCC scores that we use for risk adjustment, which were designed to explain total spending, would necessarily be accurate for adjusting individual services.

Looking at the first row, DME, most of the population is between 0.7 and 1.25; that's the 10th and 90th percentile of the national average. But the extreme use is

3.4 times the average.

Home health has a wider range for the 10th and 90th percentile, from 0.47 to 1.76, but goes over 7 times the national average at the extreme, which is McAllen, Texas. Some of you may remember Atul Gawande's New Yorker article on Medicare spending in McAllen in the entrepreneurial Medicare culture he found down there.

Hospice has a similar spread for most of the distribution. In the extreme value, it's about 3 times, not quite 3 times the national average.

Now for reference, total service use varies only about 2-fold from minimum to maximum, and the maximum is about 1.4.

In our report on regional variation, we noted that some variation was so extreme it raised questions of fraud and abuse, for example, this data from South Florida. Miami-Dade is just way above its neighboring counties in spending on DME per capita, 10 times as high as Collier County, for example, and the national average is about $250. So, on the face of it, this is just incredible.

In fact, CMS has long been concerned with DME fraud in general because barriers to entry are low, the

number of suppliers is high and prices are high. Miami, in particular, has been of concern. After an anti-fraud task force went to work there in 2007, which is after these data, claims for DME decreased by 63 percent in 1 year.

Unfortunately, historically, victories over fraud tend to be short-lived. When attention waivers, fraud returns or those perpetrating the fraud move to other sectors or cities. The HHS OIG Chief Counsel testified recently that as law enforcement cracks down on suppliers fraudulently billing for DME the suppliers have shifted to fraudulently billing for home health.

So let's look at home health. Again, there seems to be evidence of aberrant service use at the extremes, and we want to emphasize again we're focusing on the extremes in this exercise. We're not saying every area is like this or that home health does not provide important benefits to beneficiaries, but the extremes' use is very high as you can see.

Now in some counties, over 35 percent of beneficiaries use home health, and they can average over 4 episodes per user, and in some counties there are actually more home health episodes than beneficiaries.

In addition, we note that there's high correlation between the percent of beneficiaries using home health and the number of episodes per user, which is another way of saying that the more people using home health in the area the more home health they use per person.

So the Commission has noted these problems, and last March we recommended that the Congress should direct the Secretary to review home health agencies that exhibit unusual patterns of claim for payment, and Evan will review how the law has changed in this sector when he talks about home health later this year.

Hospice also shows patterns of aberrant use. In general, a higher percentage of decedents using hospice is looked upon as a reflection of access to the benefit. So Ohio, at 48 percent of decedents using hospice, is higher than the national average of 39 percent, and Mississippi, at 35 percent, is a bit under the national average.

What is somewhat surprising is that spending per capita relative to the national norm is much higher in Mississippi than Iowa. Digging a little deeper, we see that 39 percent of hospice stays in Mississippi were over the 180-day presumptive eligibility period versus about 16

percent in Iowa.

In addition, 55 percent of hospice discharges in Mississippi were live discharges versus 13 percent in Iowa.

So it seems very unusual, and we can conclude that the use of the hospice benefit is very different in these two states and that perhaps some hospices may be admitting patients before they meet the hospice eligibility criteria.

In response to findings of this sort, we recommended a series of steps in our March 2009 report, which you have in your mailing material, and Kim will report on progress on these recommendations when she reviews the hospice sector later this fall.

So who should be held accountable? Given that we've demonstrated patterns of aberrant use, who should be held accountable? The provider of the service, the physicians who sign the prescription or certify, or the beneficiary, or perhaps some combination?

It could be that there are different answer, depending if the aberrant use is from fraud, in which case the provider could be the focus and the physicians and beneficiaries could play a sentinel role, or overuse, where all three may need to be accountable. So let's look at each

in turn.

For sure, the provider of the service, the DME supplier or the home health agency or the hospice, must be held accountable, and anti-fraud efforts generally focus on the provider. The OIG and the Department of Justice have set up joint task forces in six cities to attack fraud, and they've had some success. But they often have to chase after, rather than prevent, fraud. And, as we said, providers can switch either to different sectors or to different regions, and it's always difficult to maintain pressure.

Another approach is stricter rules on what providers can enter the program and bill Medicare. For example, CMS has progressively tightened conditions of participation for DME suppliers. They now need a real address, they have to be open for regular business hours and have a storage area. They also have to post a surety bond, be accredited and now licensed in the state as well.

It could be solutions will differ by market. If there's a massive supply of some service, perhaps CMS could put a moratorium on new entrants.

Another approach is through payment policy. For

example, as the Commission has often recommended, policy can try to remove opportunities for inordinate profit by bringing payment rates closer to cost. Or, change can be more radical. For example, competitive bidding for DME not only lowers prices but also puts more financial requirements on suppliers and decreases the number of suppliers in an area.

All these services require some physician involvement at initiation. Home health and DME require a prescription or plan, and PPACA requires that the physician or MP or PA have had a visit within the last six months with the beneficiary. Hospice requires attestation that the beneficiary is eligible for the benefit by two physicians, the attending and the hospice physician, and the hospice physician is responsible for recertification. But the physician has little incentive to rigorously review the initial request or reassess ongoing use or consider alternatives to the service and often has little involvement after the service is ordered.

So could that incentive be changed?

It could be just making physicians aware of their patients' use of these services would be helpful. Knowing

one's patients were using these services at very high rates might changes one's habits, particularly if CMS started to ask questions.

Or, there could be steps to require greater involvement in the benefit, more frequent face-to-face visits, for example.

Another approach to changing incentives could be through ACOs or bundling. ACOs will include primary care physicians who will be accountable for all spending including on these three sectors, and they'll have an incentive to keep spending down, so they might want to refer to responsible providers. And the incentive exists because if service use is high the ACO will not get a bonus, but how strong that incentive will be is unproven, as we discussed yesterday.

It could be that regulations will need to allow for referrals to particular providers, for example, for home health. I think now regulations prevent discharge planners from saying go to this particular home health agency. Instead, they have to just supply a list of nearby providers.

So there is much to be worked out with this

concept.

Bundling would include payment for these services within a larger episode. For example, a hospital admissions bundle could include post-acute care. If a physician hospital team is paid the bundled rate, they will have an incentive to use post-acute care in combination with hospital care in the most cost effective manner. In a simpler example, which I guess we should call “packaging,” not “bundling,” perhaps a pair of crutches could be included in the rate for treating broken foot, or diabetes test strips and glucose meters could be bundled with treatment for an episode of diabetes.

Beneficiaries have a role in anti-fraud activities. There is a program to recruit beneficiaries in the Senior Medical Patrol and to train them to scrutinize their Medicare summary notice statements for questionable billings. There has been some success though it’s a little difficult to measure. In high fraud areas, these Medicare summary notice statements can be issued monthly instead of quarterly to provide more rapid feedback, but then beneficiaries don’t like to be swamped by even more paperwork, so some tradeoffs with that approach.

And finally, we could revisit cost-sharing for some services. Cost-sharing can make a beneficiary aware of the cost of a service and has been shown to decrease use of services. To the extent that cost-sharing is offset by supplemental insurance, it loses some of its incentive power. So there could be different rules concerning the first dollar coverage for some of these services. And, as we've discussed, there is no cost-sharing at all for home health and very little for hospice.

We've covered a lot of ground in what is in some sense a new topic for us. Some approaches may be more promising for preventing fraud and others for discouraging overuse, and what works may depend on the market conditions.

So I leave you with these discussion questions:

How can payment systems be changed to decrease incentives to over-provide?

Would more stringent conditions of participation prevent entry of possibly fraudulent or abusive providers?

Should physicians be held accountable for use of the services they prescribe or their patients receive?

What's the potential for ACO bundling or packaging to restrain inappropriate use of these services?

And should we revisit cost-sharing for some services?

Now Evan and Kim are joining me to answer any questions you may have, and we look forward to your discussion.

MR. HACKBARTH: Okay, thank you.

We'll start on this side this time, round one clarifying questions. Karen and Tom.

DR. BORMAN: Just one relatively quick question, do we have a sense that the patterns of use are different when home health, DME, hospice result from an inpatient hospitalization versus when they are prescribed or ordered from an outpatient source?

MR. GLASS: Sorry, we haven't done that in our analysis yet, unless -- have you done that? No.

DR. BORMAN: Because my sense is that, and maybe it's because the nature of surgical practice is I have a fair amount of inpatient care, but it's very easy to get caught up in hospital utilization and some of those kinds of things, and all these things kind of get rolled up to deliver care to shorten stay. And that in the end may be efficient for the system, but I just wonder if there -- it

seems to me there might be a dichotomous pattern. I don't know that, and I think it might just be worth touching base on that.

DR. DEAN: A question about the recertification for hospice and the requirement that that be done by a hospice physician, as I understand it, that requirement has been there a while. I had a long discussion with a hospice director in North Dakota who felt that it was really a huge burden because this was a big, decentralized system that covered a huge geographic area with something like 300 enrollees, and he was the only full-time employee, and it was basically, virtually impossible. I'm not exactly sure how they had been doing it.

But it seems to me that that presents, that requirement presents an inherent conflict of interest. Has that been in place for a long time? And I'm not sure how these programs have used it.

MS. NEUMAN: Yes, that requirement is statutory. So that's been in place for a long time.

And we, the Commission, have made recommendations in March, and PPACA has adopted recommendations to provide some additional accountability for recertification. So, for

example, it is the hospice physician that recertifies the patient. But the Commission recommended, and beginning in January of 2011, physicians will need to do a visit for long-stay patients before recertifying, either a physician or a nurse practitioner.

And in addition, the Commission recommended a medical review targeted at hospices that have very long stays of long-stay patients, and that has also been adopted in PPACA.

So there have been some additional steps to bring accountability around that piece.

DR. DEAN: I remember those changes. Was there any discussion about why it should be an employee of the hospice program?

MS. NEUMAN: I don't know the history of why that was put in place. I do know that depending on the circumstances a hospice physician may be the one who is monitoring a patient's care once they move to hospice. Sometimes the attending physician from the community will continue to follow them, but often a hospice physician will be, or the medical director will be, the one following them. So there could be some practicality considerations, but I'd

need to do some digging to find out the rationale for that.

DR. DEAN: Because that was the problem here. These patients were all being cared for by local physicians, and they only had one hospice physician that covered a large area, and so it was really presenting -- and it was the visit part. That's the part I had forgotten about. That was the part that was really going to create a problem, and I don't know how they've gotten around it.

MR. HACKBARTH: So what you're saying is in the circumstances that you described, of a sparsely population area and long distances, that you could get two benefits with one change. Having a non-hospice physician responsible for recertification would get you out of the conflict of interest and maybe make it easier to do.

DR. MARK MILLER: Just to reinforce, we often heard that the opposite situation was really what was present on the ground. The community physician kind of drops out of the picture after the hospice referral. So we definitely heard the other side of the argument pretty strongly in other parts of the country. Kim, right? Right.

MR. GEORGE MILLER: Have you had the opportunity to talk with any national organizations about this issue and

did they provide you any feedback or comments, particularly about some of these outliers in different states that you pointed out?

MR. HACKBARTH: Which service, George, or just on any of them?

MR. GEORGE MILLER: All three, all three services through national organizations.

DR. MARK MILLER: The way I would answer that is that throughout the work that we've done on home health in this set of recommendations we went through with you the last few rounds, and the hospice recommendations, when we went through that there were extensive conversations.

And I think both the home health and the hospice industries, less so on DME, and we haven't had a lot of focus on DME in the last few years here, but both of those groups have said, you know, what we would prefer is that if you're going to take a look at our industry in this way, that you have targeted approaches that go in after certain actors. I mean all of them acknowledge that there are certain actors out there. So the kinds of things that they feel more comfortable with are things like when you make recommendations, for example, in hospices, on hospices with

100 consistent patterns, they're more comfortable with that than other types of approaches.

MS. HANSEN: Yes, two questions. One is since this is under the overall umbrella of thinking of fraud and abuse, what is the amount that I think that the GAO had originally scored for during health care reform as to how much savings might come about if we took on the topic of fraud and abuse, and then what subset does this potentially represent from that, if we know that?

MR. GLASS: I don't know the answer to that. We can look into it.

DR. MARK MILLER: We can come back.

MS. HANSEN: Sure, just because I know that on the topic level it's a very popular topic, and it also resonates with the public in terms of doing this. I mean I think even 60 Minutes did another story in the past month or so.

And related to that is the Medicare or the Senior Patrol program. Is that a CMS program? And you said there are some mixed results. I was just wondering if you could describe that a little bit more.

MR. GLASS: Yes, I believe CMS runs it, and the idea is to train Medicare beneficiaries to look at the

statements, the summary statements, and notice whether this is something that they didn't have that, they didn't get it, whatever. And they tell them what to do if they find that out. They give them a number to call and that sort of thing. And we can give you some statistics on what the success has been.

DR. KANE: I guess I was going to go back, similar to what Jennie was asking about the beneficiary involvement. Do they get any reward if they find anything? I guess that's one question.

Then another is, as Ron knows, I've actually -- the families often hear things that just don't sound right, like laser surgery will cure your father's spinal stenosis, and there's nowhere to go easily to put down your concerns. You know. You really have to be very persistent about it to find a place to put a complaint in about a provider. So I guess is there any place where beneficiaries and/or their families can go to lodge complaints, that's easy to find and doesn't require 16 calls and being well placed to find them?

MR. GLASS: I think there are fraud hotlines to call if you think it's absolute fraud. If it's something, if someone is claiming they gave you a wheelchair and you

didn't get one or something like that.

DR. KANE: No, no, I'm talking like treatments that are really inappropriate or totally bogus.

MR. GLASS: Oh, that, yes. Again, I don't know on that.

DR. KANE: Yes. I mean it seems to me there are a lot and not just for the DME, but there are fraud issues, and that families might pick up on that. But it's pretty hard, especially if you're not right there, to figure out how to get them to the attention of the right people who will actually act on it. I just wondered if there were programs around that.

MR. GLASS: We can look into.

MR. KUHN: On that last point, the Office of Inspector General does run a fraud hotline that's a very good program and works very well.

A quick question on Slide 12, on the first dot point, particularly for the prescription for DMEPOS that you have there, if I remember right, it was about 4 or 5 years ago that CMS made a pivot from the old CMN, the old Certificate of Medical Necessity, to the prescription. Do we know, do we have any information, that that change from

the old CMN to the physician prescription, has that made a difference in terms of compliance or improvement overall in terms of DMEPOS activities?

MR. HACKBARTH: Could you, Herb, explain what the difference is between Certificate of Medical Necessity and a prescription?

MR. KUHN: Yes. The Certificate of Medical Necessity was a standard form, kind of a template that CMS had prepared but sometimes by the actual DME suppliers, that they could supply to the physician where they could check boxes and sign, and it was part of the compliance process, ultimately in lieu of a prescription. CMS, I think through a national coverage determination, got rid of the old CMN and then moved to the actual physician writing a prescription, hoping that would be better compliance, better physician engagement in the process that was out there.

And I'm just curious if we know if that's materially, if that's borne out what CMS thought at the time, if that would be that much better.

MR. GLASS: I don't know. We can get back to you.

MR. KUHN: Okay.

MR. GLASS: What date did you say it was?

MR. KUHN: I think it was about four or five years ago when that change had occurred.

DR. BERENSON: I'm interested in a question around dual eligibles for the home health benefit. Do we know anything about the interaction between whether states have home and community-based waiver programs, the generosity of those programs and how much then Medicare and the Medicare home health provision? I mean with the theory that maybe in some cases Medicare is used as a replacement for states that aren't providing that. Or, you could argue the other way, that maybe they're both being -- what do we know I guess is the question.

MR. CHRISTMAN: A while back, I did take a look at that, and there has been a little bit of work done on that, but I just don't remember what it said. I'll have to get back to you.

MR. HACKBARTH: Round one, Mitra?

MS. BEHROOZI: Thanks. It's actually on this slide. I should know this. The last major bullet point says "could try to change incentive by." I'm forgetting what the incentives are for the physicians who are ostensibly separate from the service or the product they're

ordering. What is the incentive for the physician?

MR. GLASS: I guess what we're saying is right now there's very little incentive to question the use.

MS. BEHROOZI: Essentially, it's just to make their patients happy. I mean that's like why not? Or, I mean are they allowed to own stock?

MR. GLASS: Well, I don't want to speak for physicians, but presumably right now if the -- well, actually, I was talking to a physician, and he said he does a lot of tracheotomies, and there's some DME that is provided for care of that. He kept getting these from DME suppliers, asking for prescriptions well after the tracheotomy was removed and the patient was fine and all that sort of thing, and they just kept appearing for him to sign. The easiest thing to do of course is just sign the stack of paper that comes to your desk. But he has little incentive to question it, but he of course questioned each one and didn't sign it.

But I guess that's what we're referring to. Right now, there's very little incentive for the physician to put in the extra effort to question some of this stuff, and it's easier to just sign it. That's why we thought the feedback

might be of help.

MS. BEHROOZI: But no particular incentive to order something, that's my question.

MR. HACKBARTH: One of the things you asked was the ownership and how the historic rules apply. Physicians cannot have ownership interest.

MR. GLASS: Yes. Presumably, they couldn't self-refer. It wouldn't be an in-office ancillary or anything like that.

MR. HACKBARTH: Yes, go ahead.

MR. KUHN: I want to think that I don't think there's any ownership. I think the one limited exception, but I could be wrong here, is that if someone gets an IOL and the ophthalmologist can have eyeglasses there or something like that for the convenience of the patient. But I think other than that it's a pretty good barrier.

MR. GLASS: And I think physicians can have crutches in the office and can have a supply closet.

DR. MARK MILLER: Isn't there, and this is truly a question, isn't there one other angle? I mean if the person is sort of getting a medical director, either as part of a home health or a hospice or an arrangement. I mean there

could be things like that, where it's not ownership per se.

MR. CHRISTMAN: Yes. Hospices and home health can hire medical directors. And I believe this, sort of: You do not run afoul of Stark as long as the financial arrangement does not reimburse the physician on the basis of the volume or value of their referrals.

MR. HACKBARTH: Round one, Mary?

DR. NAYLOR: I think this is a really important area of focus, and I'm wondering if it is also like everything else in our system, a moving target. So we have lots of things going on since the competitive bidding, as you reported, that started in 2009, and really major changes in incentives and disincentives that are happening as a result of the Affordable Care Act that will target these areas.

My question then is what are the advantages and disadvantages toward a targeted review? I mean to focus on review as the solution, meaning those that are outside in terms of performance, to really just target efforts in the short term on those providers that appear to be overusing or maybe misusing, abusing.

MR. GLASS: I think that's what we did do in home

health and hospice. Is that correct? Yes, our last set of recommendations.

DR. NAYLOR: So that's been done. Okay.

MR. CHRISTMAN: I guess I would just add sort of two pieces to it, which is that the targeted review, kind of you have to know what to target. So you have to have some idea of what you want to go after.

And I think the other thing that frequently comes up is people want ways to prevent bad actors from getting into the program, and the changes in the Health Reform Act do do some things that do raise the scrutiny that new providers are going to face. So I think those are some of the other pieces.

MR. GLASS: I just wanted to add on the competitive bidding. You know that went into effect, and it was stopped, and not it is supposed to start again in 2011. They started. They've had the competition, but the contracts go into effect in January of 2011. So it hasn't happened yet.

DR. NAYLOR: The fundamental question is: Is there anything else that could be done in terms of improving reviews and actions on, that we should consider as this

field is rapidly unfolding?

DR. MARK MILLER: Yes, and I mean we've tried to make -- if you think about some of the recommendations we've made, we've tried to make recommendations in the payment system to try and take some of the accuracy and incentives out of it. We've made recommendations about profiling providers and then trying to look at the tail of the distributions and try to make changes on the part of accountability for ordering the services.

I think there are still areas that even within those boxes we could continue to think about. For example, the interaction between the nursing home and the hospice is an area that I think still there are some behavior and some multiple payments that might be looked at.

I think another question to ask ourselves here is what about the beneficiary because we're sort of focusing on the physician and the provider. Does the beneficiary provide another point of view and place to have an impact?

And I would say at least on DME there is sort of this sense of yes, we'll do competitive bidding. Maybe. Okay. If that doesn't, if that horse doesn't look like it's going to leave the line, do we want to come back and say,

okay, if that's not going to happen, what should we be doing there?

That's at least some ways to think about what's happening here in front of you.

MR. HACKBARTH: Could I ask about the competitive bidding for DME point? We all know the history of that having been blocked, but Congress did reauthorize it via the Affordable Care Act. Yet, I detect some skepticism about whether in fact that will happen. Is that just general wariness or is there something specific that you know?

DR. MARK MILLER: The former.

MR. HACKBARTH: Okay.

And the discussion we had yesterday, I think we need to be reminded that only applies -- what is it -- 10 MSAs where the competitive bidding.

DR. BERENSON: If I could just say something.

MR. HACKBARTH: Yes.

DR. BERENSON: The discussion we had yesterday, I think we need to be reminded that only applies to, what is it, 10 MSAs, where the competitive bidding --

MR. GLASS: It's nine now, but we'll expand that.

DR. BERENSON: Nine now. So there's the rest of

the DME world which needs attention as well.

DR. CASTELLANOS: Weren't there some changes in the PPACA concerning fraud and abuse, and would any of these changes or issues addressed in PPACA help here?

MR. GLASS: Yes, there's a long list of them in fact, and presumably they will help indeed. We can get into more detail if you want.

MR. CHRISTMAN: I mean I guess most of those things were in areas you would kind of recognize as additional reviews, screening of new providers and things like that.

I think, just like Mark said earlier, the one that it didn't do is make any changes to sort of what the beneficiary might be able to do in some of these situations. There weren't any changes on the beneficiary side.

MR. HACKBARTH: Did the Affordable Care Act do anything to change the funding stream for fraud and abuse activities?

MR. CHRISTMAN: It increased funding for the administrative activities associated with it, and I think that was the big one.

MR. HACKBARTH: Is that via using trust fund

dollars, or?

MR. CHRISTMAN: It was appropriated, yes, yes.

DR. MARK MILLER: Those are appropriated or from the trust fund?

MR. CHRISTMAN: I believe it comes from the trust fund, yes. I'm sorry.

MR. HACKBARTH: Okay. Any others?

Okay, round two comments. Karen.

DR. BORMAN: I want to talk mainly about home health because to me the increase in that, at least in my own clinical practice over the last 15 years, has really been striking.

One of the things is surgeons make wounds. So my most frequent interaction with home health relates to wound care for patients that are being discharged. And the whole notion now is almost if you have an open wound, no matter how small or superficial or easy to get to it is, you get home health visits. It's sort of whether it's discharge planning rounds, suggestions from very good nurses, whatever it may be, there is this impetus of the notion that the patient and family can't possibly cope with any kind of open wound.

And I think we have to be sensitive to what scares people. Wounds are less scary to me than perhaps they are to many of you sitting around the table. But the reality is that lots of wounds that 15 years ago we would have had the family come in, be instructed, say, get one those little attachments for your shower and hose this off, use a mild soap like Dial or Ivory, pat it dry and then put on a clean dressing, now is a twice-a-day home visit for the first two weeks of their discharge.

So I think that to me that says several things. Number one, is there an opportunity to re-engage families and beneficiaries? That sort of translates to number one or the bottom one, revisit cost-sharing, because I think that has kind of been lost in the shuffle, and maybe Medigap kind of makes it to where it doesn't matter. But if the new insurance plans and so forth come in, I do think we need to think about that because there is this default now of providing home health.

Another thing is migration of the home health service a little bit. When I eventually get the full-form initial prescription, it has a lovely, very elegant, very comprehensive patient assessment about a whole bunch of

things that to me don't relate to the home health that I'm authorizing, and it wants to engage in a whole bunch of things about their anti-hypertensive meds or whatever, and monitoring their blood pressure and stuff, which wasn't a problem. The problem is this person has got a wound, and maybe it's a wound on their bottom they can't see, and they don't have anybody to help with. So home health is perfectly legit here as a service, but kind of all this other stuff that ratchets up the complexity and the frequency of the visits, related to all these other stable conditions. I'm not sure exactly how we get to that, but I think there is something about targeting to a purpose of the home health that maybe could lead to better value.

And then that leads me also to the forms. The forms are there are a lot of things crowded into a little bit of space, and given the volume of paper and/or drop-down screens that physicians and nurse practitioners and everybody else now encounter every day the impetus is to kind of move that paperwork, move those screens. So I think in terms of the feedback piece that would help stop the home health that goes on for 52 works for a wound that should have healed in 3 would be maybe the reminder, or the query

piece, was a very simple form and single drop-down screen: Your patient is still getting home health for this wound. When were they last seen by you or have you discharged them from care, or something -- because the forms that I get typically come pre-filled out with 99 years.

There's not a place where they can say forever or until the patient's death, but there is this 99-year box. Okay. And they're always -- when they come to you, they've got the 99-year box filled in.

So I think that simplifying forms, maybe putting in some shorter initial certification periods and maybe revisiting the cost-sharing would be ways to potentially come at it, at least the home health piece.

And I don't mean to pick on home health. It's a wonderful activity, does lots of great things for patients, but we can do it better.

DR. DEAN: This is very interesting because my problem, as the staff already knows, is just the opposite of what Karen described. I mean, I live in an area where home health is not available, and in the whole upper Midwest area, the access to these services has been declining rather than increasing. I think I probably mentioned this before.

I know I've talked some about it. There's at least 13 counties in Minnesota that have no access to home health. I haven't got an exact number. I think it's something similar in the Dakotas and Montana.

And so, I think it just reflects the fact that clearly we don't have the prices right. I mean, we're losing services in some areas, we've got over-supply of services in other areas, and I'm not exactly sure what the answer is. But clearly, we have a problem and it's a concern.

With regard to the prescriptions, those are a real problem for us, especially some of the DME things because, for instance, the ones that I have the most trouble with are prescriptions for lift chairs and prescriptions for scooters and things. These are things that there's a wide range of people could benefit from; and yet, we know that they're not going to meet the Medicare criteria and that may well be appropriate because virtually everybody with some arthritis in their knees could probably benefit from a lift chair. And yet, the Medicare criteria is much more restrictive that that.

So, Herb, I think what happens, we're actually

doing both. We write the prescription, but then we get the questionnaire from Medicare that lists these things and the criteria, at least for a lift chair is, is the patient able to get out of an ordinary chair without assistance.

Well, if you can't get out of an ordinary chair without assistance, for instance, you can't live by yourself, for one thing, and that really limits the thing. But when I sign that, and if I sign it honestly, then I'm the bad guy and it really puts us in a bind. As it came up, there's really no incentive for us not to sign it unless we're worried about somebody is going to come and really check, which isn't very likely, but it does create an ethical dilemma because we know that in a lot of these cases, people really could benefit from these. And yet, from a technical point of view, they don't meet the criteria. So it really creates a difficult issue.

I guess finally, I'm interested in the idea of the Senior Patrol because I think I've mentioned before that I've certainly had patients that come in and complain about getting things they didn't order, and I didn't realize -- I have some patients that would be happy to get involved in that, but I didn't even know it existed. Do you know how

widely that's been promoted? Because I didn't even know it existed, but I think the concept makes sense because some of these folks don't like to see things wasted and they can be pretty tough sometimes if they had a mechanism to do that or to respond.

MR. GLASS: Yeah, I'm pretty sure it's in all 50 states, but I can check.

DR. DEAN: I'd be interested to know because I think it hasn't been promoted very much.

MS. HANSEN: This is just a really short one to build on the last aspect because I think there's always been the question of how the beneficiary role is going to perhaps play into understanding Medicare costs. I think this is a really prime example of something that is very personal for people, and to even look at bills -- because normally they're transparent and you don't have any cost sensitivity.

So this may be a natural opportunity to really look at the effectiveness and perhaps amp up its ability to engage people to have greater awareness of costs and what things are charged about, because otherwise, everything is just totally transparent if you have a supplemental plan. So it just is an example of a way to start engaging the

beneficiary with a vested interest in sometimes a very, probably, investigative interest in terms of not seeing that Medicare money “is wasted.”

DR. KANE: Yeah, I think we’re kind of dealing with two separate issues here and they obviously are continuous variables as, Kate might say, between fraud and inappropriate use. I think it is hard, and I think for inappropriate use, payment systems can do something. For fraud, people are purposely trying to circumvent the system and it’s a lot harder to use legitimate means to try to deal with illegitimate behavior.

But I think the use of the -- that the beneficiary and their families should really be more engaged. I don't think cost-sharing is the answer there, so much as rewarding them financially when they find something, or giving them some share of what they recover or prevent from being spent.

So that would be -- instead of saying, “We’re going to penalize you with more cost-sharing,” I would say reward you for actively seeking out inappropriate billings or inappropriate approaches to use services you don’t need, and that’s what I was talking about when there needs to be a web site for people coming up and hovering around these

senior villages in Florida and saying, you know, having little lunch meetings to sell services that are inappropriate to somewhat unsuspecting seniors.

So reporting those people and then getting some kind of reward for it, because it does take time and effort and, you know, you think twice about what kind of reputation you might be generating for yourself if you turn people in.

The other area that it seems would be interesting to look into is what is direct to consumer advertising doing? I've seen a commercial for every type of medical -- wheelchairs and chair lifts. They play those commercials all the time. And what's that doing to demand and should it taxed or monitored or somehow controlled? Because I think it is -- people are probably going to Tom after they've been watching the TV and they would never have thought of it until someone says, "This is free to you, Medicare will pay," and well, that kind of gets you interested.

So I think the whole -- I mean, what are they saying in these commercials? How well are they being monitored? Are they appropriate? Are they really adding public interest, public value, or are they just jacking up demand that then puts the doctor in an awkward position of

having to say no or say something inappropriate.

So I think that for fraud, I think there's things outside of payment that we really should be thinking about. For inappropriate use, we've got the usual tools that we would use for any service, but fraud, I think, is different.

MR. KUHN: Yeah, on the issue of fraud, I mean, it's pretty clear from the evidence here and the news stories, there is a lot of fraud in this space in particular areas of the country and it's just unconscionable that people are stealing from the federal government and stealing from the Medicare program this way, and also, I think, abusing some seniors across the country in this effort that's out there.

And so, one area that we might want to think about on a go-forward basis is to make sure that or look at the enrollment process, the accreditation process, the bonding process to make sure those are as tight as they can be. And another set of recommendations we might want to think about is any area that we can encourage or help CMS think differently about data mining to help spot this stuff sooner than later.

As I think you said in the presentation, pretty

much in a pay and chase scenario, and if there's a way that with now the new MACS and the Medicare Administrative contractors, and the DMACS, the Durable Medical Equipment contractors and those that are out there, hopefully data feeds from their contractors can come more quickly and they can start to cite these things like the home health outlier issue we saw in south Florida, some of the DME spikes that are out there.

So we might want to look at better surveillance and sophisticated tools that could be used to help that.

The other area we might want to think a little bit about is the perennial problem of mispricing. And we talked a little bit about DME competitive bidding, and the results are staggering. The first round that ultimately Congress overturned across the ten product categories, they got a 26 percent reduction. And then on the second time, they're over 30 percent. It's north of 30 percent. So there is some opportunity there.

But the current pricing scheme that Medicare uses for DME is called gap filling, and basically when a new technology comes in with a current manufacturer price, the fee schedule says that CMS needs to use 1986 dollars. So

what CMS does, through this gap-filling process, is they deflate the product over the past two-and-a-half decades and then re-inflate based on the updates that Congress has granted in order to kind of put us in place where it needs to be.

I think that the fact that we've got a base on 1986 dollars and that we deflate and re-inflate through this gap-filling process is terribly antiquated, and I think looking at that would be appropriate.

MR. HACKBARTH: That piques my curiosity. So where does the 1986 come from?

MR. KUHN: I think that's based in statute and it's never been updated since.

MR. HACKBARTH: It is?

MR. KUHN: Yeah. It's extraordinarily difficult for CMS to do, and you might have years where there were freezes that were less than updates, so that has to be taken. So it's very arcane.

DR. BERENSON: I want to pick up where Karen was talking about that patient who had a wound. The other side of the story is what sometimes happens is the patient has hypertension and diabetes and a bunch of other things and

the home health nurse calls the surgeon who ordered the wound care who says, “Don’t talk to me, talk to the internist.” And so, I get the call and, amongst other things, would find that the list of medications that’s probably been memorialized iss wrong, that they either were wrong when the patient was discharged or I’ve been seeing the patient and have changed the medications, and there’s a real need here for coordination. This is not the time to talk about the medical home and that stuff, but I do think we do need to look more into the role of the doctors. In this case, it may not be the individual doctor, but sort of the -- or the team of professionals. I won’t even say doctors. In many cases, it might not even be a physician.

And we were going down this road last spring, as I remember, and Nancy wisely cut us off because we were going down -- we were sort of -- it was an undisciplined conversation we were having. I think we need to get back to it.

And what I would suggest, perhaps as a place to get some guidance in this area, would be the medical groups who contract with Medicare Advantage plans. The Medicare Advantage plans have to provide the Medicare benefits, the

home health and the DME benefits, and those groups, if they're capitated, have every reason in the world to figure out how to not just automatically sign the thing, but to actually sort it out.

So in your kind of a place or some of the IPAs in California, I think, we might be able to see how this could work well on the ground and then figure out how to translate it back into a fee-for-service environment. But I think we might get some information from those -- from a few of those places.

MR. ARMSTRONG: Particularly given what you just described, Bob, I think the only comment I would make would be that in our markets -- unlike, Tom, yours -- there are plenty of providers. But we are very assertively trying to increase the use of hospice and increase the use of home health, particularly for certain populations of patients who are not getting access and whose health and outcomes would be better if they had more access to these programs. So I offer that only to reinforce the suggestion that you made.

There may be ways in which we can think a little bit differently about this by looking at how, in a different payment structure, some of these solutions are discovered.

MS. BEHROOZI: Just to continue the last discussion into this one a little bit, I feel like we should be thinking about prior authorization or prior notification as a potential tool here. It's maybe not for exactly the same reasons in terms of the question I asked about physician incentives, but maybe -- and of course it couldn't be high school drop-outs who could help with this, but if you have clinicians available at the other end of the line, then maybe in places like McAllen, Texas, where the doctors are like, "Well, you know, every patient expects that I'm going to sign them up for one of these home health agencies that's been out there recruiting, and whatever, and nobody says no so I'm just going to go ahead and sign it."

It's not about disciplining them, but giving them some advice. You know, the standards everywhere else are a little different than they are there. Shaping behavior, not necessarily punitively, but just to add it to the list.

MR. BUTLER: So while I think we can make contributions on commenting on co-pays or physician involvement, I think our principal value is in payment accuracy. I think that we've done a pretty good job on that. I'd just remind us that because the costs of entry

and exit are small, we shouldn't be timid, therefore, about making adjustments in a given year, where in some services we like to phase it and be gentle. Even if we make a mistake in a recommendation, it's one of those areas where you can correct it.

I think that the where and how much is provided, for example, in home health, has changed dramatically based on payment. So there's no reason we shouldn't use that as the principal tool.

Now, as Nancy pointed out, the other issue is the fraud and abuse, which is really a little bit independent of this issue. The only thing that's curious to me is why it has popped up. I wonder what we could learn about why it -- what is it about the climate and the environments of the places where it has emerged? What would we learn from that? Because it's not across the whole country and I'd be kind of interested in what were the characteristics of those communities or whatever that permitted it. Is there a pattern beyond what the IG might find on their own?

DR. NAYLOR: So I'd like to echo Bob's and Scott's comments about we have learned a great deal in the last couple of decades about how to more efficiently and

effectively care for high risk Medicare beneficiaries. And I hope that we would use the opportunity that's unfolding as we think about creation of Accountable Care Organizations or transitional care services that are really richly based in evidence to more efficiently and effectively address the needs.

I agree, we found, in one of our clinical trials, that 50 percent of the people that we identified as at high risk for poor outcomes and were subsequently shown to have an early re-admission had not received home care services because they were not perceived as in need.

So there's a lot of work that needs to be done, both in terms of targeting the right individuals and matching them to the right services, and I think the Affordable Care Act offers numbers of opportunities with the Transitions Act and incentives and disincentives.

So the best, I think, opportunity right now is to engage the beneficiaries. They want to be engaged, their families do, they don't have a sense often about where to call. So this hotline, et cetera, that, I think, just letting them know how it is that they could help the program with communication of information, I think, could be very

helpful.

DR. CHERNEW: I agree that engaging the beneficiaries is important in a number of ways, but I think that actually in this case, some cost sharing is probably important here. There's a lot of cost sharing. We charge people if they have a heart attack for an inpatient admission. We charge them a lot of money. Some modest amount of money to pay for some durable medical equipment, for example, or other types of services, I think, could be useful in an area where it's very hard to know what the appropriate amount of the service to provide is.

I think it's going to be very difficult to solve through payment policy, although I think bundling is a good thing. I think bundling could help. But for just getting the price right, I think, is very hard because I think the bad providers might be lower cost, and we very much run the risk of driving out the good providers and just keeping the bad providers when we try to get the price right in this area, more so than some other sets of services.

So while I think we've done a number of recommendations in some of these areas about how to get the price right, and I think some of the competitive bidding

things show that we were not very close. We've gotten a lot better. I do think for a lot of these services to figure out what's in the social contract with people, you know, how good of a wheelchair are we actually really going to make sure you have for free.

I'm all for a whole series of things, but I think we need to think through exactly what that social contract is, and I do think this is an area where, in some cases, some patient cost sharing is valuable to help control demand, which is really very difficult to control in very difficult situations. And I think the problem with bundling is it does create this conflict between the provider and the patient for things the patient perceives as free, for something the provider is not getting paid for. I think some patient input is important because there's so much discretion and heterogeneity in cost.

MR. HACKBARTH: Okay. Thank you very much. We will now have out -- oh, I'm sorry, Tom.

DR. DEAN: Just a really quick comment about the whole concept of hospice. The Atul Gawande article that you sent out, I think, was really -- it was an eye-opener for me and really made me start to rethink some of this whole idea,

because I thought they made some very important observations in there. I think that we shouldn't lose track of that. The whole structure of the program and eligibility and all those things may need some deeper thinking. I just didn't want to lose track of that because I think that was very important observations that they made.

MR. HACKBARTH: Thank you. We will now have our public comment period, so let me briefly review the ground rules. Please begin by introducing yourself and your organization and please limit your comments to no more than two minutes. When this red light comes back on, that will signify two minutes are up.

And I would remind people that this is not your only opportunity to provide input to the Commission or even your best one. The best way to do that is through our staff. In addition to that, there is an opportunity on our website to provide comments.

MS. SAPHIRE-BERNSTEIN: Hi. I'm Inger Saphire-Bernstein with the American Urological Association and I'd like to comment on the discussion of growth of ancillary services in physician offices. We've been following this issue with MedPAC for several years now and we have

submitted written comments four times, including comments on the June report to Congress.

The staff report today stated that rapid volume growth of imaging and other ancillary services contributes to Medicare's growing financial burden on taxpayers and beneficiaries and it also implied that some office-based ancillaries are not clinically appropriate. The AUA does not agree that growth of in-office ancillaries, particularly imaging, has been demonstrated to have a significant impact on Medicare's financial burden. Especially since implementation of the Deficit Reduction Act, growth in imaging paid under the Physician Fee Schedule has slowed significantly and it fell below the growth of physician services. This slowing continued in 2008, 2009, and we have no more current data to indicate that that situation has changed.

Payment for imaging under the Physician Fee Schedule has been cut significantly, as staff noted, through the Deficit Reduction Act, through changes of payment for practice expense, and other cuts, and CMS has proposed additional cuts to the Physician Fee Schedule for imaging in 2011. We appreciate that staff examined growth in the

number of imaging services and payments under the Medicare Physician Fee Schedule and under the hospital outpatient department. We note that payment per beneficiary was higher in the outpatient department and that the number of imaging services provided in the hospital outpatient department cannot really be determined based on the change in the packaging policy noted in 2008, and that graph that was provided clearly did not note that and it ought to be changed if that graph is going to be used in the future.

We recognize that use of imaging and other ancillaries has been growing in all settings and some component of that use may be inappropriate. The burden on Medicare expenditures is caused by inappropriate use in all settings, not by physician self-referral per se. And so an overhead use of ancillaries is only warranted if the use is unnecessary. The report to Congress in June did note some incidents of inappropriate imaging. However, that imaging was not only linked to self-referral and, in fact, it was -- it seemed those studies cited the highest level of inappropriate use was by primary care physician referral.

We also want to state that we object to the assumption that physician investment in ancillary services

automatically leads to higher volume. We do not feel that any evidence has been provided to demonstrate that physicians order imaging that produces potentially dangerous radiation without medical necessity just to generate revenue, and we see this assertion frequently and it's very harmful to our members.

In our letter of August 3, we cited a study from the Journal of Oncology, the Journal of Urology that documented physician acquisition of imaging equipment had no impact on imaging utilization in a large urology group, and I believe that data has been shared with staff.

So just to wrap up here, we feel MedPAC should address the problem of inappropriate use in all settings rather than focus narrowly on self-referral, and the AUA is making strides in this direction and we're looking at clinical guidance on appropriate use. Thank you.

MS. NUSGART: Good morning. My name is Marcia Nusgart and I'm Executive Director of a number of different coalitions of medical devices used in the home care setting, such as in wound care, respiratory care, enteral nutrition.

First of all, I wanted to commend Commissioner Kuhn. I would totally agree that gap filling needs to be

able to be certainly fixed. But one other area that I would consider or ask MedPAC to consider for greater accountability of the use of DME could come by the reform of the HCPC coding process.

The current process is not transparent, understandable, or predictable, and the current HCPC code set includes broadly defined codes that are ambiguous and imprecise. What does this lead to? It leads to improper payment accuracy for payors and difficulty in tracking outcomes research as well as looking at utilization.

In addition, inadequate coding creates target codes, which you were talking a little bit about today in terms of the fraud and abuse, and it has a potential impact on it. Examples are broad and all-inclusive codes provide these opportunities when the lowest-cost item in a code provides a disproportionately high margin of profit for the supplier. An adequate reimbursement for codes is a barrier which also could lead to fraudulent billing, billing the item used in a code, and oftentimes that's a miscellaneous code that would certainly provide the needed reimbursement. Having an imprecise coding system and using miscellaneous codes creates serious audit issues for the Medicare program.

Since the Medicare program wouldn't be able to prove what code is used for an item, it can't prove they're reimbursed appropriately, and decreases the ability to write appropriate coverage policies.

I'm one of the members of an alliance for HICPIC2 coding reform, which is comprised of over 25 key law firms, lobbying firms, associations, coalitions, medical device companies, and reimbursement consulting firms with expertise in HCPC coding who recognize the need to take action to reform the HCPC coding system. We've had the opportunity to meet with MedPAC staff last year and have also disseminated our fact sheets and significant concerns at one of the MedPAC meetings last year. We would submit that this is an important issue and respectfully request that the MedPAC Commissioners to include HCPC coding reform in a future meeting and a future report to Congress. Thank you.

MR. FRIEDMAN: Hello. My name is Alan Friedman. I'm a board-certified pathologist in anatomic and clinical pathology, and I would like to speak about the subject of over-utilization in laboratory testing.

It seems to be that that's the concern of the committee and it seems that much simpler than changing the

system of reimbursement or changing systems is simply to monitor utilization, which can be simply done, I think, and is a much simpler process than changing the whole system and coming up with all these rules and acts of Congress.

If you simply look at, in pathology, the number of biopsies per patient, that would be a very useful data point to look at. You could look at an in-house lab versus an outsourced lab. You can look at practices that at first had no in-house laboratory and how many biopsies per patient they were doing at that time and then look later to see if that increases significantly. That would be a measure of over-utilization. And rather than changing the system, why not treat over-utilization as a type of Medicare fraud and punish it, and thereby the specter of punishment would decrease over-utilization.

So I haven't heard much to that suggestion and it seems a lot simpler than changing the whole system of reimbursement and studying all these different methods of measuring. In the field of pathology, you simply measure the number of biopsies per patient. Now, different practices will have different standards, but they can be measured in different areas and for different types of

practices and specialties and it's a very simple measure to do. It doesn't take much work at all and it wouldn't cost much, either.

The only other thing is to know whether you're dealing with an in-house or an outsource laboratory and you could have coding in the billing for that, as well.

So I just wanted to make some of those suggestions to point out how much simpler it could be and trying to address over-utilization could be much simpler, and thank you.

MS. SHEEHAN: Hello. I'm Kathleen Sheehan. I'm Vice President of Public Policy for the Visiting Nurse Association, representing nonprofit home health and hospice. And I just want to address briefly the question of what's the climate in terms of what's happening with fraud and abuse.

I think if you look at Certificate of Need, if you did a division of Certificate of Need States versus States where there is not a Certificate of Need, you'd probably see a lot of differences in terms of some of the problems that we've looked at today, and I would encourage you to perhaps do an analysis along those lines.

I also want to mention that nonprofits are very concerned about fraud and abuse. We actually have on the home health side 33 recommendations, which we'd be delighted to work with MedPAC and with Congress in terms of looking at those recommendations. We're also developing it right now for hospice.

One thing I want you to think about as you think about bundling and all kinds of other things is really patient choice. One of the difficult areas that we see right now, and I'll give you a specific example, is you have a patient who's been receiving home health from a community-based local provider that they have a relationship with and they know well, and by the way, nonprofits do a lot with education of patients and family members. That's one of the areas where they really excel. But you have a person who's associated with a home health agency. They go into the hospital. At that point, a determination is made that they need to get hospice. And in many instances, they lose their ability to make a choice. They're basically shuttled from the institution into whatever the hospice is that has been selected by the institution.

So I think as you look at financial relationships

between institutions and you look at bundling and other kinds of things, please remember that patient choice is very important and having a relationship with a community-based provider that works with the family and works with the patient, whether it be home health or hospice, makes a tremendous difference.

So we look forward to working with you, and it is true, I will say, that sometimes the providers that are not doing the right thing may have lower costs and you need to look carefully at preserving a nonprofit delivery system that really serves not just Medicare patients that you sort of take off the top, but that you look at a delivery system that is serving Medicare, Medicaid, and also charity care patients. You want to be sure -- I think that MedPAC has indicated in several instances they are very concerned about the rapid growth of for-profit delivery systems and we are concerned about the survival of the nonprofit delivery systems. So I ask you to look at that in your analysis. Thank you very much.

MS. TOWERS: I'm Jan Towers with the American Academy of Nurse Practitioners and I'd like to pull you out of the box just a little bit and make a comment about the

fact that much of the focus that has been placed on fraud and abuse has created some unintended consequences in that it actually is putting us in a position of being prohibited from doing the kinds of things that we could do in relation to home health care and hospice in terms of authorization for services.

One of the things we talk about is physicians who are signing these things and not looking at the patient, and part of that is because they're so busy that they don't really have time to do that, and yet we will not utilize nurse practitioners who would be able to actually do evaluations and perhaps make better judgments in terms of who needs care and who does not care [sic] that are highly qualified, so I would ask you to think about that as a solution to part of your problem.

MR. HACKBARTH: Okay. Thank you.

We are adjourned.

[Whereupon, at 12:12 p.m., the meeting was adjourned.]