MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, November 6, 2014
9:40 a.m.

COMMISSIONERS PRESENT:
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JON B. CHRISTIANSON, PhD, Vice Chair
SCOTT ARMSTRONG, MBA, FACHE
KATHERINE BAICKER, PhD
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AGENDA PAGE

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

MR. HACKBARTH: Okay, good morning. We kick off this morning with the very first installment of our annual work in preparation for update recommendations.

Jeff?

DR. STENSLAND: All right. Today we're going to begin MedPAC's discussion of Medicare hospital payment adequacy. Each fall we evaluate whether Medicare hospital payments are adequate using a standard framework. As we did last year, we will present our evaluation of hospital payment adequacy in two pieces. In today's session we will discuss beneficiary access, changes in hospital service volume, access to capital, and we'll also explore the relationship between volume change and costs per unit. In December we will return to talk about quality, costs, and payments.

First, Zach is going to walk you through our hospital access measures. He'll discuss how declines in admissions per capita are driving lower occupancy and how that may be contributing to the slight increase we see in closures.

Second, I'll describe a new analysis assessing the

how the declines in volume we've seen in recent years could affect costs per unit of care.

Now I'll turn it over to Zach.

MR. GAUMER: Okay. Good morning. Total inpatient admissions continued to decline as outpatient visits increased. Between 2006 and 2013, there was nearly a 17 percent per beneficiary decline in inpatient admissions. But within the last year, inpatient admissions declined 4 percent per beneficiary. The trend in inpatient utilization may suggest patterns of care are changing broadly in the United States. We observed similar patterns across different Medicare beneficiary age groups and in different geographic regions. We also see similar patterns in patients with Medicaid insurance and commercial insurance. During the same time period, outpatient utilization has gone in exactly the opposite direction, as you can see, increasing 33 percent per beneficiary, with an increase of almost 4 percent in 2014.

The trend in inpatient bed occupancy rates has tracked with inpatient utilization declines, suggesting that the amount of excess inpatient capacity is increasing. On a national level, from 2006 to 2013, hospital occupancy rates

declined from an average of approximately 64 percent to 60 percent. This statistic demonstrates that there is currently a relatively large volume of unused hospital beds in the marketplace, maybe as much as 40 percent. On average, urban hospitals have higher occupancy rates than rural hospitals, but both demonstrated declining occupancy rates over this period. So there appears to be excess capacity in both places. There is also wide variation in occupancy rates by market. Most notably, about 15 markets in the United States had average hospital occupancy rate exceeding 75 percent.

So the aggregate impact of the hospital closures and openings in 2013 was nine fewer hospitals and approximately 1,100 fewer beds in the marketplace. This amounts to 0.1 percent of all hospital beds, and because it is such a small proportion of the marketplace, we do not believe it will harm beneficiary access. In addition, given the utilization and occupancy trends. In addition, given the utilization and occupancy trends, we might anticipate more beds being eliminated from the marketplace in the future.

Specifically we observed 27 hospital closures in

2013. This is approximately 0.6 percent of all hospitals. These facilities were relatively small. Their occupancy rates were low, at 32 percent. Their low occupancy was associated with poor financial performance, as their average all-payer profit margins was negative 5.7 percent in 2012.

On the other side of the coin, the 18 hospitals that opened in 2013 were similar to others that we have seen open in recent years in that they were very small and they tended to focus on a small set of services. Some of these are traditional specialty hospitals, but the others are something new. They're small facilities offering a limited scope of services. They all appear to offer emergency room services, surgical services, and outpatient clinics, and several offer rehabilitation services as well.

Over the course of the last year, you may have seen reports in the press about rural hospital closures. This is a subject we continue to monitor.

Rural closures are happening in the midst of excess inpatient capacity as well. On average, rural hospitals saw occupancy rates decline from 47 to 41 percent.

Throughout the majority of this time period -- that is, from 2006 to 2012 -- rural hospitals were actually

underrepresented in the universe of hospital closures.

In 2013 the relative number of rural closures increased to 13 facilities, but this is proportional to the share of all hospitals that are rural.

The most notable characteristics of these hospitals are that they were on average 27 miles from the nearest hospital and that nine were critical access hospitals.

We observed that a portion of these hospitals remained open either as urgent care centers, emergency departments, or other types of outpatient clinics. It is positive thing that a health care footprint remains in these rural areas, but what is most important for access is that emergency capacity remains.

Turning to capital or access to capital, overall the hospital industry appears to have maintained access to capital in recent years. Equity markets continue to see hospitals as an attractive investment as indicated by the fact that the three largest for-profit hospital chains say their stock prices increased by over 25 percent in 2014. Many nonprofit hospitals demonstrated strong access to capital by issuing $18 billion in bonds in 2013, and in 2014

we continue to see bond interest rates that are extremely low. However, there are many nonprofit hospitals that lack access to capital markets. Exactly how these facilities gain access to capital for expanding or maintaining their resources is somewhat unclear. Some of them may merge or partner with larger hospitals or systems. And along those lines, we continue to see increases in this type of activity. In 2013, 283 hospitals merged or were acquired. This is the most in the last seven years, and it has been driven largely by the largest for-profit hospitals acquiring smaller entities.

Hospital employment had been growing significantly faster than the rest of the economy from 2008 to 2012. But in the last 18 months, hospital employment has continued at a stable rate. During this time hospital employment has grown slower than the rest of the economy.

Hospital construction spending continued at a high level in 2013 and 2014. The slight decline in the last two years may be attributable to the growth in excess inpatient capacity and the general shift towards building outpatient capacity. Industry reports state that hospitals are currently more focused on building outpatient capacity, such

as medical office buildings and outpatient clinics rather than building new inpatient beds, as they did four or five years ago. In addition, several other industry reports have detailed both hospital and non-hospital entities investing in urgent care centers and freestanding emergency departments. These two types of facilities appear to have grown rapidly in recent years.

In December we will also provide you with more information about hospital quality trends to complete our analysis of access.

And now Jeff will take you through one of our newer analyses.

DR. STENSLAND: Okay. So Zach just explained how inpatient volume is slowing and how occupancy has declined about four percentage points in recent years.

A common perception is that most hospital costs are fixed, and this would imply that cost per discharge may grow faster when volume declines. A concern may be that as hospital volume declines, we would need to give higher updates to offset the expected increase in unit costs if most costs are indeed fixed.

Another thought is individuals may think, well, if

a lot of costs are fixed and if we reduce the number of hospitals by eliminating the excess capacity, we would generate large savings through closures.

Now, contrary to these perceptions, we find most costs are not fixed, and this has several implications:

First, it means we should not expect significantly faster cost growth given the small decline in volume.

Second, cost savings from closures will exist, but they will be modest. When a hospital is closed, the hospital's fixed costs are eliminated. But that is a small share of the costs of treating those patients. Most of the costs of care are tied to the patient and will move with that patient.

Third, hospital-based ACOs do have an incentive to reduce volume. They can make up for the lost revenue by reducing their costs and by sharing in the savings from reduced admissions.

This slide looks at the long-term effect of occupancy on cost, and it simply shows that hospital occupancy has little to do with inpatient cost per discharge.

If we look at the first column, these are low-

occupancy hospitals; all have an occupancy of under 40 percent. They have a standardized cost of $12,000 per discharge.

In contrast, look at the column on the right. This are high-occupancy hospitals. They all have occupancy of 65 percent or more, and they have costs of $11,560 per discharge. While occupancy is twice as high in the right-hand column, costs are only 4 percent lower. The 4 percent lower costs is associated with 4 percent better margins, as we discussed in your mailing.

The takeaway is: Occupancy matters, but it does not greatly affect costs in the long run. This should not be surprising given that a hospital's capital costs -- the building and equipment -- are only about 7 percent of the hospital's total costs.

So that was a cross-sectional analysis that had us look at the long term. The next question is how soon can hospitals adjust to changes in volume. Over a one-year period, can they reduce their costs to reflect the lower volume of care? And this is important for the incentives such as ACOs and the readmission policy which may affect volume, and there's a question of whether they can adjust

their costs accordingly.

The first column shows hospitals that lost at least 10 percent of their volume from 2011 to 2012. Their costs grew by 4.3 percent per discharge.

The last column shows hospitals that had over a 10 percent increase in their volume from 2011 to 2012. Their costs grew by 0.7 percent per discharge. So the volume growth is dramatically different between the two groups, but the cost growth difference is relatively small.

The takeaway is that hospitals can reduce costs when their volume goes down. In general our work and the literature suggest that between 10 and 30 percent of hospital costs are fixed over a one-year period. The vast majority of costs can be adjusted when volume changes.

Now, we have provided some background on excess capacity in the system and the strength of access and the availability of capital. All of these adequacy indicators are strong. We also discussed the degree to which hospitals can adjust costs in response to the declining volume that we see. In December we will come back with information on quality, costs, and payments. At that time we can discuss hospitals' ability to reduce costs in response to fiscal

pressure.

Now it's open for discussion.

MR. HACKBARTH: Okay. Thank you.

So let me, for the benefit of the audience, just say a little bit more about the update process. As I said at the outset, this was an initial presentation pertaining to one piece of the hospital analysis.

We use for our update recommendations a payment adequacy framework that takes into account a variety of different factors, some of which were touched upon in this presentation. The factors include beneficiary access to care, access to capital for the providers, quality of care, and financial performance. And so I really want to emphasize that it is -- there are multiple considerations. It's not about simply looking at the financial margins and saying that's what determines an appropriate update.

In terms of the process, for those of you in the audience who aren't familiar with our process, next month at our December meeting I will present a series of draft recommendations on updates for each of the provider payment categories in the Medicare program. We'll discuss those draft recommendations at our December public meeting. Based

on that conversation, I will come back with recommendations in January. The actual votes on the recommendations will happen in January, and the results of those votes, the final recommendations will be included in our March report to Congress.

So that's the process that we are now beginning for at least hospital services. So let's move to our Round 1 clarifying questions for Jeff and for Zach. I have Bill and Jon, and then we'll go around this way.

DR. HALL: On Slide 3, if we look at the inpatient/outpatient utilization, the assumption we're making is that these two phenomena are closely related, and that seems reasonable to do. On the other hand, there are a lot of other factors that could influence the increase in outpatient utilization.

Do we know whether the rise in outpatient utilization is largely due to hospital-acquired practices? Or is this a general phenomenon about all ambulatory care?

DR. STENSLAND: We'll get back to you, but there are several factors that play into it. A minority part of it would be the increase in the facility fees that you see when the hospitals acquire the physician practices. Another

minority part would be the switch to observation status. And then the majority is other factors.

DR. CHRISTIANSON: Two quick questions of clarification. First, for Zach on Slide 7, indicators of accessing capital under merger and acquisitions, the second bullet point. I thought I heard you say, Zach, that the majority of activity was large hospitals acquiring small entities. But the second bullet point wouldn't suggest that to me. That suggest it's large acquisitions, you know, like larger systems buying other systems. Which is that you want to say?

MR. GAUMER: So the examples that we're drawing from here are a tenant making large acquisitions in the last year and also community health buying a large system. So that's what we're saying, that large systems are purchasing smaller systems or smaller hospitals.

There's also the example of LifePoint, which has been buying up small rural hospitals, some in partnership with Duke University.

DR. CHRISTIANSON: Okay. So it's a mix of large systems acquiring other larger systems and systems requiring small rural hospitals.

MR. GAUMER: That's correct.

DR. CHRISTIANSON: Okay. And a quick question for Jeff on Slide 10. Is that slide -- when you did that slide, did that include critical access hospitals?

DR. STENSLAND: No.

DR. CHRISTIANSON: I didn't hear you. I'm sorry.

DR. STENSLAND: No, it did not include critical access hospitals because their cost accounting system is a little different, so those are not quite comparable.

DR. CHRISTIANSON: Yeah. Okay, thanks.

DR. NAYLOR: On the same slide, can you comment on the cost per discharge in prior years? Are we seeing what have been the trends? So this is based on occupancy, but I'm looking at the Medicare cost per discharge bottom line from 2011, 2010. Are we see rises across the board?

DR. STENSLAND: We're seeing small increases in the last few years, but part of what motivated this is we saw much larger increases in the prior years, when volume was relatively flat. And then when inpatient volume went down, we actually saw smaller growth in cost per discharge. And there are some other reasons for that, but in general, the trend is toward slower cost growth.

DR. NAYLOR: Thank you.

DR. MILLER: And I wanted to make this clarification. I think it's more the next slide. We do think -- a lot of his statements about cost growth in this presentation are about how it relates to occupancy or change in volume. There are broader trends that also affect cost growth, and I think --

DR. NAYLOR: I'm talking about price and other [off microphone] -- I'm trying to figure out how much of this is a reflection of changes in price over time that would affect cost per discharge regardless of occupancy.

DR. MILLER: Yeah, and I think next month we'll talk more broadly about the trends in cost per discharge growth. But I think the intent here is to try and draw this, all else being equal, how much does volume have an effect on its price? And I think for this presentation most of your statements are really in that context. And then there's a separate conversation that will occur in December about what is the overall trend in growth and cost per discharge. Because you're right, there's a lot else going on that influences that.

DR. COOMBS: On Figure 3 on page 7, you have

double bar graphs, and I was wondering if the number of hospitals involved in deals, if you could decipher whether or not there was clinical alignment as a motivation for why deals were being made. Do we know that? Or is that something we're going to have later in terms of being able to -- is it financial alignment or clinical alignment? Sometimes the clinical services that are required force the smaller hospitals to kind of align with larger systems.

MR. GAUMER: You know, we have a little bit of a detail on what these deals are. Most of it I would say is financial alignment and a need for smaller hospitals to access more capital or for smaller systems to access even more capital. But the issue of clinical alignment, I can go back in and take a look and see if there's anything there to dig out.

DR. COOMBS: In the past we've done the mapping. I don't know if that's a possibility for where deals are occurring geographically.

MR. GAUMER: We could take a look at that as well.

MR. HACKBARTH: Additional clarifying questions?

MR. GRADISON: I realize the numbers of hospitals closing and opening is very small. It appears, from what

you've said, that the closers at tending to be full-service hospitals, replaced to some extent with more limited services, and that I think in some states like Georgia, it is actually being encouraged by the state government.

I'm interesting in whether you have -- however, I know these numbers are small of closures and openings, but have you broken it down, or could you break it down for us with respect to whether there are states which the expansion, the Medicaid expansion states versus the non-expansion states -- maybe this one year won't mean anything, but over a period of time, it might be just interesting to see what that looks like.

MR. GAUMER: Okay. That is something that we've looked at. Just out of curiosity, you probably got that tone in the mailing material. And what we see, overall about half of hospitals are located in states that chose not to expand Medicaid under PPACA, and about two-thirds of hospitals that closed, still a very small number that you're looking at here, are in states that chose not to expand Medicaid.

So we'll be looking in future years as the Medicaid plays out in 2015 and '16 to see if that phenomenon

continues to exist, but right now, there looks to be a slight relationship between the two. But 67 percent of hospitals, essentially, that closed are in those states.

MR. GRADISON: Thank you.

With regard to hospital employment, can you break down the numbers with regard to the increase in physician employment by hospitals versus other employment numbers by hospitals?

MR. GAUMER: At this time, I can't do that, but that's something that we can look at in the next month, and we plan to, so we can come back to you on that.

MR. GRADISON: Finally, on page 11, at the top of the briefing paper, there are various reasons adduced why inpatient use may continue to decline. That's a fine list.

There's a very subjective one that I didn't see there. I'm not necessarily suggesting you add it, because I know it's subjective, but my sense is that there are a lot of people out there that really are afraid of being in a hospital, and there are legitimate reasons for being afraid of being in a hospital, which is based on a lot of data that's been accumulated over the years.

I only mention that because, in close calls, it

might have some bearing on occupancy.

Thank you.

MR. HACKBARTH: Can I follow up on Bill's question about physician employment numbers?

It seems to me that those numbers might be a little bit squirrely in that there are a lot of different ways that you might choose to structure a relationship between hospitals and physicians, some of which are literally employment in the traditional sense, but others might include contractual relationships that from the perspective of the outside world in terms of their economic behavior, they're not employment relationships, but practically, they're the same. So I'm not sure if I, as I'm thinking like a lawyer here, would necessarily put a whole lot of credence in numbers that are strictly based on traditional employment relationships.

MR. GRADISON: My interest in it really goes to what impact a significant increase in relationships, however they are defined, might have on fixed cost, but I appreciate that then depends a lot on what is the contractual relationship.

MR. HACKBARTH: Right.

MR. GRADISON: And my sense of it is that there are greater expectations and built-in protections with regard to the work efforts of physicians than there used to be, but that is really where I am coming from.

MR. HACKBARTH: Yeah. So the question is an important one. I am just not sure how robust the data are to reliably answer or address your question.

Other clarifying questions? Warner.

MR. THOMAS: Just a couple of questions on the analysis, the group of hospitals. Did you look at any sort of regional differences or the size of the facilities as far as occupancy by the various size of facilities and/or teaching/non-teaching? Do you look at that? Are there any trends or differences there?

MR. GAUMER: In terms of closures?

MR. THOMAS: Not necessarily. Just in terms of cost. So, I mean, when you look at the occupancy percentages, it may look very different in a larger or midsize facility versus smaller, and I just didn't know if there's -- you know, we're kind of making the conclusion that there really are not a lot of fixed costs. I don't know if there is any difference based upon the size of the

facility or not. I was just curious whether that was anything that was examined.

MR. GAUMER: Teaching/non-teaching, I don't think we see a big difference.

We do see a difference in size. So this general analysis I have presented here is for the hospitals that have more than 2,000 discharges per year, which is the vast majority of them, and there are some hospitals that are really small. Those at 500 or 2,000 was another category we looked at, and for those hospitals, a bigger share of the costs look like they're fixed, like maybe half.

MR. THOMAS: Right.

MR. GAUMER: And there's a couple of reasons for that. One is they tend to have really low occupancy, like about 33 percent occupancy. So you think for every full bed, you have a lot of empty beds.

MR. THOMAS: Correct.

MR. GAUMER: And so you have more fixed cost per discharge that way.

Also, with some of those small hospitals we visited, it is harder for them to somehow reduce their staff. Like if you have 4 pharmacists and 12 pharmacy

techs, it is easy to reduce one. If you have one pharmacist and that is all you have, it is hard to go from one to zero.

MR. THOMAS: Core staffing, right.

Was there any sort of review? I guess the question is would it be helpful to us to understand or to see a little bit deeper analysis of what that looks like by size of facility, so that would be a question.

I guess the other question is it seems as though we are really looking at cost per discharge as we know more and more services are on an outpatient basis. How are we determining access for beneficiaries to outpatient services and outpatient cost?

MR. GAUMER: When we look at outpatient volume, that's largely what we do to get at beneficiary access to outpatient services that are being provided by the hospital.

This year, we are also looking at adjusted admissions to see in general what's going on with combined volume.

MR. THOMAS: Right.

MR. GAUMER: What am I missing here?

DR. STENSLAND: In terms of cost, we will come back in December and look at the growth in cost per unit for

outpatient and inpatient.

MR. THOMAS: Outpatient.

Yeah. Because, I guess, you know, obviously you have shown the trends of there is a reduction in inpatient, so we could certainly make the assumption that access for beneficiaries should be certainly adequate or maybe improving, frankly. I guess the question is what is it on the outpatient area of where we see a tremendous increase in utilization and a transfer from the inpatient to the outpatient arena and what sort of impact may that have on access.

And I think really the economics of hospitals are changing, and looking just at the inpatient component probably only tells you a part of the story.

MR. HACKBARTH: So, Warner, on that question, the beneficiary access to outpatient services, what we do do as part of the physician and other health professional fee schedule discussion is survey Medicare beneficiaries about their access to care.

MR. THOMAS: Okay.

MR. HACKBARTH: From a beneficiary perspective, I would guess that when you ask them do they have trouble

getting a physician appointment, they are not making distinctions between what is a hospital outpatient or a physician office. They are just saying I can get to see a doctor when I need to or I can't, and so that's more how we get at the question of can beneficiaries see physicians when they need to.

MR. THOMAS: And I think, probably, more of my question is around if we make a determination around hospital costs strictly on cost per discharge, is that really what we should be looking at in total, given that so much more of the services in a hospital are on an outpatient basis. That is really probably more of the question, and I am just trying to understand that area.

MR. HACKBARTH: And we will come back to that topic, rest assured.

MR. THOMAS: Okay.

MR. BUTO: Warner, before you move on, I just wanted to ask, doesn't the Commission analyze ambulatory sensitive conditions, so conditions that would show up if people were having difficulty accessing outpatient care? I think that is another way to get at your question.

MR. THOMAS: Okay, thank you.

And then the final question is just -- really, it's just a point of clarification. On the inpatient, when we look at discharges, how are claims that are being reviewed or in the RAC process handled? Are they in the number or out of the number? I don't know how material that is to the total amount. It may be immaterial to the total amount. I just was curious.

DR. STENSLAND: They would be in the number, initially.

MR. THOMAS: Okay.

DR. STENSLAND: I'm not sure it's even always consistent that people actually go back and refile claims to say this is now I switched to an outpatient. I think it probably just stays in there as an inpatient claim.

MR. THOMAS: Okay, thank you.

DR. MILLER: Any comment on how material it is? We had a discussion, and I think some of the view is it probably doesn't influence this a lot.

Well, I want Jeff to either say yes or no to that.

DR. STENSLAND: Yeah, not a lot.

DR. REDBERG: Thanks. It was an excellent chapter, and I just wanted to go into a little more detail

on what was driving closures and openings, but I think Alice and Bill and Warner kind of addressed a lot of the issues.

So the only one left that I wanted to still look at is in the openings. Do you have any sense of what was driving? You said a lot of them were very small hospitals. Were they in areas where there wasn't any other hospitals? Do they seem to be in more rural areas, undersupplied areas in some way? Is there some way to project where these are occurring?

MR. GAUMER: Yeah. We have a little bit of a sense. They do tend to be slightly more urban than rural. They don't seem to be targeting extremely rural locations, so we are not seeing a lot of critical access hospitals opening up out of those. Is it 18? I would call it more ex-urban locations.

A few years ago, a lot of the new hospitals were what you or I might call a "specialty hospital." They focused on one type of surgery or ortho or something. Now they seem to do a little bit more of a mix, ER as well as ortho and some outpatient clinic stuff, so they're kind of diversifying a little bit. But they are still very small facilities that are opening that seem to be getting at a

niche to challenge the larger hospitals in their area. So they are not isolated locations. Yeah.

DR. HOADLEY: Two questions. One, will you include in the December session, an update on uncompensated care and uncompensated care payments?

DR. STENSLAND: Nothing much has changed. If you want it, I'll do it.

DR. HOADLEY: Okay.

[Laughter.]

DR. HOADLEY: I mean, if the answer is nothing has changed -- I mean, obviously, at some point, we are going to see big changes as a result of ACA-related stuff, but it's probably too early.

DR. STENSLAND: We will talk about how the pool of uncompensated care dollars as shrunk as the number of insured people has expanded and then how that affects hospitals.

DR. HOADLEY: Okay.

And then my other question, on Slide 4, on occupancy rates and really more on the comments you made about some of the variations, urban, rural, and regional, obviously occupancy rate has got an enumerator of patients

and beds and a denominator of beds, and so the trends or the variations in one part of the country and another or urban versus rural could be driven by either enumerator or denominator changes. Do you have a sense if one is more important in what's been happening than the other in terms of some of those variations?

DR. STENSLAND: I think it is mostly all in the enumerator. We don't see a lot of bed change going on.

DR. HOADLEY: Okay. And is that also true sort of, say, urban to rural or regional, so that when you see the difference in occupancy rate, urban versus rural, it is more driven by patients than, say, beds per capita?

DR. STENSLAND: I think that is true, and I think there's some stuff in your mailing materials. I think it's still there. For brevity, maybe we took it out, but the decline in use is bigger in the rural areas than in the urban areas, and there just tends to be some more things that are happening in urban areas than in rural areas. And part of this might just be the moving surgeries to places with higher volume, things like people are getting are getting helicoptered away for their reperfusion now rather than staying in the rural area and getting thrombolytics and

that kind of thing.

DR. HOADLEY: Okay, thank you.

MR. HACKBARTH: Clarifying questions? Any?

Let me ask a question that I asked last year and can't remember the answer to. When we talk about occupancy rates, are we talking about staffed beds as opposed to just licensed beds?

MR. GAUMER: Yes. These are staffed beds.

MR. HACKBARTH: What I can never quite come to grips with is why an institution would continue to staff beds if they are chronically at, say, 60 percent occupancy.

DR. STENSLAND: I think to answer this -- they have it as a staffed beds question, but I think the answer to this really is, is it a staffable bed. So do you have a room with a bed in there?

For example, we had a hospital we visited that had all -- they reported all these staff beds, but there was one whole wing, they just don't use at all.

MR. HACKBARTH: Right. Right.

DR. STENSLAND: So you are not hiring people to go there. You're not buying any new equipment for in that wing, but they still report them as staffed beds. And I

kind of think of it more as staffable.

MR. HACKBARTH: So if that's the case and so we're doing an analysis based on the staffable beds and looking at changes in those occupancy rates and trying to assess implications for what costs are variable, given that we are using a bed count that includes lots of beds that don't have any staff associated with them, doesn't that make the analysis sort of weird?

DR. STENSLAND: I think that's kind of the point, at least for the variable ones we studied, because at least for the long term, when we studied these plays with really low occupancy, they don't have a lot higher costs. And part of that, you can think of, "Well, we just shut off that whole wing. We don't have any people there." So it's saying in the long term, you can shut off the wing and have very little extra costs associated with that empty wing.

MR. HACKBARTH: Yeah, yeah.

DR. STENSLAND: With the other one, it's a year-to-year variation, so you are changing from one year to the next year, and that's just saying, "Well, if you have fewer people in the hospital, you have fewer people looking after those beds," and you can make those employment changes.

Likewise, if you have more people in the hospital, start filling those staffable beds, and you start staffing them, then your costs go up.

MR. HACKBARTH: Yeah, okay.

This staffable beds concept, I'm not sure how --

DR. COOMBS: Glenn, you asked this question last year, and I just want to say there are local things sometimes in operation, like the DPH, Department of Public Health, will license a hospital for a certain number of beds. That means that hospital should be capable --

MR. HACKBARTH: Right.

DR. COOMBS: -- of filling those beds, even though they don't fill those beds. So sometimes it's the -- I can't speak to the rural --

MR. HACKBARTH: Yeah, I understand that.

DR. COOMBS: -- but I can speak to the suburban hospitals. Sometimes it's that you have to have the capacity to take care of those beds in which you've been licensed for.

MR. HACKBARTH: Right. And to me, that's sort of not all that a useful number. It's sort of an artificial construct.

Kate is going to educate me, thought.

DR. BAICKER: No. I'm going to ask a follow-up question related to that, that seems like one way of getting at that as well as getting at what we think of as really access. Do you only have a measure of average occupancy per hospital year, or do you also have a measure of the variants or the sort of peak flow? We don't want hospitals to be operating at 100 percent occupancy, because they need capacity for what is lumpy admissions, and that would also get at this question of, Is it ever staffed, or is it really like the wing is shut off?

So are there available measures of either variants or max occupancy or the 75th percentile of occupancy for that hospital to get a sense of what's really surge capacity versus not capacity?

DR. STENSLAND: We don't have that data. That data does exist, and some people have looked at it, and they often suggest, "Well, you really don't want to be going above 80 percent occupancy, because there are a certain amount of variants there." Then the economists all have a footnote in their papers that there is a little normative question over how important is it to always have that surge

capacity versus the savings by having a little less surge capacity.

MR. THOMAS: Glenn, just a comment on the staffable component. You can correct me if I am wrong, but my guess is the occupancy rates do not include observation patients that sit in inpatient beds, which --

MR. GAUMER: We did include that.

MR. THOMAS: Okay.

MR. GAUMER: We didn't used to, but --

MR. THOMAS: But that's in the numbers now?

MR. GAUMER: It's now in the numbers, and swing beds are built into that, as well.

MR. THOMAS: Because I know that has a material impact for most organizations.

MR. HACKBARTH: Other clarifying questions?

[No response.]

MR. HACKBARTH: Let me ask a round two question, Jeff. This pertains to your statement about the potential implications of this analysis for ACOs.

So, if I understood you correctly, you said this suggests that maybe a hospital-based ACO can reduce admissions and still do okay.

Now that -- implicit in that is how much the hospital shares in any ACO savings which, in turn, is a function of both what the regulatory rules are -- you know, the 2 percent threshold and the share of the savings. But it also includes other issues like, as Dave as pointed out, what costs are incurred to achieve those reductions and then how savings are split between the hospitals and physicians.

So my point isn't to disagree with what you say but just that there are actually a lot of things that go on that determine whether, in fact, a hospital-based ACO, the hospital, benefits from reductions in admissions.

Round two comments?

Jay and then Mary and Alice.

DR. CROSSON: Yeah, I think my comment, to some degree, builds on what you just said.

So I was pretty pleased to look at the analysis that shows that hospitals seem to be able to respond to reductions in admissions because if they were not able to that would create a pretty significant barrier to hospitals being part of ACOs or, in other ways, accepting population-based payment, which is a direction that I think is a good direction.

On the other hand, if you look at how the hospital community is viewing the movement towards global payment, or population-based payment, there a sense at least in some, among some, that it's an existential threat.

And, in order to deal with that, they need a business plan which includes hiring a lot of physicians and trying to buy market share and, essentially freeze out the hospital at the other side of town.

So there's a difference, it seems to me, between -- and maybe you were getting at this as well -- between the analysis we have and at least the reaction of some hospitals out in the community.

So it's hard to know how it's going to transpire.

And one would hope that adaptation of some sort, like you describe, with creating positive incentives for hospitals as part of the global payment incentives, is a good thing.

However, it seems to me that long-term it's probably in our interest to track -- and I think it's already being done, but to continue to track perhaps in more detail the nature of the hospitals who do fail at the game of musical chairs and end up closing.

And the question is really are they the right hospitals to close?

Do we have, as we've found in some other areas of payment, a general picture which is salutary, but in certain parts of the country, in certain types of hospitals, we have hospitals failing, who, because of their impact on the community, beneficiary access or other reasons, probably should not be failing?

And it's just a long-term hope that, particularly if the numbers of hospitals closing are not that large -- if we're talking about, for the moment, double digit, single digit numbers of hospitals -- that we could gain over time some experience that might tend us to think about a policy issue down the line.

DR. MILLER: If I could, a couple things.

I think to your first point about the perception; I think it's right on point.

And I think in some ways the intent and the reason that we went through this analysis is on the cost anyway, on the volume and cost relationship, there is this wide perception it's all fixed. You know. And so in the short run, you really take a big hit.

And I think your analysis is saying, wait a second. You know, maybe there is more and Alice's comment about what happened in her community.

To your second point on the hospitals that close, I thought this was in the paper, but also, there is so much traffic that's run through my head. So I might not remember.

I thought we were sort of saying these hospitals tended to have very low occupancy. They had been in financial trouble for some period of time prior to this.

MR. HACKBARTH: It's in the paper.

DR. MILLER: Was it? Okay.

Yeah, so some of that got in there.

So I'll stop.

DR. CROSSON: I think my comments were more future-oriented.

That may be the case now.

The question is over the next few years, is that --

DR. MILLER: Flip, I see.

DR. NAYLOR: So, thank you. This was a really outstanding paper.

I have been perplexed by the issue of -- I am sure I still am -- the relationship between bed occupancy and our Medicare programs and different options.

I do come at this thinking about what we know from evidence about who should be in those beds among the Medicare beneficiaries; who would benefit from hospitalization.

And we still know that beyond the issue of capacity we have large numbers of beneficiaries in those beds who don't need to be.

So that's my frame.

I probably was among the ill-informed about the fixed costs and what proportion we now know from your analysis, which was terrific, are fixed costs.

But I still guess I wonder; whether or not for the low occupancy, the third that are in the low occupancy, should we not be thinking about what it is that we can do?

Twenty percent fixed costs is still real dollars in that if you spread it among the third that are in the low occupancy it's still a substantial amount of Medicare dollars.

I'm wondering; should we not be thinking about

incentives to help those facilities transition, very sensitive to the point being raised about making sure that we're doing it with -- and as the paper reported -- the rural, attention to the needs of people in rural and so on?

But can't we work toward helping in payment policy transitions to other kinds of services, knowing that we still have too many people in beds that don't need to be there?

I don't know if that made any sense, but --

DR. MILLER: Well, yeah, because in some ways, it connects to Jay's comment.

So, if you expect some reduction in beds and closures as a result of what looks like the secular inpatient admission, you do have this issue of if you are an isolated hospital and the only source of care and should you have supports for that.

Or, alternatively, I take your comment as or should our policy in those kinds of situations support some other configuration of care?

You know, an emergency room with a good transportation system. I'm being very glib here, but you see what I mean.

And I think those are conversations, and I think it does kind of implicate what we end up talking about, particularly in isolated and rural areas, if this trend is going to head in this direction, for both the fixed costs point and the isolation point that Jay was making.

MR. HACKBARTH: Okay. We are getting down to our last few minutes.

Can I see the hands of people who want to get in on this round? So, one, two, three, four.

Okay, Alice.

DR. COOMBS: As far as the hospital employment, I'd be interested to know whether or not these were people tied to clinical activities, direct clinical activities. I think that would be an interesting data set for us.

I think that in terms of hospital fixed costs it's one of those things that correlates with what the hospital's goal and mission is in terms of the services that they provide.

For instance, if you have a trauma service and you think that that's an essential part of your clinical services, then that becomes a part of the fixed costs for the whole umbrella organization.

However, if margins decrease and you decide that that service, you can no longer afford it, that service is eliminated. And the fixed costs certainly go down because you've eliminated a very costly service.

One of the things is to balance the requirements of the clinical services for your area. For instance, if you're the only trauma center, level one trauma center, in a large geographic area, that could mean that the Medicare beneficiaries would not have access to those services.

But I think hospitals are moving toward this thing of Center of Excellence and being able to regionalize certain types of care.

And I think the problem we get into now is that everyone wants a PET scanner; everyone wants a number of things.

And that's calculated into many of the hospitals' fixed costs because having that instrument is one of those things where we say a standby capacity -- is it standby capacity; is it something that's an essential part of the clinical program?

So it's hard to kind of get your arms around what is fixed costs because fixed costs is a product of what you

think is necessary for your community -- the community that is being served.

And I think hospitals are doing okay with a reflection of the volume decrease and still being able to do quite well.

I worry about the maldistribution of some of the DSH hospitals and some of the hospitals that are marginalized by vulnerable populations and not having the payer mix. So that may become an issue in terms of their sustainability.

It's one thing for us to just see Medicare -- patients through the Medicare lens. But it's another thing to see, well, how does that hospital function with the payer mix that it has to be able to do a better job with the Medicare beneficiaries as well?

So I think those are the things that I would be concerned.

And Centers of Excellence doesn't mean mergers and acquisitions. I mean, there are ways that you can have clinical programs that are tied to other programs without the financial obligations as well.

DR. SAMITT: So I have one comment and one

request.

Great job on the chapter.

The comment is that I was actually surprised with these results for the same reasons that other described it. I had perceived that fixed costs would be higher in the hospital setting.

And I actually think that this study that you've done is good news. It's good news because the paradigm seems to be that salvation for hospitals is in volume when now the reality from this is that it gives hope for health system-sponsored ACOs or health system-sponsored MA plans.

And I would hope that this work would motivate more hospitals to consider alternative payment structures where to date it seems as if there have been some that have resisted that notion for fear of this fixed costs issue, which seems to be less of an issue.

My request pertains to slide eight, and your comment about niches that have been created points me to the development of freestanding emergency departments.

I would like to understand a bit more about that in the future:

Where are these freestanding ERs developing?

What is their payment infrastructure?

What is the intent of freestanding ERs?

And is this the development of sort of a new trend that we should be carefully watching to see whether they make sense and to what degree that improves the quality of care or the cost of care for both inpatient and outpatient services.

DR. NERENZ: Well, again, to compliment the work here, the point here about fixed costs, I think, is profoundly important. It challenges conventional wisdom and, as others have said, has implications for ACOs and other initiatives. So I just love the analysis done here.

The focus you had was on costs, and that's fine.

I just wonder as we go forward if there are any issues related to quality that we could look at under the same label.

I think there's this widely understood volume outcome or volume quality relationship, and presumably, hospital downsizing would run in the wrong direction for that. But it remains to be seen whether that's significant within a fixed period of time within a hospital.

And then also, I'm thinking about some issues of

personnel specialization, where a relatively large hospital can have OR nurses who specialize in this or that kind of procedure, and as a hospital downsizes, presumably, you would lose some of that ability.

You know, your own example of the pharmacist and the pharmacy techs would be sort of just one example of that.

So I'm curious as this goes along; are there any inflection points in the downsizing process where you cross a critical mass line, where a function you need to have you can't have anymore, or full-time now becomes part-time, or presence becomes absence?

And I know that's beyond the scope of what you've done, but I'd be curious about some of those things going forward.

MR. THOMAS: This would be some additional, and I brought this up in the clarifying questions.

But you do comment in the chapter around comparing some regions that had pretty significant differentials in occupancy.

And I think it would be helpful for us to understand if there are different cost trends based on the

geographies and based on the difference in occupancy and maybe higher occupancy geographics versus lower occupancy geographies.

And just, is there anything that can be learned from that?

And, once again, the size of the facility, does that play a role in those areas or not?

The ones that are referenced are more urban, but then you also make comments about the rural areas where generally you're probably going to see lower occupancy in the rural areas anyway.

MR. ARMSTRONG: Actually, the points that I was going to make have been made already.

I do think it's worth just acknowledging -- this analysis is terrific.

It's a pretty narrow question, though, and I was impressed by the degree of flexibility in costs with fluctuation in census but putting it in the context of the chapter next month, I think, is really vital.

I'm not sure if this relates to next month's chapter or not. I also just have to acknowledge that this evaluation of payment policy and its impact on access to

hospital services is interesting.

But I'm also very interested in the huge regional variation in just the beds per thousand and the degree to which -- whether it's beds per thousand or days per thousand Medicare beneficiary, how those ratios regionally have an impact on the overall cost to the Medicare program.

To the degree that, too, could be part of the chapter that we're talking about next month, I would find that interesting.

If that's beyond the scope, at some point, I think that's a relevant issue for us.

MR. HACKBARTH: Okay. Thank you very much, Jeff and Zach.

Now we'll move on to hospital short stay issues.

While our presenters are getting settled, let me just say a word for our audience about this. This is our second or third discussion of this?

DR. MILLER: It's our second or third.

MR. HACKBARTH: Mark confirms it's our second or third conversation about this.

And we will be moving toward recommendations, I hope, but they are not likely to happen in time for

inclusion in our March report.

As will be described here in the presentations and discussions, there are a number of different closely related issues that we are including under the rubric of short stay, hospital short stay policy. And rather than peeling off individual items, we're going to try to produce a package that covers the range of issues, but that's going to take us a little time to put together.

So, with that preface, are we ready to go?

MS. CAMERON: Good morning. Today we are here to continue the discussion of short stay hospital issues. We will be responding to questions that you specifically raised in the September meeting, and we'll begin to discuss policy options that arose from that discussion.

Before we start, we want to thank Julian Pettengill, Jeff Stensland, and Valerie Aschenbach for their contributions to this work.

In today's discussion we are going to briefly recap the issues that have arisen around short hospital stays, CMS' efforts to address these issues, and beneficiary and provider characteristics associated with observation stays. Then we'll discuss a range of policy options that

could be considered.

As we discussed in September, Medicare's inpatient admissions criteria have historically been ambiguous and open to interpretation.

One-day inpatient stays are common and paid at a higher rate than similar outpatient stays.

The payment difference has spurred RACs to focus on the appropriateness of one-day stays, and they have denied many of those claims.

In response, hospitals have appealed many RAC denials leading to an appeals backlog. At the same time, hospitals have increased their use of outpatient observation.

In turn, beneficiary advocates have expressed concern about the increased use of observation because of its effect on SNF coverage and beneficiary liability for self-administered drugs.

Combined, these events led to the establishment of the two-midnight rule.

In September, you asked about the differences in beneficiary characteristics between short inpatient stays and outpatient observation stays.

We found that across 15 selected common diagnoses, beneficiaries receiving one-day inpatient stays have a higher prevalence of chronic conditions and have a higher median risk score than beneficiaries with an outpatient observation stay. These beneficiaries were also more often discharged home with home health services compared to beneficiaries in outpatient observation stays.

In looking at beneficiaries by length of time in observation, we found that those in observation for 24 hours or longer more closely resembled beneficiaries with one-day inpatient stays.

In September, Jay and other Commissioners suggested that we explore mathematical ratios that might enable auditors to target or regulators to reduce payments for hospitals with abnormal admitting practices. In response, we created three hospital-specific ratios as examples; there maybe other ratios suitable for these purposes as well.

The first ratio measures one-day inpatient stays relative to all inpatient and essentially all outpatient stays which we define as outpatient observation stays, outpatient emergency department visits, and outpatient

surgical stays. The second ratio measures outpatient observation stays relative to the aforementioned denominator. And the third measures outpatient observation stays lasting 48 hours or more relative to all outpatient observation stays.

We see one-day inpatient stays occur across all hospitals and at a high rate for a subset of hospitals. When we looked at 10 percent of hospitals with the highest utilization rate of 1-day inpatient stays, we found that these hospitals tended to be urban, teaching, and for-profit.

The use of outpatient observation stays varied even more than the 1-day inpatient stays. Small rural hospitals were highly represented in the group of hospitals with a high observation rate, we believe because these facilities can least afford to risk denials of one-day inpatient stays.

Lastly, in looking at the ratio of outpatient observation stays longer than 48 hours, we found that a disproportionate share of the outlier hospitals were small facilities with fewer than 100 beds and low volume. Because these facilities have such low volume, they only account for

about 1 percent of the payments for long observation stays.

Kim will now describe several policy options for your consideration.

MS. NEUMAN: To address the complicated set of concerns that have arisen related to short inpatient stays and observation stays, several different types of policies could be considered. Today we'll talk about three types.

First, we'll discuss payment policy changes that could be considered to reduce the payment difference between short inpatient stays and similar outpatient stays.

Second, we'll discuss changes to the RAC auditing process and hospital rebilling process for short stays that could be considered.

Third, we'll discuss potential policy options to address beneficiary concerns related to observation and SNF coverage and self-administered drugs.

Before we get started, one thing to note is that both the payment policy options we will discuss and the RAC options we will discuss are potential replacements to the two-midnight rule. If the two-midnight rule were replaced, we would anticipate that the prior admissions criteria, which was an expected need for at least 24 hours of hospital

care, would be restored.

So first payment policy. In September, we discussed the idea of creating DRGs specifically for one-day inpatient stays as a way to reduce the payment difference between one-day inpatient stays and similar outpatient stays.

With one-day-stay DRGs, the payment rate decrease for inpatient one-day stays and increases for inpatient stays of two days or more.

Overall, we assumed the policy would be budget neutral, meaning inpatient payments in aggregate would not change.

To illustrate the effects, we did a simulation of a one-day-stay DRG policy. We created one-day-stay DRGs for a subset of DRGs with the most inpatient and outpatient overlap.

We took 94 existing DRGs, and we split each DRG into two DRGs: a DRG for stays of at least two days and a DRG for one-day stays only. We then took the newly created 94 one-day-stay DRGs and collapsed them into 44 one-day-stay DRGs by grouping one-day stays for similar conditions together. We then re-estimated the payment rates for these

new DRGs.

So in terms of the effects of one-day-stay DRGs, hospitals that have an above average amount of one-day inpatient stays as a percent of all inpatient stays (within the DRGs affected by the policy) will experience a revenue decrease while other hospitals will experience a revenue increase or no change.

As shown in your mailing materials, across hospital categories, the impact on revenues was minimal.

Also, effects were generally small for most hospitals. Revenues increase for about half of hospitals and decrease for the other half. Eighty percent of hospitals would have a positive or negative revenue change of 1.5 percent or less.

In terms of the effect of one-day stays on financial incentives, it's mixed, as you can see in the next chart.

These charts show the payment differences between inpatient stays and outpatient observation stays for selected medical DRGs under current policy in 2012 versus the one-day-stay DRG policy we simulated.

On the left you can see that under current policy

an inpatient stay was paid an average of about $3,100 more than a outpatient observation stay for the medical DRGs in our example.

Now looking at the right chart, we see that under the one-day-stay DRG policy, the payment difference between an outpatient observation stay and a one-day inpatient stay narrows to about $900. However, a payment cliff is created within the inpatient payment system: a two-day inpatient stay is paid on average about $3,100 more than a one-day inpatient stay.

So overall a one-day-stay DRG policy has tradeoffs. It reduces the payment difference between a one-day inpatient stay and a similar outpatient stay while creating a new payment cliff within the inpatient payment system.

In terms of the auditing implications of the two payment policies, under current policy auditing has focused on one-day stays because that's where the payment cliff is located. Under a one-day-stay DRG policy, there would be less need for auditing of one-day stays, but likely a need for targeted auditing of two-day stays.

On a related note, in September there was some

discussion of site-neutral approaches to paying for short inpatient and outpatient stays. A site-neutral approach might set the rate for a one-day inpatient stay and an outpatient stay meeting certain criteria at the same rate. So looking at the chart on the right, you can think about site neutral as finding a way to set the left two bars at the same level. If you do that, the cliff between an outpatient stay and an inpatient one-day stay goes away, but the cliff within the inpatient payment system (the right two bars) become evens larger. So in that sense, a one-day-stay DRG policy and a site-neutral approach have some similarities.

MR. GAUMER: Okay. Now turning to the options related to RAC reviews, we have three different RAC policy options for your consideration. These are independent options that are capable of being packaged together.

It's also important to note that these three policies are written as if there was not a payment policy change in place. If a payment policy change were to be in the package of policies, these RAC changes might be defined somewhat differently.

Hospital industry research suggests that RAC

reviews of short inpatient stays affect the majority of hospitals.

In addition, information from the HHS Office of Medicare Hearings and Appeals demonstrate that the number of hospital appeals resulting from RAC inpatient claim denials is overwhelming the claims appeals process.

RAC audits and the lengthy appeals process have added administrative burden and extra administrative costs to hospital budgets. Based on the variation we have observed in hospitals' use of one-day stays, there may be opportunities for RAC audits to be more targeted. For example, using the one-day-stay ratio we've developed, we know that 10 percent of hospitals account for 20 percent of all payments for one-day inpatient stays.

One policy option here might be to target RAC reviews of inpatient appropriateness toward hospitals with highest rates of one-day stays, as an example, the 10 percent of hospitals we referred to on the last slide. A targeted method might identify a relatively large percentage of one-day-stay payments, but do so from hospitals that tend to use more of these one-day stays. This approach might also reduce hospital administrative burden and give

hospitals the incentive to keep their admission patterns consistent with their peers. As I stated a moment ago, this option might be defined somewhat differently if the Commission were to package a payment policy change along with these RAC policy options.

Now, the budgetary effect of changing to a targeted RAC method is that the aggregate value of recoveries would likely be lower. Therefore, this policy might increase program spending and have a budget score associated with it.

However, the magnitude of the aggregate value of recoveries under a targeted method is unclear because we do not know whether or not inpatient claims tied up in the appeals process will be settled or which fiscal years these claims might be tied to once they are settled.

The other policy alternative to consider here stems from a comment that one of you made at our September meeting, which was to use the one-day-stay ratio for a hospital-level payment penalty. We can talk about the pros and cons of that more on question.

In September we described the conflicting time frames involved in RAC audits and the hospital rebilling

policy. Under these policies, CMS permits the RACs to review claims up to three years beyond the patient's discharge date and hospitals to rebill Medicare for denied inpatient claims within one year of the patient discharge date. Initiated by a question from Warner in September, we have learned that RACs commonly deny claims beyond the one-year rebilling window because they review the oldest claims first and work their way to the most current claims. Data from CMS confirm that 75 percent of RAC-denied inpatient claims occurred beyond the one-year rebilling window.

One policy option to consider in this case is to allow hospitals to rebill denied inpatient claims as outpatient claims within some period after the RAC notice of denial. This would ensure that at the time a claim is denied by the RAC, the hospital has the option to rebill outpatient rather than appeal. It would also give the hospital a set time limit to choose between rebilling and appealing a RAC denial. Alternatively, the RAC and the rebilling policy time frames could be made more consistent, such as by shortening the RAC look-back period for short stays.

Similar to the previous policy concept, this

policy would lower the amount of aggregate recoveries by the RACs and, therefore, increase program spending.

Different from CMS' other audit contractors, RACs are paid a contingency fee based on a percentage of dollars they recover. This method incentivizes the auditor to thoroughly audit Medicare claims, and it does not require additional money from CMS's administrative budget to fund the RAC program. To a certain extent it is a self-funding program. However, this compensation structure also incentivizes RACs to focus on the high-dollar inpatient claims, even if there is risk that the denial could be overturned on appeal.

If a RAC recovery is overturned on appeal, the RAC must return the contingency fee. However, the RAC faces no penalty if they have a high rate of appeals or overturns.

One policy option to consider is to adjust RAC contingency fees based in part on the rate at which the RAC claim denials are overturned on appeal. Therefore, if a RAC had a low overturn rate, they would receive a higher contingency fee percentage. This payment structure would increase RACs' incentive to focus on cases where evidence of improper payment is strong and where they have a high

likelihood of being upheld on appeal.

This policy option may increase spending slightly by reducing the number of claims that the RACs are willing to risk challenging.

Okay. Now turning to the issue of the SNF three-day-stay policy:

In September we also began our discussion about the SNF three-day-stay policy. The congressional intent behind this policy, when it was created in 1965, was to create a SNF benefit that was strictly a post-acute care benefit. They also intended to prevent Medicare from becoming a long-term care benefit.

To be eligible for SNF coverage, a beneficiary must have a three-day inpatient stay in the hospital. In addition, the time the beneficiary spends in observation does not count towards the three-day threshold.

Various stakeholders have expressed concern about the interaction between the SNF three-day policy and observation status because beneficiaries receiving observation services are at greater risk of not qualifying for SNF coverage and may face high financial liability if they are actually discharged to a SNF. This concern is

real, but we believe it is affecting a small group of beneficiaries. Specifically 100,00 stays in 2012 were in the hospital for three days and did not meet the SNF coverage criteria because part of their three days was spent in observation status. Among this group, about 11,000 were discharged to a SNF, and for these beneficiaries we would expect that they would be left to pay for their SNF care out of their pockets.

Making changes to the Medicare SNF three-day policy could be extremely expensive. The policy option we have assembled for the Commission's consideration is among the most conservative approaches to this issue. This option would retain the three-day threshold, begin counting beneficiaries' time spent in observation towards the three-day threshold, and most importantly, require that for at least one of the three days the beneficiary is formally admitted as an inpatient. This concept would maintain the post-acute care nature of the SNF benefit by requiring the inpatient stay. It would also expand the SNF benefit to the growing number of beneficiaries who spend time in observation status.

By contrast, a less conservative policy option

would be to drop the inpatient admission requirement from the proposal. And at the far end of the spectrum of options would be to discontinue the existing SNF three-day policy completely.

The policy option we have included in this slide would increase program spending because it would expand SNF coverage to more beneficiaries. This option would increase program spending to a significantly lesser degree than the two less conservative options I mentioned a moment ago. The degree to which spending will increase for the policy option is somewhat unknown, however, because there is considerable potential for a large behavioral response from beneficiaries, hospitals, or, most importantly, from nursing facilities who house Medicare beneficiaries full-time. Lowering SNF eligibility could cause nursing facilities to send more of their full-time residents back to the hospital to recertify for SNF coverage. It could also make it easier for beneficiaries and hospitals to increase patients' length of stays in order to qualify for SNF coverage, or it could make it easier for hospitals and physicians to discharge beneficiaries to SNFs who had previously been discharged to home health.

In this presentation we have outlined several new policy options related to RACs and to the SNF three-day policy for the Commission's consideration. All of these new policies have the potential to increase program spending. However, it is unclear exactly how much these new policy options may increase program spending. MedPAC has proposed recommendations that would produce program savings in the past. Some the Congress has acted on, and others not. In addition to those previous recommendations, the Commission could consider the following policy ideas to generate savings. These ideas have merit in their own right, and we offer them here now because the other policies we are talking about today generate spending.

With regard to hospital-related budget offsets, the Commission could consider expanding the hospital post-acute care transfer policy to include hospice transfers. The Commission could also make an adjustment to the IPPS base payment rate.

With regard to SNF-related budget offsets, the Commission could consider a benefit redesign approach, whereby beneficiary financial liability was increased to reflect the richer SNF benefit. This could be done through

either the Part A deductible or a SNF co-payment.

Alternatively, the Commission could consider reducing SNF payment rates through one of three mechanisms. The Commission could recommend that CMS recover overpayments made to SNFs in 2011. The Commission could consider creating a payment policy for nursing facilities that inappropriately send their long-term residents back to the acute care hospital to recertify for Medicare SNF coverage, or it could make an adjustment to the SNF-based payment rate.

And Kim will now walk you through the issue of self-administered drugs.

MS. NEUMANN: So our last issue is self-administered drugs. Medicare's hospital payment systems cover self-administered drugs for inpatients but not generally for outpatients.

Hospitals bill outpatient beneficiaries for self-administered drugs at full charges, and beneficiaries pay out of pocket for the drugs. Those with Part D can submit a claim to Part D and may get partial reimbursement.

It is common for beneficiaries in observation to receive self-administered drugs. It appears about 75

percent of beneficiaries in observation receive these drugs, and for those beneficiaries who do receive self-administered drugs during their observation stay, the average charge was about $209, and the average cost of the drugs to the hospital was an estimated $43.

Anecdotally, some hospitals report they do not charge beneficiaries for self-administered drugs. Other hospitals indicate that self-administered drug charges are a source of patient dissatisfaction, but they believe they are required to charge beneficiaries for these drugs under laws prohibiting beneficiary inducements.

One policy option that could be considered is to permit hospitals to waive charges for self-administered drugs for hospital outpatients receiving observation if the hospital wishes to do so.

The OIG recently issued a proposed rule defining some exceptions to the rules governing beneficiary inducements. Although self-administered drugs were not specifically mentioned in that proposed rule, the Commission could consider commenting on the self-administered drug issue in response to that rule.

So that concludes our presentation. In your

discussion, it would be helpful to get feedback on the policy options we've discussed. We would also be glad to answer any questions.

MR. HACKBARTH: Okay, thank you. This was really well done, Stephanie and Kim and Zach.

Let me ask a clarifying question about Slide 8, and I think this is for you, Kim. In fact, we talked some about this yesterday.

So under either of these scenarios, there is still a cliff and roughly the same magnitude between the bars on the right side. So if one were to adopt the right-hand model, the one-day stay DRG model, it seems to me that implicit in moving in that direction is that somehow the cliff between the one-day and two-plus-day payment is not as much of a policy problem as the cliff in the left-hand diagram between observation and inpatient, that somehow the incentives are not as bad or somehow the monitoring of the effect of those incentives on hospital behavior is easier in the one-day stay DRG versus the current policy.

Could you just explain a little bit more about the argument that the cliff on the right-hand side isn't as bad as the cliff on the left-hand side?

MS. NEUMANN: So there are clearly tradeoffs. The argument to be made in favor of the chart on the right-hand side would be the argument that the line between and outpatient observation stay and an inpatient admission is very murky, even for clinicians on the ground, and if that is murky, then shouldn't you be paying those things similarly. And if you do, then you get that picture there with those two bars, roughly, but then you do get this bigger cliff between a one-day and a two-day stay.

And there, as you point out, there is a cliff that you might be worried about as a vulnerability, and the difference about that cliff is that if a provider were to extend care to get the higher payment, that's clearly an attempt to get higher payment by extending the services they are providing, more of a clear abuse situation, compared to inpatient versus observation, is that more just confusion rather than trying to game the system. And so that would be the argument to set it up like that.

The one-day and observation are more like similar care, pay them similarly; one-day and two-day, different care, different rates.

MR. HACKBARTH: Yeah. So I am not being

argumentative here. I am really just trying to understand. So you pointed out that from a clinician standpoint, judging whether a patient is appropriate for observation or inpatient, it's gray. It's not clear to me that it isn't just as gray, clinically, the difference between a one-day and two-day inpatient stay. That's the part that I am not quite getting.

MS. NEUMANN: I think from an auditor's perspective, I think judging either one of those cliffs is going to be difficult. I think if you think about it from the perspective of the hospital's behavior, the divide between inpatient and outpatient folks, say, is murky, right, and they could have a hard time deciding which line to go on.

A hospital that is trying to do the right thing could get that decision wrong in the view of an auditor. A hospital that is trying to do the right thing, lengthening a stay for the purpose of getting higher payment is not quite consistent with that.

MR. HACKBARTH: Okay.

MS. NEUMANN: So there is sort of a difference in sort of what the motivations are at the different cliffs.

MR. HACKBARTH: Okay. So, as we go around, I invite the clinicians among us to jump in on that conversation, if you are so inclined.

Let me open up the Round 1 clarifying questions. I think we started on this side last time, so we will start over here with Dave and move down the row this way.

DR. NERENZ: Thank you.

My question is really about this point, although if we can just flip back to Slide 6.

The size of the cliff depends on how you've modeled the various DRG payments. I am curious when you use the word "split" here on the bottom of Slide 6. How did you do the splitting of the dollars in the current DRG when you divided them into a one-day and then a two-or-more day? What was the formula for that?

MS. NEUMANN: So we used the regular formula to calculate DRG weights, and so we just took the cases that -- let's just take chest pain. We took the chest pain DRG, and we took the one-day stays, and we put them into their own group. And we took all the other stays, the longer stays, and put them into their separate group.

And then the relative weight process calculates

the average cost of the cases in each of those two buckets, and then the average cost, as compared to the average cost of everything in all the other DRGs, and then the payment rates are set relative to those differences.

DR. NERENZ: Where does that information come from?

MS. NEUMANN: The average cost?

DR. NERENZ: Yeah. I mean, I know when the folks at Yale developed this in the early '80s, they cite it with stopwatches, and they looked at what it cost to take care of a patient first day, second day, third day, that sort of thing. Do you go back to that kind of source?

MS. NEUMANN: So the hospitals report on their claims' charges at the revenue center level, so different charge for ER, different charge for drugs, and so forth.

DR. NERENZ: Each day.

MS. NEUMANN: It's not even days. It's cost -- it's for the whole stay, there's charges on there, and then we convert the charges to cost.

DR. SAMITT: Two quick questions. When you did the analysis of the one-day stay, was that the only scenario that you that you did a simulation for, or did you also

consider other options like a one- to two-day short stay?

MS. NEUMANN: At this point, we have only done the one-day.

DR. SAMITT: Okay. And on Slide 13, did you evaluate for the policy option that's been recommended regarding the three-day threshold, what impact that policy would have on either the 100,000 stays on the 11,000 stays?

So if that policy had been in place, how -- I guess this would be for you, Zach -- how many fewer of these would be affected?

MR. GAUMER: So we did not put a dollar amount on this policy, leaving that for the folks at CBO.

You can kind of get a sense, though, in looking at this number. So you've got 100,000 stays that were in the hospital for three or more days. About half of those had an inpatient stay boiled in there.

DR. SAMITT: Okay.

MR. GAUMER: So you are looking at about 50,000 claims -- 52, I think -- and if we made the assumption that something like 20 percent went to a SNF ultimately -- and I think the average is about 26 currently for all inpatient -- you arrive at a place close to -- actually close to about

11,000, 10- or 11,000 claims. So that's as far as we went.

DR. SAMITT: Thank you.

MR. HACKBARTH: Clarifying questions? Jay and then Kathy.

DR. CROSSON: I just want to be complimentary, as well. I thought that this paper and particularly these slides have gone a long way to helping to collapse this very complicated set of issues into some specific choices.

However, a lot of them have significant financial implications, both in terms of increasing Medicare costs and perhaps decreasing them, as well. And I just wondered if you set aside the behavioral offsets you talked about, as we go further along the line, to what extent will we be able to have ball-park figures for some of these choices that we may need to choose among in terms of the financial impact, or are we going to be making these decisions more qualitatively than quantitatively?

DR. MILLER: I suspect in the end, it will probably be some mix of that.

What we tried to do is when you come down to saying, "I want to develop a recommendation along this line," we will develop a recommendation, and we will go

through, and we'll go through the specific language, which you are all very familiar with. We will also engage CBO in a range type of way, not a point estimate -- in a range type of way as to whether they can give us a ball park.

Some of this stuff is very behaviorally driven, and so their ability to kind of crank that out, I wouldn't want to speak for them. The hope would be we'd be able to give you some kind of range, but I suspect we will be operating a bit, and some of it will be quantifiable, and some if it will be the second thing you said, which I've forgotten now.

DR. CROSSON: Qualitative.

DR. MILLER: "Qualitative," that was the word, which was a better word than I was going to say.

MR. HACKBARTH: And just for Kathy and Warner, our practice has been that when we make recommendations that would increase Medicare expenditures, as judged by CBO, we customarily include offsets for those, and we can and will come back and talk more about that when we get closer to that juncture. But that's the discipline that we apply.

Kathy?

MS. BUTO: My clarifying question goes to one of

the offsets on Slide 15. I just needed further explanation. Extend the hospital post-acute care transfer policy to hospice transfers? Is this the policy regarding transfers that reduces the payment to the second hospital if there is a discharge to another hospital, and are you trying to extend that to hospice? That seems to be an apples and oranges situation where hospice is a very different level of care, but I would be interested to know what you meant.

MS. NEUMANN: So the post-acute care transfer policy reduces payments to hospitals when they discharge patient to post-acute care settings, like SNF, home health, psych, LTCHs, more than one day below the mean length of stay for the DRG. And the one setting that it doesn't apply to currently is hospice, and so the OIG has done a study where they have looked at this and recommended that hospice be included as one of the other sites that this policy applies to, and so that's what's intended here as an idea for discussion.

MR. HACKBARTH: So, Kathy, it is similar in concept to the hospital or hospital transfer policy, but --

MS. BUTO: I was thinking of some -- yeah.

MR. HACKBARTH: -- it's been more in recent years

extended to post-acute.

MS. BUTO: To post-acute. Thanks.

MR. HACKBARTH: Yeah.

Clarifying questions? Kate.

DR. BAICKER: So I think what Glenn's question was getting at, going to Slide 8 about the cliffs and thinking about how discretionary is the behavior that gets you at each of the cliffs, and your answer, I interpreted it in part to be calling it an "observation stay" versus calling it an "inpatient stay." It's all kind of the same to the patient, and the physician may, therefore, feel a lot more uncertainty and discretion over that; whereas, having somebody stay a whole extra day in the hospital is observably different.

As your comment about the cliff points out, you could then say, well, what about a two-day and a three-day one and then everything? And then what about two, three, and four days? And pretty soon the DRG system is gone. So the whole DRG principle -- and there's a clarifying question here -- is supposed to be about just paying for what the patient should cost and then leaving the clinical staff to figure out how to best take care of that patient, and

folding in the observation stay, that could just be part of the whole package.

So to what extent could those cliffs that we see be undone if they were allowed to differ more based on DRGs? I am somewhat confused about the extent to which these average costs mask very different-looking cliffs for the 10 DRGs that are in here, or if the steepness of the cliffs is, by construction, the same for each of the DRGs? And if it's the latter, if we think that there are some DRGs where you really should probably mostly be in the hospital two days and some DRGs where you really probably mostly don't need to be in the hospital, can you do this in a revenue-neutral way by changing the slope per DRG based on how much, what we think the individual patient should experience, or is that already baked in and I'm just confused?

MS. NEUMANN: So this chart is trying to summarize the more detailed results that we have. Underneath this chart is a DRG-by-DRG-level cliffs, and then just for presentation, we presented them as an average. So, for each DRG, the size of the cliffs will look a bit different, and it will depend partly on how many one-day stays there are in the DRG versus longer stays. And DRGs vary on that count.

So I think, if I'm getting the answer to your question, it is kind of baked in. We wouldn't expect each DRG to get paid exactly like this. Underneath it would be DRG-specific rates with different cliffs.

DR. BAICKER: So then adding -- that makes sense to me. Understanding where patients are located currently along those bins would be helpful in knowing how big a problem the cliffs are. Like it could be that in the two-day big jump are a bunch of patients in -- and I know this is restricted to DRGs, where there is substantial overlap, so that's limiting the problem here, but it could be that there are a bunch of patients with a usually long-stay DRG populating the high bar and a bunch of patients with usually short stays populating the low bar, and for any given patient, there's not so much of a cliff in place, or at least it could be constructed that way, in a revenue-neutral way, I would think, so that patients are -- for any given DRG ex-ante, there's not as much of an incentive to game which category people are in. But maybe I probably just need to think more about the specifics and how that goes across to the other DRGs that aren't on the chart.

DR. MILLER: I take her question as can we look

underneath this and see how much risk there is for the second -- I think the second cliff is what you are focused on -- problem, looking at where the bodies are -- I mean the patients are versus the --

[Laughter.]

DR. MILLER: Wow! That was a big mistake, a very big mistake. I'm sorry.

Where the patients are and the size of the cliff, that's what I'm hearing here.

MS. UCCELLO: So still on this slide, you mentioned kind of in passing that you could actually make the observation in the one-day the same, and then that would increase the cliff of the two days, depending on how Kate's question goes.

But my question there is, then if those were to be made the same, would we go the extra step and say they're all classified as inpatient? And if so, then that kind of has ripple effects on many of these other questions we have. Maybe this is more Round 2, but I'm just trying to understand.

When you briefly mentioned that, were you anticipating that these would kind of, in a sense, all be

classified then as inpatient, or would there still be a distinction? They would just happen to be paid the same.

MS. NEUMANN: I think that's a philosophical question that you could answer either way. I mean, there's ways to structure it, so you just convert these to inpatient, and there's ways to structure it where you're doing some kind of capping approach between the two payment systems, and so that would be a decision point.

MR. HACKBARTH: So, Cori, just walk me through the links that you see to the other issues if we were to characterize --

MS. UCCELLO: Well, the SNF --

MR. HACKBARTH: Well, if it's just a one-day inpatient stay, it's not going to qualify for SNF coverage.

MS. UCCELLO: Oh, that's true. I guess maybe I'm thinking it's more that you just eliminate the term, I mean, the category of --

MR. HACKBARTH: Yeah, I follow that, but it's how that would affect these other issues. You know, it would affect the drugs issue. Then the hospital could provide the drugs without any question.

DR. HOADLEY: It would affect cost sharing.

MR. HACKBARTH: It would affect cost sharing, yeah.

MS. UCCELLO: And the RAC I think would --

DR. MILLER: But, I mean, how else --

MS. UCCELLO: I'm not sure that this is something that I necessarily think is something we want to pursue.

MR. HACKBARTH: No, this is good.

MS. UCCELLO: I'm just trying to think through these.

MR. HACKBARTH: This is good. Did you --

DR. MILLER: No, no.

MR. HACKBARTH: Okay.

DR. HOADLEY: I feel like this might have been asked at the last session, but in the RAC review situations when -- what happens to the beneficiary co-pay if the original thing is rejected and/or if it's rebilled?

MR. GAUMER: The beneficiary is -- their portion is left unchanged, so they're unaffected by any change.

DR. HOADLEY: So they don't get either a refund if it would have been lower or pay extra if it would have been higher in the alternative billing scenario.

MR. GAUMER: I think there was some conversation.

Kim, I'm thinking about in future policy setting that they might require the hospital to give back money if the status had changed. Am I -- why don't we check on that?

DR. HOADLEY: Okay.

MR. GAUMER: I think overall the beneficiary is left unchanged.

DR. REDBERG: Thanks. That was a really excellent chapter and I think really a complex issue because a lot of different parts.

I have some clarifying questions and then some clinical comments. Should I save the clinical comments for Round 2 or go ahead now?

MR. HACKBARTH: Go ahead and do them now.

DR. REDBERG: Okay. I'll do the clarifying first on the RAC. So I wanted to understand what percentage of all the 3.75 billion -- this is from page 8 in the mailing materials -- that the RACs identified in overpayments, what percentage is related to this two-night -- to the short stay issue?

MR. GAUMER: So it's varied in the last three years. It's ticked up actually each year, but about 90-ish percent of those dollars are attributable to short inpatient

stays -- excuse me, to inpatient stays, and a majority of those are the short inpatient stays. And we don't have exact dollar numbers, I do not believe, on the one-day stays.

DR. REDBERG: So that in itself maybe is a little curious to me, because certainly there are other things that are also high cost that probably are -- and related to that, then there's a number of other Medicare administrative contractors and zone program integrity contractors, and it's not really clear to me what they do and how they interact with the RACs or how their role interacts with the role of the RACs.

MR. GAUMER: Okay. I'll take a swipe at this one. So there are several contractors out there that are performing audit functions. The RACs are doing most of the post-payment review, and that's, I think, why we're talking about them. The MACs are involved doing review. It's prepayment, and I should caveat that the RACs are doing a little bit of prepayment review currently as part of a demonstration project.

But in terms of the post-payment, the RACs are the big show in town, and the CERTs and the ZPICs, those guys

are doing more monitoring of error rates and those types of things.

DR. REDBERG: I'll just make a comment because it's not really -- but it seems like there's potential to improve the prepayment side of the Medicare contractors, because it seems that right now they're incentivized to pay claims quickly but not to be sure they're paying appropriate claims, so they pay fraudulent claims perhaps as quickly as they pay other claims, and there could be -- I think prepayment review there is room for closer looks and less things ending up as post-payment review.

But on the clinical side, I wanted to comment because I am a cardiologist and a lot of these short stays are chest pain admissions, as we've talked about. And I did spend last week as the CCU attending for UCSF, you know, and now I notice when I come in in the morning, because of the work hours issue, the person, the resident who admits at night is different than the one that I work with during the day, and so they write the orders, and now I have to co-sign their orders on the patient and say whether I think this is an observation or an inpatient stay when I've really barely met the patient.

So, you know, I think it's a very hard distinction to make, and certainly, you know, if we talk about our site neutrality, you know, having the same patient in the same bed getting the same services but being paid differently, whether I call that observation or inpatient, doesn't make a lot of sense to me.

But, similarly, you know, if I know that now I've said that this patient was inpatient and that means they should stay here more than two days, there are a lot of ways, you know, you can do things as an inpatient or an outpatient, do stress testing, wait for more tests.

And then the last thing, and it's still a clinical comment, you know, chest pain is a very big issue, obviously, for this, and I have to say that I look at it and think it gets murkier even earlier, before we kind of keep them for observation, because, for example, a few years ago there was a study called the ROMICAT study that looked at could you get patients out quicker if you did CT or stress testing in the emergency room. It was published in the New England Journal. And I wrote an editorial that went with that in the New England Journal and said the question isn't which test you should do but should you be doing any test in

the emergency rooms, or should these patients just go home because they've already shown they're low risk because they had normal EKGs and no leak of cardiac enzymes. And if you look at their rates of events, they're 0.1 percent. And there was no difference no matter whether you did a lot of tests or not. And I said I think we should just be sending them home from the emergency room without all these tests, and they can follow up as outpatients.

And I got a lot of very positive comments from a lot of primary care doctors and other doctors that said they thought we were admitting way too many chest pain patients to either obs or inpatient, except for the emergency room doctors who wrote and said that I didn't understand how hard it was to be an emergency room doctor and be afraid of being sued because chest pain is so difficult. That's my last point.

So there was just an article now in the New England Journal a few weeks ago from Daniel Waxman and a few people at RAND, I believe, where they looked at the effect of some state reform in malpractice -- I think it was Texas, Georgia, or North Carolina -- where they tried to take away the effect of this fear of malpractice that emergency room

doctors often cite in chest pain admissions, and they found there was absolutely no change in behavior. They weren't ordering any less testing. They weren't, you know, sending more people home. And so, you know, this argument that we have to order tests even though we know these people are very low risk and can go home based on malpractice is perhaps not, you know, really the case and that it's more entrenched, and perhaps there are other financial incentives to doing more testing as an outpatient -- as an observation or inpatient. So I think that we could probably look even further back in the process.

MR. HACKBARTH: Okay. That's the end of Round 1.

Let me see hands of people who have Round 2 comments to make. Craig, is your hand up? So seven, okay. We'll use our process. Craig will lead off, and then we'll see who wants to pursue that line of commentary next.

DR. SAMITT: I was thinking in a very different direction until I heard Cori speak, and that really changed my perspective on this. I actually was less intrigued about creating a one-day-stay DRG and more interested in solving the problems, the RAC changes, the SNF three-day policy. But in some respects, the notion of eliminating observation

status altogether in many respects in the most elegant solution of all. In essence, if we say we're going to pay observation status and one-day stay equally, then for each of these other downstream problems, the issue goes away, for the RAC changes, including even the SNF three-day, because in essence, if someone is just staying one day, whether it's observation or inpatient, you're not achieving the three-day regardless of whether it's observation or inpatient.

So that may have not been what Cori was alluding to, but I actually think that that would be a solution that potentially solves all of these issues altogether.

MR. HACKBARTH: So the idea has some appeal to me, but I don't understand how it resolves a difference in payment between now the observation/one-day inpatient stay versus the bigger payment for the two-plus inpatient stay. You've still got a cliff. You've still got a payment incentive. And that's the underlying issue that drives all this debate.

DR. SAMITT: Well, I think we'd want to hear more about the degree to which the new cliff that gets created is more onerous or more problematic either from a cost perspective or from an audit perspective for the hospitals,

because we're not going to eliminate the RAC audits altogether. In essence now, the RAC audits begin to focus on two-day, not one-day, which should hopefully lessen the burden at the hospital level. But it should resolve many of the other issues, self-administered drugs, SNF, three-day, and so on and so forth.

MR. HACKBARTH: Okay. So who wants to follow --

MS. BUTO: A question about his comment. When you said it would resolve say the self-administered drugs, are you, Craig, suggesting that the new combined thing would be treated as an inpatient then?

DR. SAMITT: Yes. So what if we essentially said there is no longer observation status --

MS. BUTO: Just inpatient.

DR. SAMITT: -- that there's inpatient only, but inpatient one-day is paid in essence at the observation rate going forward?

DR. CROSSON: So I think I'll start off with the observation. I think it was H.L. Mencken, that for every complex problem, there's a simple solution which is wrong.

MR. HACKBARTH: I think he was on the Commission when I first joined.

[Laughter.]

DR. CROSSON: I mean, I kept looking through this, like this has got to be simpler, must be something in here. And I do have -- I do understand what Cori and Craig are suggesting. But as I think some others have said, including you, Glenn, I have a hard time understanding how it would actually resolve the next cliff problem and that, in fact, I think that -- I have a hard time, you know, as a former clinician at least, thinking that the decision about outpatient, observation, and one-day is more complex, then once you've got this potentially risky patient in the hospital making the determination about where they need to observe the person or second day, it's the same sort of qualitative judgment that needs to be made. So I have a hard time with that direction.

I'm more interested in the notion that was suggested, which is, you know, could we instead look at a more focused policy on those hospitals that have a very high ratio of short stays and impose some sort of penalty system similar to the hospital readmission policy, costing that out to determine whether or not and at what level that would have to be set to make up for the second piece, which I

think from you perspective would be to get rid of the RAC audits entirely as being cumbersome, as adding to hospital costs, creating all the problems in terms of the hospitals being able to rebill and all of that would disappear.

And then, you know, I have some other comments about the SNF-related issues I could talk about later unless you want me to do that now.

MR. HACKBARTH: Let's just think about this [off microphone].

DR. CROSSON: Yeah.

MR. HACKBARTH: So does anybody want to pursue this thread further before we open up? I have Alice and then Dave.

DR. COOMBS: So in terms of the elimination of the observation status, I'm just thinking about many of the patients who are in the hospital who come in for day surgery that, for whatever reason, they're done either late in the day, they need to be observed for nausea, vomiting, or pain control. It's not a very complex admission, and it doesn't have the level of complexity of co-morbid conditions that, you know, someone in congestive heart failure who needs to be diuresed and paid attention to very closely.

So these patients are observation truly. They're truly observation in the sense that you're just monitoring them and making sure they're at some state. And it's not major resource requirements in those patients. It's not equivalent to a one-day hospitalization where you're like all over them, I'm diuresing them, you know, you're doing a bunch of interventions that may require more than the one day. But it's clear that those patients have a lot more resources.

If you get rid of the observation and you make the patient who has a septoplasty, who's going to go home at some point, the same as someone who is -- I mean, the level of severity is another issue, but it has a different type of resources requirement, I think that makes it very hard for clinicians to kind of process, they're all the same now. And then the other piece of it is the midnight-to-midnight rule because a lot of the people who are having surgery in the hospital would probably not qualify because they don't cross those time frames in terms of admission, procedure, and being able to get out. And they might elope into an extended stay, 36 hours possibly. So what do you do with those patients? Because they're certainly not a full

admission. After 24 hours, you know, some of them are extended observations.

DR. BAICKER: But wouldn't they be different DRGs? It's not that they'd be paid the same. It's that they wouldn't be in a different bucket, but they'd still have their own DRG; where if it's just observation after a non-complex procedure, it wouldn't be paid very much. But I'm still confused about what the import of calling it an observation stay versus not is.

MR. HACKBARTH: I have a clarifying question on observation days. Are all observation days paid equally? Or is there a variation based on diagnosis, anyway analogous to DRG inpatient? I thought it was just an observation day is an observation day.

MR. GAUMER: That's right. If you cross eight hours in observation and a couple of other criteria, you get paid a flat rate. That's the way it is currently. In 2012, when we were looking at it, there was a dichotomous thing going on where, if you came through the ER, you were paid one rate; and if you came through a clinic, you were paid another rate. Those would be considered less severe cases.

MS. NEUMAN: There's one other nuance, and that is

that in order for observation to be payable, you can't have had a surgical procedure on the day of or the day before. And so what happens is if you get a surgery and they monitor you, you know, afterwards for a normal period of time, you just get paid the regular surgery rate, and that's built into the surgery payment rate under the outpatient payment system. So observation is mostly medical.

MR. HACKBARTH: Yeah. So if, in fact, we were to go Cori's route of merging -- you're going to live with this now, Cori.

[Laughter.]

MR. HACKBARTH: Merging the observation, we'll say Craig's idea, merging the observation and the one-day inpatient, there would be a redistributive implication to that. If you said, well, we're going to move away from flat payments for observation to some sort of variable diagnosis-based payment for this new merged type of unit. And so that would be just something to pay heed to. It would move money around. There would be winners and losers.

So now moving on --

DR. COOMBS: I just want her to refer to Table 6 on the handout on the -- you did a delta between surgeries

and OP and one-day versus observation. What were you referring to on -- it's page 14.

MS. NEUMAN: So on page 14, we have medical DRGs where we're comparing the inpatient payment to the observation payment for -- the total payment for observation patients with those medical conditions. And then we have a separate line which is surgical DRGs, and those are surgical patients whether they got observation or not in the surgical line.

MR. HACKBARTH: Okay. So we have Dave, who still wants to pursue this merging of the two types, and then Warner the same, and Jack. Okay.

DR. NERENZ: I think it is an interesting idea, and when I was trying to think about this problem that runs through a lot of this about just trying to distinguish this murkiness or the gray area about what distinguishes a patient in this category versus that category, and observing that the amount here that you show for the one-day is relative low, so there is this cliff between the middle bar on the right and the green bar. And then I started wondering, you know, back to the old development of the DRGs, one of the things in my head is that the first day of

a long stay is typically an expensive day. It's when the workups are done, the consults are done, the tests are done, that sort of thing. But it's not uniquely expensive here, which suggests that there's something different about what's actually being done for these one-day stays. And there's not a lot being done, which then just seems to argue that maybe this is not such a bad thing because -- I mean, this idea of combining.

So my question, finally, is: Are there ways that these patients can be clinically distinguished sort of the one-days in which it is effectively observation, whether you call it that or not, and then the two-day or longer stays where it seems to have become something else, there seems to be more going on? You know, you said -- you know, we worry about this cliff, the second cliff, because it's sort of arbitrary. A hospital or a doctor can just extend the stay. And I'm sort of questioning, is it really arbitrary or are there actually meaningful differences there between the patients?

You know, we worry about are there differences between the blue and whatever we call that yellow color. But I'm saying maybe there aren't. But maybe there's some

meaningful differences between the yellow color and the green color, and that actually is clearer -- maybe. A question.

MS. NEUMAN: We haven't looked at the difference between the one-day stay inpatients and the longer inpatients, but it sounds like you're interested in something similar to what Stephanie did comparing beneficiary characteristics but within the inpatient system.

DR. NERENZ: That's where it would go, yes.

MS. NEUMAN: Yeah.

DR. NERENZ: I'm sort of looking to Rita and other clinicians for some validation of this because if it's just nothing but green murkiness all the way through here then the Mencken quote probably applies.

But I'm just wondering; where do we find some clarity in the clinical characteristics of these patients that might actually then lead us to meaningful groupings for payment?

DR. REDBERG: I think that certainly there are differences between those one-day and then the patients that really do stay longer and why they're -- and the observation patients that have the lower intensity work-ups.

But there are so many gray lines in this that I think having that kind of payment cliff would really not create very good incentives and just would, I think, create more problems.

DR. MILLER: And that's the other thing I would just encourage you guys to focus on because the other way to think about it is we're trying to set payment in a way that doesn't necessarily intervene with the clinical decision-making; it sort of tries to reflect what could be the clinical decision-making.

And then perhaps the other part of the conversation is -- and then if you see something aberrant, that's where you focus your auditing or your oversight.

And I've heard what Alice has said in some of our conversations with hospitals, that a true observation stay is a different intensity than a one-day stay and then certainly if you go to two and three-day stays.

I don't what the facts are, but I mean, I have heard Alice's point said more than once in our conversations.

And so I get the mashing it together and having a single rate and saying this is really all that different

from a payment point of view may be attractive, but I think there are certain clinicians who do view these things as separate events, murky as it is.

And so I would just stay focused on this, and the clinician should definitely raise the points about, on the ground, is the person really making distinctions between observation one day, that type of thing.

MR. HACKBARTH: I'm going to let Bill jump in here before Warner.

DR. HALL: Thank you.

I think I mentioned this in September, that we tend to give our clinicians a lot of credit for being real wise wizards and really gurus in this whole problem of prognosticating on a lot of older people.

It just ain't true. We're not all that good. Even the best of us are not that good.

So I think we should go kind of slowly here in terms of real substantive recommendations and just a couple of ideas along those lines.

First of all, I agree that what we usually call observation patients are fairly easily identifiable. There's a whole subset of these where you're pretty sure the

direction you want to go in, and therefore, you don't want to expend additional resources. So having the opportunity to not make a decision on admission is okay.

But I worry more about the one and the two-day issues here, particularly as we start to see a much older population.

I just defy anyone to be able to say with reasonable accuracy that you can tell at the point where you have to make the decision.

I think Rita raised this point; it's often before you even see the patient where this is going to be an admittable or not admittable patient.

So I think we should throw a number of other factors into this.

For example, what are the implications of these policies if we also throw in 30-day readmission penalties? There's a lot of incremental evidence now that in our passion to reduce the length of stay that we're actually creating a lot more readmissions, particularly in the subset of the older patients.

So I think we really need to try to understand much more precisely; what are the clinical criteria we're

using?

Right now, the tail is wagging the dog.

Tell me, Doctor, is this an obs patient? Is this a one-day admission?

And you have to make a decision at that point, but I don't think we're really ready to say that we're really that good at it.

So, as we go forward, I think we should look at the implications of short stays, whether, in fact, that actually increases both the costs of medical care when you factor in readmissions, and just the general burden of inconvenience to patients and the health care system overall.

So I'm a little uncomfortable were we to make really major decisions at this point on this issue. I think we just don't know enough, clinically.

And maybe people will disagree with that.

MR. HACKBARTH: Just give me a second, Warren. I'm trying to actually figure out how to frame the question, and I'm struggling to do that.

So Bill has raised a dimension of this that we really haven't focused on much, and that is the other end,

the readmissions.

And I've heard people say, well, observation status is being used now increasingly as a way of avoiding the readmission and the associated penalty that would come with it or could come with it.

My vague is, in fact, we have looked a little bit at that issue and whether there has been an increase there, but I'm struggling to remember what we found.

MR. GAUMER: So this is the question of observation and readmissions and the connection.

MR. HACKBARTH: Yeah.

MR. GAUMER: There has been some research on this coming out of HHS in recent years, suggesting that there is not a connection -- at least, there wasn't in 2013's data -- between readmissions and observation stays.

MR. HACKBARTH: Okay. Go ahead, Kathy.

MS. BUTO: What about one-day stays; any high rate of readmissions related to those short stays or not?

MR. GAUMER: We haven't looked at that, and that is something I think we can take a look at.

DR. HALL: And that's a key point. We shouldn't lump observation and one-day in the same pile.

MR. HACKBARTH: Go ahead.

DR. BAICKER: So it's interesting to understand that these patients are characterizable in some way, obviously, not in every case but in some cases, which again, to me, makes them sound like their own DRG in some sense.

A lot of these cliff problems are when we start to define the payments again based on a specific unit of care that's delivered instead of based on a bundle. And that's unraveling the incentives that were supposed to be built into the DRG.

And this false or very murky distinction between an observation stay and an admission is, again, about how you're labeling a specific unit of care, not about the underlying need of the patient.

So can we think of that as its own DRG that is reimbursed based on what the average needs of patients like that are, not based on the length of stay?

And then at the end it's going to be too much for some patients and too little for some patients, but on average, it's right, and so the hospital is okay. And that's how the whole system is meant to work.

Or, is there something special about these kinds

of patients where that's just not a viable mechanism?

MR. THOMAS: So, going back to the comments made earlier about combining the payments and also thinking about the issue of going slow on this, I mean, to me, what appears to be clear is that we have payment cliffs today.

And we may be talking about changing and doing a combining, but we have payment cliffs today.

And we have payment cliffs actually in the greater-than-two-day lengths of stay because you look at DRGs and you have patients that have complications or don't. That's another payment cliff which we haven't talked about, but that is another payment cliff in the DRG system.

The criteria between observation and one-day is unclear. I mean, we hear it from physicians all the time. It's an evolving situation with the patient, and it's hard to make a determination immediately on just trying to take care of the patient, whether an observation, whether they're going to be there as an inpatient.

It's also clear that this a target of the RACs. I mean, I don't know the exact numbers, but it seems like it's a high percentage of the 94 percent of the claims that are reviewed are in this arena.

So it does create a problem.

And we know a lot of those are reviewed after the one year. So you, essentially, have an issue for the providers here because they did provide the care. It may have been an observation, but they can't turn around and get paid for the care they provided.

You know, it appears to me -- I mean, the reason I think the combination of the payment makes sense is because the way I kind of think about this. My mental model is it ends up being a lower acuity DRG just as you have a higher acuity DRG for someone that has complications.

And I think we're going to continue to see length of stay decline as we see improvements in technology, and I think hospitals are working on improving the care in the hospitals.

So I think we're going to see more folks going to much shorter, lower acuity DRGs, and I think this type of model can help address that.

If you look at -- you know, surgery that a few years ago was a two or three-day length of stay could be outpatient or could be observation today. Are we accounting for that appropriately?

And then if you talk about the observation payment that you actually brought up, Glenn, I mean, there's no diagnoses associated with it.

So, regardless of how acute that patient is, it's kind of a flat payment.

So, if you think about this more as a short stay DRG or a lower acuity DRG across all of the DRGs, just like we have DRGs that have complications, to me, that -- and we're always going to have payment cliffs, whether it's two or three.

I think it's better to have less payment cliffs than more, but you're always going to have some payments cliffs, and you're always going to have organizations that try to push that and some that try to adhere to it appropriately.

But I think the combination of the payments makes a lot of sense because of all the issues we have today that we're trying to deal with and the fact that I think this problem is going to continue to be exacerbated as we see shorter lengths of stays and more admissions of our seniors, quite frankly, because we're seeing such an increase in Medicare.

MR. HACKBARTH: If we were to, as Craig proposed, do away with observation status and have the one-day DRGs, I'm just trying to catalogue some of the implications in my head.

It's not clear to me that that obviates the need for RACs and all of that because you still now would have this significant payment cliff; that's an open question. We've heard some difference of opinion on that, but that would be one thing that would still be on the table, potentially.

If you go to a one-day DRG, eliminate observation, I think that increases beneficiary cost-sharing. So that would be a second implication of that.

It does obviate the question about the outpatient drugs being covered.

What are the other issues here?

DR. CROSSON: It would not impact the SNF.

MR. HACKBARTH: It would not impact the SNF.

DR. SAMITT: Eliminates the liability with the longer length observation for the beneficiary as well. Wasn't that referenced in the chapter?

There were some higher costs/liabilities for some

beneficiaries?

MR. HACKBARTH: Out-of-pocket costs for patients that really have long observation.

DR. SAMITT: That's right.

MR. HACKBARTH: You're saying that could end up exceeding the inpatient deductible in the extreme case.

DR. SAMITT: That's right.

DR. MILLER: And then you, I think, have already made this point earlier, not in this last recitation, though. Depending on what we're talking about -- and I'm kind of feeling like I'm hanging onto the back of a train here -- if you're saying that -- well, no, this --

MR. HACKBARTH: Is the train going in the right direction?

MS. BUTO: Slow-moving train.

DR. MILLER: I can't see around it. So I can't tell.

This is what every meeting is like for me. So it's nothing new here.

So, if you're talking about taking a block of outpatient activity that's observation and now calling it -- you know, it's going to be inpatient, and there's going to

be this new set of DRGs. There's a set of mechanical questions about recalibrating the systems and a set of redistributional issues that you had mentioned earlier.

MR. HACKBARTH: Jack has been waiting patiently. Is it on this same issue of merging?

DR. HOADLEY: It's on the cost-sharing issue.

MR. HACKBARTH: Okay. And then we'll get back to -- Jack.

DR. HOADLEY: So, I mean, I was going to raise exactly what you just said.

I was looking back at the table in the September thing that you included in our handout, and the inpatient cost-sharing is, in that table, $1,156; the average outpatient is $282. So we're talking about a very substantial difference.

There is some, of course, variation in the outpatient cost-sharing depending on 20 percent of what.

But I think it's really -- I mean, I was going to raise this relative to some of the other distinctions. We kind of -- we did raise that at the last discussion, and it kind of didn't come up in this room. And I think it's very important that we think about what that means.

I mean, yes, there are supplemental insurance issues that could go along with that, but if we go to this, which is appealing, it is going to increase the cost-sharing liability for people in most cases.

Yeah, there will be a few cases where the cost-sharing in outpatient would have actually been higher, but those, I think, are quite rare.

And so I think we really need to think about that, and I don't know whether that means to make some further adjustment to that, which gets us into a whole other complicated policy area, which would be hard to get into.

Even if it's protected by supplemental insurance, it's going to eventually feed into the cost of those policies. So, I mean, it's not like you're completely shielded from it even though you may be shielded at the point of service.

MR. HACKBARTH: Of course, we also -- you know, looked at from the MedPAC perspective, the other avenue there is to benefit redesign where, in fact, we've suggested doing away with this current structure of separate hospital inpatient deductible, et cetera.

And so, obviously, that requires legislation. But

if that were to happen, that would be an opportunity to rationalize this as well.

DR. SAMITT: Wouldn't the inpatient cost-sharing go down?

That may be another clarifying question, but --

DR. HOADLEY: Because it's a flat one-day charge.

DR. SAMITT: Regardless. So even if you created an in-patient one-day DRG, you still would maintain the same degree of cost-sharing.

DR. HOADLEY: Unless you make -- I mean, that's what I'm saying. If you want to then say the hospital cost-sharing that's normally this $1,156 for this special case of a one-day stay would be lower, that's sort of like a bigger deal in terms of thinking about -- anyway.

MR. HACKBARTH: It's conceptually doable.

DR. HOADLEY: Conceptually doable.

MR. HACKBARTH: And it would have cost implications, et cetera.

Okay. So, on this side, we have Kathy, Jay, Mary, Alice, Bill, Dave, and then we'll probably be getting close to time.

Kathy.

MS. BUTO: Okay. So I'm having real difficulty with this because I see, if we try to carve out a special DRG or even special payment rate across observation status and a one-day stay, the question coming up of other instances within the DRG system where something changes and there's a reduction in the length of stay that theoretically reduces cost, leading a conclusion that more DRGs should be gone into and other adjustments made, and then, quite frankly, the question of then adding payments to DRGs where maybe a new procedure has come in or a new technology has come in.

I know there's a new tech DRG, but it's hardly ever -- add-on, but it's hardly ever used.

So I think of this as the unraveling of the DRG system, pure and simple.

And our getting into the individual DRGs causes me pause. I mean, I think there could be a very good case made for it, but what I haven't seen in the discussion so far is some analysis of the recalibration system of the DRGs and why that doesn't actually take into account reductions in stays.

Maybe there aren't enough in each DRG to really

make an imprint? I don't know.

But I think it was Bill or Kate or somebody who suggested that we think about the nature of the DRG system and this issue of averages, where you're going to be underpaid and overpaid over time.

If we just go after those areas where we think there should be reduction in payment, then we ought to be -- I think we're really basically saying let's look at the DRG system and let's begin to sort of take it apart, selectively. And that really bothers me.

So let me just say that; I'd like to see more analysis of why the recalibration system doesn't work to at least address this problem.

And then this idea of targeting the RAC reviews to those hospitals with high one-day stay rates kind of makes sense.

The thing that I don't get about the RACs is sounds to me as if they're not using medical necessity as the judgment for where they take penalties or recommend penalties be taken or changes in reimbursement. And that's the underlying -- should be the underlying -- judgment behind who goes into a hospital or not.

So I really am very troubled by this approach. And I think it's pretty radical and we're maybe just seeing a part of it.

And I would go back to Jack's point -- the beneficiary. If you move this to an inpatient DRG at a lower level, the inpatient deductible is going to end up paying most of that shift. The observation stay, at least in many cases, will moderate the cost.

So that's another troubling aspect of this.

MR. HACKBARTH: Let me go back to your first point about recalibration, and I want to just make sure I understand it and that everybody is grasping the potential significance of this.

So you are pointing out that there is an established process for adjusting the relative -- the weights for the DRGs to reflect changing patterns of care, and so to the extent that we see that within certain DRGs, we have a lot more very short stays, that over time the recalibration process means that the payment rate for those DRGs automatically goes down, albeit with a couple-year lag.

And so there is this automatic mechanism already in place, which might make us less concerned about changes

in patterns of care and shortening of the average length of stay than we otherwise might be. That is your basic point.

MS. BUTO: Or at least help us understand what the dimension of the problem is.

I'd point out that procedures like angioplasty were overpaid for some period of time --

MR. HACKBARTH: Right.

MS. BUTO: -- until the DRG for bypass surgery caught -- well, they were paid under bypass surgery until they had their own DRG. So there are many, many examples where you could go into the system and say, "Wait. This is really overpaying. That is underpaying. We ought to adjust that."

MR. HACKBARTH: So here is my question, Kathy. Let's stipulate all of that about recalibration having a good effect in the right direction. That is an averaging process, and to some extent, what is motivating the RACs and all that is that it's the unique behavior, disproportionate behavior of individual institutions that might be deemed as gaming, and it's not solved by an averaging system.

So what I hear you saying is you think recalibration won't solve it, but you actually think that

maybe recalibration plus RAC, maybe better targeted, is the way to go.

MS. BUTO: Right. If that's the case, in other words, there are aberrant players in this game, then taking sort of a system approach to solving it seems like we may be taking too great a risk, given what we are opening ourselves up to is all I am saying.

MR. HACKBARTH: I'm unraveling of the averaging system for what is in fact a problem that is aberrant behavior among a few. Okay, so that's a really helpful framing of the issues.

Now, we had a bunch of people here. Is everybody still wanting to talk about the idea of going to merged one-day inpatient observation? Who wants to talk about that? And let's get --

DR. COOMBS: [Speaking off microphone.]

[Laughter.]

MR. HACKBARTH: You're gaming me, I think. I think we need a RAC review of -- Jay is confident he wants to talk about that.

DR. CROSSON: Well --

DR. NAYLOR: We're on a cliff. We're on a cliff.

DR. CROSSON: What I'm confident about is that I am at risk of making the same point twice, which is a faux pas, so I am going to try to say it differently.

I have some concerns similar to Kathy, perhaps a little bit difference here. To go back to the problem, what problem are we trying to solve? The problem we're trying to solve, I think, at least this problem, this part of the problem, is that we think that Medicare is overpaying because Medicare is paying for patients in the hospital who could be managed at a lower payment level in observation status.

So the question is, really, what is the range of mechanisms that we could be applying to help, if not totally solve that problem, at least turn it back in the other direction?

My concern is that we focused too narrowly on this set of -- this issue of changing the nature of the cliff or changing what we call things, which may, as Kathy suggests, create in fact more complexity, may unravel some aspects of the payment system we already have, and may just simply create new incentives, which could have as yet unappreciated increase in Medicare cost.

So I just hope as we go through this that we don't deal so narrowly with this question, because I think that -- I hope that we can explore, and this is going to get into all the issues of what does that cost versus save and whatever, but that there may in fact be better ways to go about this that are not as complicated and not as potentially fraught with unintended consequences, although everything is.

We know that we can influence hospital and medical staff decisions through other mechanisms, creating penalties, focusing the RAC audits, if we want to keep the RAC infrastructure in place, but particularly, I am attracted by the notion of a relatively straightforward and simple incentive focused on those hospitals that appear to be overusing or abusing the use of short stays, and that we could create a Medicare add-on penalty. We'd have to cost all that out. And it could be substantial enough and simple enough to obviate at least part of the use of RAC audits, which hospitals find some difficult to deal with.

So I am asking for us to have a broader discussion whether or not this is the right solution or not. I don't happen to think it is. I'm not sure I know the right one,

but I think there are some other things that we could look at.

MR. HACKBARTH: Mary.

DR. NAYLOR: Actually, I want to build on that same line of thinking. First, just exquisite chapter, because it lays out the complexity of this issue and where I think we probably won't want to go, which is to a -- what is it? -- two-midnight rule.

But, anyway, I think we have -- in the history of observation, why was it established? It was established because, as Bill said, we know as clinicians we can identify people who need some level of support or observation for a period of time to determine next steps, and what's happened then as a result of changes in policy, it has become used for other means, and we need to get on top of that.

One opportunity we might have is to say aligning with some of our interest in site-neutral policy is to think about site-neutral observation, which would say hospitals aren't the only place where observation can take place. In fact, there are many evidence-based approaches that are enabling people to move from the emergency room back to their home for observations around heart failure,

cellulitis, a whole host of common DRGs, and so on.

So separating this out -- and this is really reinforced in your work, which suggests that people that come in for one-day stays, inpatient stays, are different than those that are in the observation.

So it seems to me that thinking about the observation status and opportunities to make that site-neutral helps us to reinforce the data, which is it is a different set of people, and we should be giving many more options for their observation.

I think the cost-sharing issues for beneficiaries is extraordinarily important, and I would be very leery about doing anything that would change their cost burden when we know it's not clinically appropriate or needed.

DR. COOMBS: I agree with Mary, and the cost sharing from observation is far less than the cost sharing that would occur with switching to the one-day.

And as I was thinking about it, if you were to have some kind of model where you had Hospital X has 25 or 30 percent one-day hospitalizations and then, as Craig has proposed, you drop the rate down to the observation rate, which you guys have put in the chapter as 1600, you are

losing 30 percent. The hospital itself would lose 30 percent of the revenue on those patients right off the bat. Does that sound good?

And so the next piece of that is that how does that jibe with the remainder in terms of decision-making for the hospital. That two-day looks very attractive. It's beginning to look very attractive. So I'm just saying that the cliff creates incentives that are not just -- we're not just talking about beneficiaries, but also the providers in that category.

So if you try to merge the observation and say aren't they essentially the same as the one-day, I think there are a lot of differences that I think everyone has kind of discussed already.

And I wanted to sneak in this, and I really would like to stress that I think to implement the transfer rule for hospice would be not a good idea, and I would like for us not to include that because of the fact that it is a big amount of energy that is poured into the whole process of hospice, and to have the two-day rule, the three-day rule impact the patient's ability to get to hospice and having to be financially responsible for that I think is a wrong

direction.

MR. HACKBARTH: Rest assured that we'll come back. Getting to offsets, it seems like a long way right now, but we would talk much more extensively about those options.

Bill Gradison.

MR. GRADISON: This may sound hopelessly naïve, but the screen that I am trying to think through has to do with a sense of, in my mind, unfairness to ding the hospitals for the exercise of clinical judgment by the physicians, and the hospitals don't decide this stuff, or maybe they do. Maybe I am missing something here, but I'd like to hear a lot more discussion about how these decisions are actually made.

Granted, if there are outliers -- this is picking up, I think on Jay's point -- if there are outliers, maybe that is the thing to focus on, but to have these policies reviewed for all hospitals when it is actually not the hospital or institution that is making the decision is something I have a lot of trouble with.

MR. HACKBARTH: Bill, we crossed that bridge in 1983. Most of the stuff in a hospital is either decided by or at least strongly influenced by the physicians who may or

may not be employed by the hospital.

DR. CROSSON: The hospitals don't readmit the patients, either.

MR. HACKBARTH: Right.

Like I said, we crossed that bridge 30 years ago, I think.

Dave.

[No response.]

MR. HACKBARTH: Okay. So we have got actually 15 minutes still left here that Kathy wants to --

MS. BUTO: Glenn, I have neglected in my fervor over the unraveling of the DRG system to mention that I really liked the recommendations on the rebilling symmetry. There are a number of things that clearly are almost like in the form of injustice between the RAC and the hospital. The fact that there is no penalty for a high overturn rate on the part of the RAC, that struck me as -- again, so they're out there, they're bounty hunters without penalty. All they have to do is return the money if it turns out they're wrong.

And then the two other points I'd just ask you to consider is that on self-administered drugs, potentially

just having them included in the outpatient payment -- the payment to the outpatient department as opposed to their having to come up with a separate structure to coordinate with Part D or -- you know, there were some other things that you mentioned there.

I think that was it. Oh, one other thing was I think one of your offsets -- this is again minor -- had to do with allowing observation days to be counted toward the three-day stay, and you said potentially at least one of the days would have to be in the hospital. Why not two? If it were two, that would reduce the cost. I mean, you could do either one, but, anyway, a minor point.

MR. HACKBARTH: So just sort of label the topic that you want to bring up.

DR. HOADLEY: It is on self-administered drug, I would make a similar point to what Kathy did.

MR. HACKBARTH: Okay. Why don't you go ahead, Jack.

DR. HOADLEY: The policy option that is proposed here is to permit hospitals to waive charges. It seems like if you just required them to incorporate the charges, that the dollar figures that we're talking about here would have

an infinitesimal effect on the outpatient perspective payment rate, and it would fix all those problems. If you permit them to waive it, that's better than nothing, but it would still leave people, would leave hospitals with a strange decision. It would leave some people unaffected, and it just seems like easy to take that next step.

MR. HACKBARTH: Rita, did you have your hand up? Just sort of label the topic for me first.

DR. REDBERG: It was also on self-administered drugs, but I'm happy enough with what Jack said.

MR. HACKBARTH: Go ahead.

DR. REDBERG: Just that the idea of the current system where you are charged a lot of money to take the drug you brought with you, it's not really clear to me why we don't let patients take their own medicines, and sometimes it's a problem because their medicines aren't what we have on formulary, and then it's difficult, because they don't want to take -- you know, they believe, for whatever reason, what we have --

MR. HACKBARTH: When I asked about it last time, the releasing, the hospital people said it's a question of liability.

DR. REDBERG: That's what I'm always told, but I don't understand the liability.

MR. HACKBARTH: Yeah. Well, that one probably is beyond our purview.

DR. REDBERG: That particular pill that I looked at.

The other, I just had a comment, which was -- because I found this whole sort of redoing of the one-day inpatient and outpatient very complicated and then the payment cliff. The goal is I think that we are trying to make sure we are taking better care of our patients, so I'm just not sure this does it at all. I think really you start thinking that a system where hospitals and doctors get an amount of money to take care of patients and then they decide what is the best thing is really going to lead to better patient outcomes, because then all the incentives are to improve patient care and not to figure out whether it's a one-day or a two-day or an observation. And so that's in the bigger picture where I think we need to be going if we really want to spend our money on things that are good for patients.

MR. HACKBARTH: So if I could, we're down to our

last ten minutes -- go ahead.

DR. CHRISTIANSON: I just had a comment or a question for Jay, I guess. I was intrigued with your notion of something like a readmission penalty modeled after that, you know, to sort of focus on hospitals that seem to have a lot of one-day stays. But then you sort of followed it up with a comment that said, "And maybe if you did this, it would mitigate a lot of the problems with RACs."

So just the question for you is: Do you see this as a replacement? Or do you think that we should be trying to address right now some of the problems, I think the fairness problems that Kathy talked about or some of the problems with RACs right now and working on your suggestion kind of as we go further?

DR. CROSSON: You know, I think to a large extent, that's a financial question. In other words, easy for me to say, but we have to sort of model what this penalty would look like, what amount of money, how many hospitals it would be applied to, how it would change over time, what could be saved for the Medicare program by doing that, versus what's being saved in the RAC audit process. And we could end up in different endpoints. We could say, gee, you know, if we

really did this, just based on the pressure it would apply to the hospitals that are abusing it, there would be a significant amount of savings, and it would eclipse the savings from the RAC audit process, in which case we could dispense with that. Or you could end up with a policy that says, no, the RACs, if applied in a targeted way, could further augment the incentives created by the penalty. And I could imagine any combination of those, but in the end, it seems to me that there's a financial element to this that would be deterministic, because if the numbers were in one direction, it would strongly push you in that direction; but if it's way under -- if this proposal or idea was only a rounding error on the amount of money saved by the RAC process, then it wouldn't be viable.

DR. CHRISTIANSON: Yeah. So my question really was kind of like is it an either/or, or in the meantime do you think that we should be focusing on -- if we can reach some agreement on maybe some of the things that we think are kind of egregious about the RAC process, that we should be making recommendations about that as well?

DR. CROSSON: Sure. I mean, it depends on, you know, how long this is going to go on, but yeah, I mean,

it's just similar to the process we have often, which is, you know, should we try to fix the fee-for-service payment process while we're waiting for the evolution of a different payment process, and the answer generally is yes. If we were to decide three months from now that there's enough -- or four months or whenever, that there's enough to be gained through this penalty process, learning perhaps by the dynamics of what's been created in the readmission payment penalty process or some other way, and it really did obviate the need for RAC audits, then we might just stop fussing with that.

MR. HACKBARTH: So if I could, what I'd like to do is for our last ten minutes give people an opportunity to focus on the SNF dimension of this, which we really haven't talked very much about.

I think I said at the last public meeting that the three-day requirement for SNF seems archaic to me. That was instituted in 1965 when the average length of stay, I don't know, was 13 or 14 days, or something like that. We're in a very different world today and have a very different policy focus where we're trying to not just reduce the average length of inpatient stays but also more consistently move

patients from higher-cost, more intensive facilities to lower-cost ones. And the 40-, almost 50-year-old three-day rule seems archaic and inconsistent with that movement.

The rub, of course, is money, and as I've thought about this between the last meeting and this one, as much as I might like to eliminate the three-day rule, you know, there are some potential bad ramifications from that, one being that it creates this dynamic or reinforces this dynamic where patients that are in nursing homes not on Medicare benefits can convert patients to much higher paying Medicare patients, and that's really, I think, a significant potential problem with eliminating the three-day rule.

So what the staff have tried to do in today's presentation is say, well, maybe there's a middle ground, and, Kim, refer me to the right page -- I think it's 13, 14, thereabouts. And so I'd like people to react to this idea of counting observation days towards SNF eligibility provided that there is at least one inpatient day. Any comments on that specifically?

DR. SAMITT: I like it. The one-day-stay issues aside, I think the sub-elements, the recommendations for RAC, three-day stay, the self-administered drugs, all in

some respects make a lot of sense, including this one.

I think as we start to talk about elimination of the three-day-stay rule, it starts to become a bit too onerous and disruptive and costly. But at a minimum, this addresses the problem that has been identified by beneficiaries associated with observation.

MR. HACKBARTH: Now, I do need to flag for you all, we don't know how CBO would estimate the cost of this and what the price tag would be. And so that would have to be something that we take into account later. It wouldn't be free relative to current law, but how un-free it might be, I don't know.

Other reactions on this?

MR. ARMSTRONG: Yeah, just echoing Craig's comment, actually building on a comment Rita was making earlier, you know, we live in a world where we don't deal with these financial issues; it's all prepaid. And the decisions are purely made on what's the most cost-effective -- or actually effective, clinically effective way in which referrals would be made to these different locations.

It just seems to me that -- and, by the way, this three-day requirement is -- it's irrelevant to us, and we

often will admit patients directly to skilled nursing facilities from emergency rooms. And, you know, if you looked at our patterns, you would say that this standard really has very little bearing on what the clinical practice, uninhibited by these financial constraints, should look like.

I would be interested -- I have no idea the answer to this, but I would be interested, you expressed concern about the increased spend to the Medicare program of eliminating the three-day requirement. It seems to me there could be a real savings as well by putting the patient in a more cost-effective facility as opposed to keeping them in the hospital for a certain number of days before they trigger eligibility. And I don't even know how you would evaluate, but at least inherently to me it's just not purely a cost to the program issue. There could be a real balance to that cost.

MR. HACKBARTH: Two quick comments on that.

One, I see your point. Ultimately it doesn't matter what you and I think about what the cost implications would be. It really matters what CBO thinks. So that's one point.

The other thing I'd just remind folks of is that CMS has begun to waive the three-day rule in contexts like the Pioneer ACOs where the providers are bearing some financial risk because the incentives they face are more like the incentives that you folks face. And so I just wanted to put that on the table. Okay.

DR. HALL: So I think a basic principle of geriatrics is that hospitals are dangerous places for all Medicare recipients, but they're particularly dangerous for people who are on the more frail side, i.e., the ones that are trying to get into a nursing home. So from a clinical standpoint, I think it's very compelling to do something to get rid of this three-day rule, because that's the time when we can not only occasionally do good but we can do some real harm to people. They're much better served in the SNF or the long-term care environment. We should take that into account.

DR. HOADLEY: It seems like, I mean, one of the ways to think about this is to separate the issue of the specific problem related to the observation days, which is what the policy option here kind of addresses, versus some of these broader things that we're bringing up, because, I

mean, it strikes me that, first of all, just to understand the broader implications, to Scott's point, I mean, if there's potential for some savings, it's got to interact in a complicated way with how PPS payments -- because Medicare doesn't say just because somebody stays a little less, given that it's a DRG payment; on the other hand, over time the DRG payments could evolve to capture that savings, so it's a little more -- or you could legislate in a way that sort of takes some of those savings. But I think if we're thinking of it at that level, we should lay that out and get some analysis that helps to understand that.

If we want to at least solve -- solve -- if we want to at least help on the problem that's specifically related to observation stays, then it seems like the policy recommendation here, if it's something we want to bundle with whatever else we end up doing, makes a lot of sense, unless we do something that makes this moot, which is a better way to solve it.

MR. HACKBARTH: Any other comments on SNF?

MS. BUTO: Just a question, I guess. Taking the option that the staff recommended or suggested be considered where at least one day would be inpatient, would that in any

way exacerbate the one-day-stay issue, do we think, if we went to that format? I just raise that as a question.

DR. CROSSON: Yeah, I had a similar point, and to think about this from the perspective of the physician who feels that his or her patient needs to be in a SNF, right now he would have to hospitalize that patient for three days in order to get what you needed to get done. In this setting, you would only have to do it for one day, right?

So the question is -- I mean, it's probably impossible to answer from a perspective of what behaviors would be incented by changing the policy in this direction. Would it, in fact, encourage physicians, as you just said, to put the patient in for one day, therefore one-day admissions would go up? Or would it have the reverse effect, which is to decrease the physician hospitalizing the patient for three days in order to get them into the SNF? I don't know if that's knowable.

MR. HACKBARTH: Yeah, and as Jack says, you know, it depends in part on what the other pieces of the package are.

Any final comments on SNF? If not, I think we are -- yeah, we are out of time. Thank you, Stephanie and Zach

and Kim. Really good work on this.

We'll now have our public comment period before we break for lunch, and before you begin, could I see -- if you want to make a comment, could you please line up at the microphone so I have an idea of how many people we've got wanting to speak?

Okay. It looks like just one, so before you begin, let me just restate the ground rules. So begin by telling us your name and organization. You will have two minutes. When the red light comes back on, that signifies the end of the two minutes. And as always, I remind people this is not your only and certainly not your best opportunity to contribute to the Commission's work. Do that first and foremost by contacting the staff, or you can send Commissioners letters, which the staff will help you get to the right place. We do read our mail. Or you can post comments on our website.

MS. TOMAR: I'm Barbara Tomar. I'm with the College of Emergency Physicians. I just wanted to make a few quick comments about observation.

First, I think it might be easier for the confusion that has arisen over the last several years about

observation when patients are up on really a medical floor for three or four days versus observation in critical decision units adjacent to the emergency department. About 40 percent of hospitals do have those units. It's usually the larger hospitals. And the literature is showing that the length of stay for most of those patients is about 14 hours, and over 70 percent of them are treated and released. So it's a good use of resources, we think.

But the other thing I was wondering is why is the allowable length of stay in observation gone up so high. I mean, Medicare used to use 48 hours. Maybe it should be 24 hours as opposed to some of these more complex solutions that you've been wrestling with today.

One of the other things I would just observe is that because the RACs have concentrated so heavily on short stays, it's sort of provided the incentives for a hospital to move people to observation up on the floors, and CMS allows hospitals to change the patient's status from inpatient to outpatient during the course of the stay, which further complicates the confusion and upset for beneficiaries.

One other point I just wanted to mention, I would

love to see MedPAC staff do some research into how Medicare Advantage and the Pioneers are using direct admits to SNF under what kind of clinical criteria. I think that would be really helpful to understand this, too.

Thank you.

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

[Whereupon, at 12:35 p.m., the meeting was recessed, to reconvene at 1:30 p.m. this same day.]

AFTERNOON SESSION [1:29 p.m.]

MR. HACKBARTH: Okay. It is -- actually, it's not. It's 1:29. You can put your heads on your desk and --

[Laughter.]

MR. HACKBARTH: Now it's time. Okay. So welcome to the afternoon session, and first up is Medicare Advantage. Carlos?

MR. ZARABOZO: Good afternoon. Today ,I will present some information on three separate topics in the Medicare Advantage program.

The first two topics I will discuss are issues that Commissioners have asked about at recent meetings. One is the status of provider-sponsored organizations in Medicare, and the other is the topic of the composition of networks in Medicare Advantage plans and rules for network adequacy. The remainder of the presentation will be a discussion of the work we have done looking at the margins of MA plans.

Kathy, you and others asked about the provider-sponsored organization option in Medicare Advantage, an issue that is getting attention because of the formation of accountable care organizations and the desire of some ACOs

to assume more risk.

In 1997, the Balanced Budget Act authorized several new contracting options for Medicare health plans, including the provider-sponsored organization, or PSO, option. Initially, a PSO could receive a federal waiver of the requirement to comply with state laws governing plan solvency by meeting federal solvency standards. However, such waivers were not available after 2002.

The BBA provision did result in there being a state law option referred to as a "PSO state-licensed plan," as they were called in Medicare contracting reports. Although initial predictions were that there would be hundreds of PSOs, there ended up being very few, with the last state-licensed PSO ending its contract at the end of 2012. However, a number of provider-based organizations do have Medicare Advantage plans and are able to meet state licensing requirements as HMOs and PPOs.

Glenn, you asked a question about the rules that MA plans must follow in terminating providers. Press reports from the end of last year and the beginning of this year have called attention to the issue of the network make-up of MA plans and when plans can terminate providers. The

rules, incorporated in regulations, are that a provider can be terminated with a 60-day notice, and affected beneficiaries should receive a 30-day notice of such terminations.

What was controversial at the end of last year was that beneficiaries had not been made aware of provider terminations until after the annual election period, which would have been their opportunity to change to another MA plan or to go to fee-for-service Medicare.

In response to comments that CMS solicited about possible changes to rules on provider terminations, CMS announced a change in policy whereby a plan must notify CMS 90 days in advance of a major change in providers due to terminations.

CMS also instituted a policy whereby beneficiaries could be given a special election period to choose another plan or fee-for-service Medicare. This would apply to beneficiaries affected by a major change in networks when the change is occurring outside the October-to-December annual election period cycle. The new special election period rules would allow an affected beneficiary to leave a plan in the middle of a year.

The rule changes that CMS instituted were less than what beneficiary advocacy groups had asked for in their comments, and CMS did leave open the possibility of making additional changes in the future.

In any case, an MA must always continue to meet network adequacy requirements, and CMS is in the process of developing an audit tool to ensure ongoing compliance with network adequacy requirements. We will continue to monitor this issue.

What I am going to talk about next is an analysis that we have not done in the past, which is an examination of the margins of MA plans based on historical data that plans submit to CMS. When we have examined margins in the past, the results were based on prospective information in the bids for the following year.

We are examining margins as part of our role of surveying the landscape of the Medicare Advantage program, which we will continue at the December meeting. Looking at plan margins gives us a better understanding of the MA sector, what the trends are for the sector, and what differences exist among different types of MA plans or in different geographic areas.

One thing to note is that, as of 2014, MA plans are subject to a medical loss ratio, or MLR requirement, whereby at least 85 percent of revenue must be used for the provision of medical benefits.

There are specific rules for determining the allocation of expenditures between administrative costs and medical costs for MLR purposes. As pointed out in the mailing material, the rules can be different from the way in which costs are allocated in the bid data. The MLR requirement can also have an effect on plan margins in that the 85 percent MLR requirement can impose bounds on an organization's margins to the extent that more of the plan's revenue has to be used to provide benefits.

In 2012, based on the historical data that plans submitted to CMS with their 2014 bids, the revenue-weighted average margin across all MA plans was 4.9 percent for Part C; that is, for Medicare benefits and extra benefits plans were required to provide, excluding drugs under Part D.

Administrative costs averaged 8.8 percent, and benefit costs therefore averaged a little over 86 percent of revenue.

Very few companies reported negative margins, but

we did see a lot of variation in margins by plan type or other plan characteristics. We will be reporting on the Part D margins of Medicare Advantage prescription drug plans at a later date.

This graph shows the distribution of margins by company within MA on a revenue-weighted basis. The negative or zero margin group with the red bars comprised 8 percent of all MA revenue in the data that we examined. As noted in the mailing material, our data included about 90 percent of the MA enrollment in 2012.

In the last three bars, you see that the majority of MA revenue went to companies that had margins at or above 5 percent. The year 2012 was the first year of the phase-in of the MA payment changes made in the Patient Protection and Affordable Care Act of 2010, and as of 2014, MA plans have been subject to a premium tax. So we may see changes to this distribution in years after 2012.

This graph shows margins on a company-wide basis. As explained in your mailing material, one company can have a number of MA plans and a number of types of MA plans. Each plan can have a different margin level, including a combination, for one company, of plans with negative

margins, along with plans that have positive margins. The company-level margins give you a sense of the overall financial position of companies participating in MA, but in order to look at differences by plan type and by other plan characteristics, as we do in the next few slides, the analysis has to be done at the plan level.

In looking at differences in margins by plan type or other plan characteristics, we found that HMOs had higher margins than other plan types, with a difference of a couple of percentage points between HMOs and local PPOs, for example.

For-profit plans had higher margins than not-for-profit plans. The pre-tax margins of for-profit plans were over 4 percentage points higher than for non-profit plans, and between employer-group plans and non-group plans, there was a difference in margins of almost 3 percentage points.

We looked at a subset of plans that we could identify as older versus newer plans and found that older plans had higher margins.

In the case of special needs plans, such plans had margins that were twice the level of non-special-needs plans. On average, though, not-for-profit special needs

plans had negative margins. Almost all the not-for-profit special needs plans were plans for beneficiaries dually eligible for Medicare and Medicaid, or D-SNPs.

We also looked at some geographic and demographic characteristics. We found that plans operating in areas with high per capita fee-for-service Medicare expenditures had higher margins. More interestingly, we also found differences based on the type of Medicare-Medicaid dually eligible population that was dominant in a given plan.

There are two types of dually eligible beneficiaries. Those who have partial Medicaid eligibility are entitled to have the Medicaid program pay their Medicare Part B premium and, for some, Medicare cost sharing. The full dual category includes beneficiaries who have the same benefits as partial duals but also have full Medicaid coverage of additional services, such as long-term care not covered by Medicare.

In looking at plan margins, plans with a majority of beneficiaries with partial dual status had higher margins than plans with a majority of enrollment consisting of beneficiaries with full dual status.

In terms of their relative expenditures in fee-

for-service Medicare, the full dual group has higher average Medicare expenses than the partial dual group, leading the Commission in past work to suggest that the MA risk adjustment system should be modified. Instead of the current situation of having only one single-risk adjustment factor for dual status, there should be one factor for the full dual category, who have higher average fee-for-service expenditures and a different factor for the partial dual group, who have lower average fee-for-service expenditures. Making such a change will improve payment accuracy for both of these types of plans.

The next two plan characteristics that we will talk about are related to each other. Our analysis showed higher margins among plans with higher average risk scores and higher margins among plans with a greater share of beneficiaries with the diagnosed condition that is a payment factor under the MA risk adjustment system, based on hierarchical condition categories, or HCCs.

This result may seem counterintuitive but could be explained in different ways. The difference in margins may indicate that, compared to fee-for-service Medicare, MA plans are more efficient at treating sicker patients, and

that the cost advantage over fee-for-service becomes greater the sicker a person is or becomes. However, coding practices may also be a factor here.

The MA risk adjustment system uses Medicare's fee-for-service population to determine the relative risk factors for different diagnosed conditions based on diagnostic data and expenditures in fee-for-service. The risk score of a beneficiary in MA is based on diagnostic data coming from fee-for-service for the preceding year, if the person was in fee-for-service, or from diagnostic data for the prior year submitted by the beneficiary's MA plan.

In recognition of coding differences between MA and fee-for-service, the Medicare statute requires a coding adjustment to reduce the risk scores of enrollees in all MA plans because coding is more intensive in MA than in fee-for-service. A recent article by Kronick and Welch cited in your mailing material notes that some MA plans code more intensively than other plans, which suggests that a possible reason for the differences we see in margins based on relative risk scores and diagnostic data, as shown on this slide, may reflect differences in coding practices across plans.

In December, we will come to you with our annual MA update to give you a broader picture of the MA landscape. I look forward to any questions you have and your discussion of any additional analyses you would like to see on today's topics, and also remember that if you have no questions at all, that's fine.

[Laughter.]

MR. HACKBARTH: Can we put our heads on our desk?

MR. ZARABOZO: Yes, please put your head on your desk. It's nap time again.

MR. HACKBARTH: Okay, thank you. Thank you, Carlos.

Could you put up Slide 6 for a second.

I was a bit surprised at the 8.8 percent administrative cost on average for MA plans. That is the sort of number that I think of customarily for large employer-group plans, maybe a little bit on the high side for that setting, but still, it's lower than I expected for what is an individually marketed product.

So I am just curious to learn a little bit more about it. In particular, an angle that occurred to me is that although this is an individually marketed product, it

is in a particular setting where you have basically an exchange type of mechanism, and CMS is sort of organizing the market to some degree.

Then I went from that to, well, gees, I wonder if we had an organized market for supplemental coverage where the administrative loading factors are really high, so that beneficiaries who want traditional Medicare could get supplemental coverage at a much lower cost than in the disorganized market that exists there.

So that's sort of the series of thoughts I went through. Reactions?

MR. ZARABOZO: Well, one thing to note here is that this is across all plan types, which includes the employer-group plans, which have a lower administrative cost, because they do not market to individual beneficiaries. An employer-group plan comprises about 18 percent of the total MA enrollment.

MR. HACKBARTH: And what is the number for the employer-group plans?

MR. ZARABOZO: The number is lower. It's --

[Pause.]

MR. HACKBARTH: If you can't find it quickly, you

can just give it to me later.

DR. MILLER: Just put your head down on --

MR. ZARABOZO: Yeah, I'm making it up as I go along.

[Laughter.]

MR. ZARABOZO: 6.3 percent for employer-group plans.

MR. HACKBARTH: Somewhat lower.

MR. ZARABOZO: Yeah.

DR. MILLER: The other thing I was going to ask, it's on the same thing. Might there be some definitional issues between -- okay. The actuary is nodding.

MR. ZARABOZO: Yes. There can be definitional issues, and another point that Cori raised, which I will respond to, because she's not going to ask the question because she's shy --

[Laughter.]

DR. MILLER: I'm trying to figure out whether we should put Carlos up here in the future. This is getting like real personal.

[Laughter.]

MR. ZARABOZO: Yeah. The question, the

distributional question is pointed out in the mailing material. I cited an article by Jamie Robinson which said the plan structure in different types of plans, you may have a lot of administration being done at the medical group level and so on, so that appears as medical cost for some types of plans. And those types of plans have large enrollments in the MA program.

The other point is this again is a percentage of revenue, expressed as a percentage of revenue. So in areas where -- the GAO did a similar study based on 2011 data, and so areas of high benchmarks, you as a percent of the revenue -- this is a lower percent. The administration is a lower percent, and so in lower benchmark areas, the administration is a higher percent, because to some extent, these are fixed costs or they are sort of per-unit cost; that is, the cost of paying a broker to enroll somebody is uniform.

MS. UCCELLO: Let me just, though, build on that, just to clarify. The definitions used here are the MLR definitions of the denominator anywhere or not.

MR. ZARABOZO: No. The definition -- what this shows is for bidding purposes, what has been stated by the plans as administrate -- we wanted to be clear about that.

MS. UCCELLO: Okay. So that is different than the MLR --

MR. ZARABOZO: Right, that is different.

And, for example, the MLR, you include quality-related activities, and it is also after taxes, is another difference. Yeah.

MR. HACKBARTH: Okay. Clarifying questions? I think we start over on this side this time. Jack?

DR. HOADLEY: So a couple of things, and this is really very useful information.

On the network adequacy, I noticed in the text of the write-up, you said CMS will determine these sort of definitions of what constitutes a major change for both purposes of notice and special enrollment periods. I assume special enrollment periods are a fact of this year, or is it next year? And do we have any information on what --

MR. ZARABOZO: I think it's 2015. Yeah, next year, 2015.

DR. HOADLEY: Next year.

And do we have any information on sort of how they are going about that definition, or have spoken to that yet?

MR. ZARABOZO: Well, I haven't talked to CMS about

that particular point. I gather that it's sort of like you plan and we agree, yes, this is a major change, and that is why you are notifying us, this is a major change, the 90-day requirement.

DR. HOADLEY: So case-by-case?

MR. ZARABOZO: Yeah, case-by-case.

And then CMS says, "Well, yeah, and this will -- we think this is a major effect on beneficiaries, and in particular, these beneficiaries will be entitled to a special election period."

DR. HOADLEY: I mean, that seems like something worth sort of watching as it proceeds.

MR. ZARABOZO: Yeah.

DR. HOADLEY: My other question is on the bid information, and it's really -- you know, some of your analysis you did at the company level and some at the plan level for all the reasons you explain, and my question is, to what extent is a company able to cross-subsidize across different plans or move its fixed cost around, you know, the same way we have conversations about hospitals in different functions? And I can't remember if CMS has any rules relative to bids.

MR. ZARABOZO: They have tolerances for where the margins should be and whether you can have a negative margin, at what point and so on. So that there are supposed to be -- for example, the D and C margins are supposed to be relatively close. At the company level or even at the contract level, I'm not sure how that works, a plan under the same contract number, plans across companies, how the tolerance is applied in those situations.

DR. HOADLEY: And therefore, the implications for some of the differences that you see on plans with more low-income beneficiaries or whatever, to the extent that they want to show it or they want to keep a premium down, how much ability they have to move things around. It seems like that's not a problem, obviously, when you are looking company to company, but it could become an issue looking at some of the other kinds of characteristics.

MR. ZARABOZO: Yeah.

DR. REDBERG: So I was just wondering, on page 24 in the mailing materials, under network adequacy standards, you refer to the minimum provider to enrollment ratios. Can you give us an idea of what those are, and are they the same all over, or do they vary?

MR. ZARABOZO: They vary by type of county. That goes on to the next section to explain that urban -- for example, large urban county and rural county, there's a different standard in terms of time and number of providers, time to reach the providers, distance of providers.

DR. REDBERG: I did see that, but I still wasn't -- like what number of provider to what number enrollment, for example?

MR. ZARABOZO: Well, they have a list at CMS of here is this type of provider or you have to have this number within this kind of geographic area, so I mentioned the 23 categories. I think it was we.

DR. REDBERG: 33?

MR. ZARABOZO: 33 practitioner specialty codes. That's where they say you need X number of these. Given this type of county that we're talking about, you need X number of this specialty to meet the network adequacy requirement, based on what we expect your enrollment to be.

DR. REDBERG: Okay.

MR. ZARABOZO: Yeah, same distance and time requirement.

DR. REDBERG: Thanks.

DR. SAMITT: My questions are about the PSO. I'm curious about the intent on the creation of the PSO option in 1997, why it was created, as well as whether the notion behind the Pioneer ACO, whether that is -- the intent is to evolve the Pioneer ACO into a PSO-like solution for delivery systems that are interested in alternative or capitated payment for their entire Medicare population. So can you elaborate a little bit on --

MR. ZARABOZO: On the first part, it was because -- and Kathy was around for this particular episode in history. Providers wanted to be able to contract directly with Medicare, avoid the middleman, as they put it in the paper. And they felt that they could not meet the solvency requirements and thought, well, we don't need to because we can be responsible for the provision of care. It's not like we're contracting with an organization that's going to run out of money and not pay us. We will agree to not let ourselves be paid if we run into a problem, that kind of thing.

But because of the direction of health care in America, on the private side it was all going to managed care; on the Medicare side, the BBA was intending to make

more managed care options, capitated options, including the private fee-for-service option. The providers wanted to be there to be able to contract directly with Medicare.

DR. SAMITT: Thank you.

MR. ZARABOZO: And the second question, I would have to defer to the ACO people. I'm not sure that --

DR. STENSLAND: There is a difference [off microphone].

MR. HACKBARTH: What Jeff said was the enrollment aspect of Medicare Advantage, including provider-sponsored plans versus ACO, which is assignment.

MR. GRADISON: I'm trying to understand better the issue of network adequacy both in the exchanges under the ACA and more particularly in the subject before us. And the reason I am a little uncertain about this is that I could imagine that there would be some providers that would sign up, but that having signed up and participating in -- or being listed as being available, a couple of things could happen that might make them less available than it looks on paper. One would be their panel is full. Another might be that as a matter of policy and running their own practices, they'll only accept a certain percentage of patients from a

particular payer.

How do these rules deal with those situations? Which I don't bring up with the thought that they're unusual. I would think they'd be fairly normal, that you phone up -- for example, there's a great shortage apparently of psychiatrists. You get one that's listed, but you call them and they might see you in six months, if you're lucky. You know, that sort of thing.

MR. ZARABOZO: Well, the CMS rule is that you have to have a contract with the provider in question. What I have not asked CMS is this particular issue: What if the provider is saying, "I will only take X number of your members," or "I'm currently not open"? I'd have to talk to CMS about whether that is a factor when they evaluate the network adequacy of a particular plan. So capacity of the provider --

MR. GRADISON: I'm not just asking about some practice that wants to limit its proportion of patients that are covered by a particular payer, but also a situation where somebody says, "My panel's full. That's all I can handle." But they're still listed, but they're not really available for more people. So perhaps you might look into

that, if you don't mind, and for the future.

Thank you.

MR. ZARABOZO: Yes.

DR. CROSSON: Carlos, on the PSO issue, which I want to come back to in the second part of the discussion, the waiver authority that was put into the law and then expired, presumably that gave permission to this PSO world to contract differently under Medicare. Was that also the waiver authority that superseded state solvency requirements? Are those two the same, or are they different?

MR. ZARABOZO: Yes, the waiver is specifically a waiver of the state solvency requirement, and so -- but it also -- there was a requirement that said you have to go to the state first, and if you're being delayed in your application, if you're being denied for the following reasons, then, yes, we will consider you for a federal waiver of the solvency requirement, and you can operate as an MA plan.

DR. CROSSON: So just to clarify, when we use the term "waiver," that was a waiver of state solvency requirements or --

MR. ZARABOZO: A waiver of the federal --

DR. CROSSON: -- a waiver of allowing a different contracting mechanism with Medicare?

MR. ZARABOZO: No, it was only a waiver of the federal requirement that said you have to be licensed as a risk-bearing entity under state law. So this says we will waive that particular federal provision which says you must meet state law and say, no, you don't have to meet state law. You can meet federal law on this particular issue, just the issue of solvency.

MS. BUTO: And just to follow up on that, Carlos, explain what -- so let's say a state -- I mean, a PSO is successful in getting a grant of a waiver that was time-limited, according to your paper, I think, to three years. What was waived? And what liability did the -- or financial responsibility did the federal government take over? Was it reinsurance? Or how did it counteract allowing a plan not to meet state solvency requirements?

MR. ZARABOZO: Well, it had to meet the federal solvency requirements that you negotiated in the negotiated rulemaking.

MS. BUTO: Thanks.

[Laughter.]

PARTICIPANT: They worked very well.

MS. BUTO: They worked so well we didn't get any PSOs, as I recall.

MR. ZARABOZO: But what it did --

MS. BUTO: But, really, I'm asking you to remind me. Were they a lot less onerous? Or were they -- because I thought they were pretty darn onerous when they were laid out.

MR. ZARABOZO: There's not -- you don't have to meet any solvency requirement. It was, yes, you meet a solvency requirement, here's what it is, you have to post a bond, we have to determine your net assets and so on. There's a few examples in the paper about, well, when we determine net assets, we will count your health service delivery assets, we will not count, in terms of reducing the net assets that you have, subordinated debt from your providers to the extent it's withhold. So those kinds of things made it easier, but not, you know, totally simple to the --

MS. BUTO: No, I appreciate that, and, again, the reason that a couple of us asked about this option was I

believe it's still on the books. The waiver authority is gone at this point, right?

MR. ZARABOZO: From looking at some state laws, it appears to be still on the books that you could be a PSO, quote, state licensed, and just for the Medicare product, yeah. On the state books.

DR. MILLER: The state has to make --

MR. ZARABOZO: I'm sorry. On the state books where they say, "And here are the requirements to be one of these things," which match the federal --

MS. BUTO: Well the federal piece was the waiver, and that expired. So in order for the waiver to be reactivated, you'd have to, you know, get another law passed, I think, right?

MR. ZARABOZO: Right. But what happened s that many of the states that appeared adopted sort of like word for word. The federal government says here's the solvency standard for this kind of entity.

MS. BUTO: Right.

MR. ZARABOZO: We'll take that and say, yeah, you can be a PSO state licensed in our state because we have adopted what the federal government says is an appropriate

solvency standard just for you, not for the other people that we're licensing here in the state.

MS. BUTO: Right, right.

MR. HACKBARTH: But what proportion of states?

MR. ZARABOZO: Well, I only looked at a few states -- I looked at the states where there were -- you know, Florida and Texas and New Mexico -- New Mexico I think was the federal -- so I was just looking at a few of them to see if they were still on the books. I don't know how many states actually did incorporate that provision.

DR. CROSSON: Can I just paraphrase maybe I thought what Kathy was asking? Because it was sort of similar to what I was asking. So the provision, the existence of Medicare Advantage PSO, it still exists as a potential alternate contracting mechanism, but it can't be employed because the waiver authority which would be necessary is gone. Is that right?

MR. ZARABOZO: No.

DR. MILLER: I would say one thing differently, and you tell me -- the door you have to walk through to get it is through the state.

DR. CROSSON: At the moment [off microphone].

DR. MILLER: At the moment. And so when you said "on the books," I just wanted to clarify that the federal door has closed, because the waiver has gone away. You can walk into this setting and be paid as an MA plan, but I think you've got to walk through the state door.

MS. BUTO: The only technical question I would ask you to -- and you may know the answer already -- is whether the requirements that were negotiated are still there, even though they can't be activated because you don't have a waiver. Have they disappeared as well?

MR. ZARABOZO: Well, no. See, this is what Mark is saying, which is those requirements were incorporated into state law --

MS. BUTO: Oh, okay.

MR. ZARABOZO: -- and said you can be a PSO state licensed. There's no Federal waiver, but, look, you can meet the federal solvency requirements under state law.

MS. BUTO: Which gave certain flexibilities for provider-based managed care plans.

MR. ZARABOZO: Right.

MR. HACKBARTH: But if I understand it correctly, the federal door to this could be opened with a legislative

change as simple as changing the expiration date of the waiver authority.

MR. ZARABOZO: Yes.

DR. CROSSON: That's what I was asking [off microphone].

MR. ZARABOZO: I hate to give the simple answer, but yes.

DR. MILLER: You have no idea what this is like [off microphone].

[Laughter.]

MR. ARMSTRONG: And I don't want to belabor that whole insolvency issue, and perhaps it's a Round 2 point, but I think there are a whole host of other issues with respect to creating level playing fields and other requirements and taxes and so forth that I think we want to be really clear about as we think about the policy implications.

The question I had was, Carlos -- and you acknowledged this is margin information out of the year 2012. And I'm just thinking, wow, that was a long time ago, and a lot has happened since then. I just wonder if you have any insight into or when you might know more about,

like, 2013 at the very least, given some pretty significant structural changes.

MR. ZARABOZO: I think in December we can tell you more about more recent years.

MR. HACKBARTH: Other clarifying questions?

MR. THOMAS: I just had an item that was brought up earlier on the difference between the reference in the document of the benefit percentage and the MLR. Can you tell me more about that and what that means?

MR. ZARABOZO: In the bid that the plans submit to CMS, they state themselves here is what we apply towards benefits, here's what is administration, and here's our margin. The MLR rules are quite specific as to what can be counted as administration benefits. For example, as Cori brought up, the benefits include quality-related activity. That can be classified as a benefit, and it's also -- taxes are removed in terms of determining the revenue. So what percent of revenue is towards benefits, that's an after-tax number.

MR. THOMAS: And do we ever look at or have we looked at the percentage that's indicated as benefits in the bid versus what is actually expended on benefits?

MR. ZARABOZO: This is what the GAO did. They looked at the 2011 information. We're looking at 2012 here. They looked at 2011, and they compared what did you project versus what actually happened. And they found that overall across plans, other than employer group plans and special needs plans, the projections pretty much matched the actual. Not so for employer group plans and special needs plans. Special needs plans were more profitable than projected; employer group plans were also more profitable than projected.

MR. THOMAS: It just seems like, at least recently, there's more dollars that are being considered, you know, in the medical costs that are non-medically oriented, not necessarily going towards benefits. I didn't know if in any of your research you came across that type of information.

MR. ZARABOZO: Well, definitely the quality-related activities, again, are specifically classified as benefits, not administrative. So that -- I mean, you could argue that point, well, maybe they're really administrative, not actually direct benefits.

MR. THOMAS: And does that appear to be growing as

a percentage of the total expenditure? Do you see any movement there?

MR. ZARABOZO: We haven't looked at that specifically. I know that the plans were being asked to report that. I think in the -- whether this rid of bids or they've reported a couple of years to separate those categories. But we haven't looked at that. And I think it's -- once the MLR information is in -- which will not be until the end of 2015. It starts in 2014, but we will not have the data available until probably after 2015. We can look at, you know, what is the distribution of these kinds of dollars in the overall revenue scheme.

MR. THOMAS: TO me, it may be interesting to just understand how much of those dollars at the end of the day are really in "quality activities" and what does that mean and it's really going to benefits for beneficiaries.

MR. HACKBARTH: Okay. Any other Round 1 clarifying questions?

MS. UCCELLO: So in Table 3 in the text, in the mailing document, you break out benefits and admin and the margin percentages. And I think when I was reading it, I thought that those were actual, but now are you telling me

that that's just from the bid itself?

MR. ZARABOZO: No. These are from the 2014 bids in which the plans state the 2012 actual.

MS. UCCELLO: Oh, okay. Thank you.

MR. HACKBARTH: Others?

[No response.]

MR. HACKBARTH: Let me ask Carlos about what CMS is doing on changes in the network. If I understood you correctly, you said that if there's a significant change in the network, CMS is creating a special enrollment opportunity for beneficiaries to switch plans, and that could either go to another MA plan or back to traditional Medicare.

Now, if you choose to go back to traditional Medicare, an important consideration is whether you'll have access to supplemental coverage. And if it's a beneficiary who has significant health issues, the ease with which they can go back to supplemental coverage, get supplemental coverage, I think is, shall we say, variable.

Could you just sort of walk through that for me?

MR. ZARABOZO: I think the way the statute reads is if there is a special auction period, then you have the

Medigap right.

MR. HACKBARTH: You do? Okay.

MR. ZARABOZO: But I need to confirm that for sure. I think they may even have specifically said that in these circumstances, yes, it is one of those kinds of special election periods that you have a guaranteed-issue Medigap option available to you. But I can verify that.

MR. HACKBARTH: Okay. Then that sort of leads me to another question. So as I understand the roles, if when you first become eligible for Medicare, you have a guaranteed-issue right to supplemental coverage. However, if your initial election is to enroll in a Medicare Advantage plan and then you decide, well, it's not for me, I want to go back to traditional Medicare, you no longer have the guaranteed issue --

MR. ZARABOZO: Actually, if your initial election was Medicare Advantage, I believe the rule is, yes, you do have a special election --

MR. HACKBARTH: So both ways? In other words, it doesn't matter if you initially enroll in traditional Medicare or --

MR. ZARABOZO: Only, I think, if you went -- the

first option that you -- I'm going to hesitate a minute here. If you went directly into MA, then you change your mind, you do have, even after a year, I think it is, a --

MR. HACKBARTH: Okay.

MR. ZARABOZO: -- special election period where you can say I have guarantee issue of Medicare.

MR. HACKBARTH: Okay.

MR. ZARABOZO: What I am not sure about is whether if you go into fee-for-service -- let's say you turn 65 and you go into fee-for-service for three months and then you go to MA, it might be the case that in that period also your first MA election also gets you the special election period. In other words, the case that you pointed out, fee-for-service, MA first time -- MA first time, I didn't like it, I want to go back, I get an SEP. So I'll have to check on it to make sure that that's also the case.

MR. HACKBARTH: Yeah. There was some -- in fact, we had an e-mail exchange about this. There was something I read that made me think -- and perhaps it was just an incorrect statement in the article -- that, in fact, if your initial enrollment was into MA, then you weren't guaranteed -- you didn't have guaranteed issue.

MR. ZARABOZO: No, that's --

MR. HACKBARTH: That's not the case.

Okay. Round 2 comments?

DR. CHRISTIANSON: I'm a little leery about making comments given how quick Carlos is today. I think I can take him on.

I have three comments.

First, I guess -- first, it's great to see these data, and so I really enjoyed reading the chapter.

I'm assuming that we're contemplating doing this on a yearly, or annual basis, and updating and having trends and things like that.

MR. ZARABOZO: I'm looking at Mark. I think the answer is-

DR. MILLER: Anything to keep them busy.

DR. CHRISTIANSON: Good answer.

MR. ZARABOZO: So the answer is no, apparently.

DR. MILLER: The idea was to build it into the landscape thing each year.

DR. CHRISTIANSON: Yeah. So that being said, then there's a lot of, I think, interesting analyses that you

guys could contemplate going forward.

I'm wondering if you're thinking about doing some of the same stuff as the analysis of the data hospital data, where you look at market structure and margins and things like that as you go forward, and if you have an analysis plan for what you can do when you start doing longitudinal data.

MR. ZARABOZO: We do intend -- again, I'm looking at Mark here -- to look at the ins and outs of who's coming in or leaving the Medicare Advantage program, that kind of thing. I think for December we're hoping to be able to do that.

DR. CHRISTIANSON: And we had this really nice analysis a few years ago that Jeff and the hospital crowd did, looking at margins, according to different kinds of Medicare margins, depending on different kinds of market structures, and I'm wondering if something the same might be done here.

DR. MILLER: I wouldn't overbuild it. This is our first pass. We're diving in.

We're diving in on D. We expect to bring that forward next month.

Yeah, we'll develop a plan if you have ideas.

DR. CHRISTIANSON: My second comment was I think this whole network adequacy is going to be extremely important going forward as more people enroll in MA plans and also because of the spotlight, that the health exchanges have focused on network adequacy.

And I think part of whatever plan we have should -- you cited some of the CMS criteria in terms of judging network adequacy.

I'm wondering if we have our own thoughts about what would be good metrics. It would be worth thinking about, and I would love to see it by type of plan and over time.

So, I mean, this chapter, I understand, was a first pass at the data, but I think network adequacy is going to need to be addressed at maybe the same level of attention that margins are, actually, as we go forward.

And then finally, you've got data on type of products, and I was wondering if it's possible for you to tease out MA plans that offer what are essentially ACO organizations as subproducts.

And I think if you could tease that out and track

that over time, that's one impact of ACOs that we don't track. But to the extent that ACOs are creating organizations that can accept risk and are then offered as MA plans, I think that's another impact of creating ACOs, and it would change the environment, I think, for MA plans.

So I don't know whether you can get data at that level of product detail, but if you could, I think that would be of interest to the Commission.

MR. ZARABOZO: Maybe. I mean, it's possible.

DR. CHRISTIANSON: Yeah.

DR. MILLER: Well, we'll come back to you. I'm not immediately sure how we would do that, but we'll come back to you.

MR. ZARABOZO: Yeah, I think a lot of it is press reports on these people are now more -- you know, a lot of the plans like to announce; we now have this big system in our --

DR. CHRISTIANSON: Right. So even a plan web site would be one --

MR. ZARABOZO: Yes, plan web sites and -- yeah.

MR. HACKBARTH: I just want to clarify one thing for the audience.

So, assuming that we go ahead and, as Jon suggested, report these data on a regular basis and include them in our March report, in that sense, it would start to look more like what we do for hospitals and some other provider groups.

However, there is a fundamental difference. In the case of hospitals and home health agencies and SNFs, et cetera, by law, the way the system works, there is an annual update to the payment rates for whatever the unit of service is, and by law, we are asked to recommend what the appropriate update is.

That is not the way either Medicare Advantage or Part D works.

So, even if we're -- and I know you know this, Jon, but this is for the audience.

Even if we're reporting margin information, don't expect that to be followed with a proposal that the rate should be adjusted up or down as a result of that information. It's a different payment mechanism altogether.

Okay. So is there anybody who wants to pick up on Jon?

Scott.

MR. ARMSTRONG: Just the point Jon made about network adequacy, I'm not even sure that that's a particularly useful term. I realize it implies that we're protecting our beneficiaries from inadequate networks, but my hope is as we look at this we recognize that managing to a high quality, narrow network is a way of advancing better quality, better outcomes, better health.

And I would just say for our organization we have much more flexibility and, frankly, are more effective at accomplishing those goals through a rigorous evaluation of who is in and who is not in our network than we can as an MA plan.

So my hope would be, as we go forward with this evaluation and taking a position on these questions of network adequacy, it's not simply what's the line by which you judge whether someone can be pulled out of your network. It's a much more complicated issue than that.

DR. CHRISTIANSON: And that was basically behind my comment -- is we need to think of our own metrics and how we want to do it.

MR. HACKBARTH: On that issue, I would also second what I think Bill Gradison was pointing out earlier. A

network in your case means one thing.

Conceptually, somebody could reasonably look at Group Health of Puget Sound and say, are there enough physicians to see this enrolled population?

When you're dealing with networks of providers that deal with a bunch of different payers, assessing whether there is, in fact, clinical capacity there, not just names on a network list but actual clinical capacity to care for patients, this network adequacy stuff really doesn't get at the fundamental issue of whether the patients can get the care they need when they need it. It's a little bit superficial for that.

MR. ARMSTRONG: Yeah, and just to add to that point, our experience is not only with our own providers. We're working with a very narrow network of hospitals and physicians who are dealing with a full spectrum of other insurers as well.

Our view of what the program's responsibility versus MA plan's responsibilities and the criteria we use to judge, to Jon's point, adequacy -- it's a lot more complicated than are there enough doctors.

MR. HACKBARTH: Jack.

DR. HOADLEY: Yeah, so I had very similar comments.

I mean, I think what this really suggests to me is if we want to dig a little deeper into this issue we really do need to think about the difference between different models of plans and what the concept of network adequacy really means because I think -- Bill's point earlier; there's a lot of plans out there.

And we've seen it not just in Medicare but in other programs -- Medicaid -- where there's a paper network that isn't real because so many of the doctors aren't taking new patients or are only taking a small quota of patients.

But it is a very different environment when you're dealing with a traditional insurance company running a PPO than when you're dealing with an organization like Scott's.

And does that suggest we need to get some different set of rules to apply?

Where is the line drawn?

I think that's hard, but I think it still raises a lot of issues that are good to talk about -- as the move toward narrow networks, for all the value it can have when run right, if run badly, can just mean an inadequate

network.

I think one of the questions I've always wondered about is how much monitoring is there beyond the basic rules. So, when you talk about, okay, they submit numbers and at least CMS is doing a basic check of numbers, are they looking underneath that for things like whether people are taking new patients?

And again, that's been an issue with some of the Medicaid programs, where they didn't do any -- they set up a decent set of rules, but they didn't check underneath it to see that those rules were really being followed more than just some kind of a paper submission.

So I think those are some areas.

The only other point I would make on the sort of going forward with the sort of margins analysis relates to my question earlier.

Where these questions are about the differences across companies, you know, there's a lot of things that are pretty straightforward, where we're starting to look at things in plans. And that's where a lot of the interesting questions come when it's the plans that serve low-income patients and the PPOs versus the HMOs and so forth.

If it looks like a lot of that is somewhat an artifact of accounting, the same problems we run into when we look at things like hospital outpatient departments, then we've got to really be careful about what we're doing.

And if we can get any more insight into how that's typically done by these companies that offer this large range of plan products and how much the CMS bid rules allow them -- because I've always heard it stated that you can't really subsidize -- cross-subsidize from one product to another.

But what does that actually end up meaning in practice? I think the better we can understand that, the more we'll know how much to make of that kind of analysis.

DR. REDBERG: So I thought this chapter was really helpful and a great start to look at Medicare Advantage.

After we establish margins and network adequacy -- you know, I see those as kind of intermediate outcomes.

But we really, I think, have to, when you talk about metrics, talk about clinical things that are meaningful to patients. We really need to look at health or how the patient is feeling in these different plans and compare to fee-for-service.

Are they living longer?

Are they -- is their quality of life good?

Are they functioning independently?

You know, sort of meaningful.

Just having access to a doctor is not really an outcome, to me.

You really want to look at how are patients are doing, and I just would like that to be our metrics in future rounds.

MR. ZARABOZO: Of course, in December, we do talk about quality to the extent that we can talk about quality.

MR. HACKBARTH: Just to add on to that, three or four years ago, we were asked by Congress to look at the specific issue of developing metrics by which we could compare Medicare Advantage plans to fee-for-service in the same area.

Suffice to say, it's easier said than done for a lot of the measures. The data sources are very different.

And we made some recommendations of how we could move towards that goal, but there are some complicated issues involved there.

Okay. So we're on round two.

Is it something other than network adequacy?

Anybody who wants to touch on network adequacy before we leave?

Alice, network adequacy? You're up.

DR. COOMBS: So I just wanted to speak to something that someone has already talked about a little bit but with a different lens, and that is, in terms of the ability to monitor or to assess what a network should look like, I think narrow networks are fine.

It's when there's a major change where 10,000 providers are dropped at one fell swoop and --

MR. HACKBARTH: That is major.

DR. COOMBS: And it has untoward effects, and there's not this process -- there's not time for the process of actually having some kind of plan where you say this has reached a critical level.

I think that we have to be anticipatory in some strategy to say this is actually a critical threshold mark. How that's done, I'm not sure.

But it really is a change in the network of functioning systems that are already underway, and then suddenly, you have providers drop.

And it also can impact not just primary care providers, but say you have one dialysis doctor because two of the other ones' contracts are terminated. That's huge in terms of being able to do dialysis on this large, large population.

So I think we always think primary care-centric, but there are some specialties that we should really be concerned about in the critical level.

And I think it's the change in the network because it's good to have a narrow network.

And I think Scott, you know, you guys have probably done an incredible job. But when there's a change and there's not a lot of time to have a response to it.

MR. HACKBARTH: I think you're absolutely right, Alice.

And sometimes the two issues of narrow networks and change are conflated into one issue, and they're really very different issues.

And, personally, I believe plans should have a lot of freedoms to do narrow networks for the reasons Scott has described.

But that's a different thing than bait and switch

and saying you advertise one network and then people get in and you switch the network on them. I think that's a real problem.

Now, Carlos, I heard you say that, in fact, CMS -- is it a proposed rule, or is it actually now final -- what to do when there's a major network change?

MR. ZARABOZO: This is in the call letter. So it is CMS policy.

MR. HACKBARTH: Yeah.

MR. ZARABOZO: It is, yeah.

MR. HACKBARTH: And so they define what constitutes major and then what the beneficiary rights are as a result of that, and that includes the special enrollment period that we touched on earlier.

DR. COOMBS: Just being practical, how quick is a beneficiary notified when something like that happens?

MR. ZARABOZO: Again, the regulations say you must make a good effort -- a good faith effort to notify the beneficiary within 30 days or give 30 days' advance notice to the beneficiary of this occurring.

DR. COOMBS: And so I read that. But how often does that actually happen?

I'm just curious in terms of --

MR. ZARABOZO: Yeah, I don't know. I don't know, yeah, the compliance level, so to speak.

MR. HACKBARTH: Okay. We're ready to open up a new topic.

Let me see hands of people who want to get and go in a new direction.

Cori, just label where you want to go for a second.

MS. UCCELLO: Just some margins, more in-depth analysis.

MR. HACKBARTH: Yeah. Anybody want to pick up on that?

Scott and -- okay, we've got several people who want to go that way.

Cori, you lead it.

MS. UCCELLO: So I've already shared some of this with Carlos, and because I'm trying to overcome my shyness, I'm going to force myself to say it out loud, in public.

So -- no? Stop?

So I'm just really intrigued by some of these margin differences, and I've been trying to think about,

well, what's causing some of these negatives, what's causing the positives.

And I don't think -- this is not something we need to do for December or this year but maybe as we continue this on in the future, trying to understand better:

Are the margins low because the bids were too low?

Because they were trying -- if they're new, are they trying to get more market share; so it's a strategic kind of thing?

Or, did they bid too low because -- inadvertently, because they're just not as good at managing care?

Are there differences -- I mean, is it the coding that's just causing differences in the revenues that are coming in?

Just trying to get more at some of those things that are underlying and trying to figure out if we have concerns about what's going on or not because the bids were -- you know, we see the margins, but the bids aren't equal.

So there's a lot of moving parts here.

So it's hard to assess what it is that's going on.

MR. HACKBARTH: In order to evaluate what's going on underneath, Craig, what do we need?

DR. SAMITT: So thanks for the introduction. You know, it's been a while since I've asked for encounter data.

You know, I would echo Cori's questions.

I'm intrigued by the variation in the margins here, and I think we need to understand in greater depth if there's capacity for analysis of a few things.

I mean, I'd be interested in elaborating further on the coding differences that you've referenced. I think that would be important to look at.

I would be interested in understanding how the various MA plans pay their providers and to what degree does subcapitation influence margins or protection of margins.

Do we see that more in the plans that are subcapitating providers?

And should we also even be looking at the margins of the subcapitated providers, if we can get at that as well, as well as utilization differences?

Are we seeing innovation in the MA plans that are driving favorable margins, and is there something to be learned from that even as it applies to traditional Medicare?

So encounter data may be very helpful information

to layer against and compare with some of the margin information that you've already analyzed. It may offer some additional insights for us to look at.

MR. HACKBARTH: Carlos, what do we know?

What does CMS collect about the methods by which plans pay their network?

Does CMS know who's capitated and who's paid on discounted fee-for-service?

MR. ZARABOZO: I'm not sure that they know that. I don't think they know that.

But when MedPAC, a long time ago, asked, I think, Marsha Gold to look at what is the payment arrangement between providers and plans, it had to be go to each plan and say what are you doing with your providers.

I'm not sure that CMS has a way of knowing, for example, the capitation is entirely -- the MA payment is 95 percent goes downstream. I'm not sure that they know that.

And I'm not sure that we can really look at a subcapitated level to see what's happening, even with the encounter data.

MR. HACKBARTH: Without a special study. You know, commissioning some plan work.

I have Bill and then Dave.

MR. GRADISON: The discussion of marketing costs has caused me to think a little bit more about what role exchanges could play in the future.

And these exchanges can come at least in two different varieties. One would be the ACA exchanges themselves, whose purposes could be broadened. And another would be the private exchanges that are cropping up and giving choice to apparently an increasing number of privately insured through employer-paid plans to make choices.

Cross-cutting that, there's a question of whether -- if exchanges were increasingly used, what would be the payment rate?

And of course, one initial answer is use the current bidding system but look into whether exchanges might help to lower marketing costs without changing the reimbursement level, just as a way to constrain cost.

Obviously, a further step in the analysis -- and I'm sure it's controversial, but I think some day it might be worth taking a look at -- is what if we moved away from this current -- I was going to say very complicated; that's

true, too.

If we moved away from the current method of establishing bids and used an exchange system where the plans market themselves at whatever price they want to market and compete with each other, as is happening in the ACA plans today.

So this is nothing immediate. But the interaction between what we're talking about and exchanges, looking perhaps a few years in the future or something, I would encourage us to take a look at.

MR. HACKBARTH: Is it on this particular issue, Kate?

DR. BAICKER: So this competition idea, I think I had in mind that plans would attract enrollees by offering better benefits with lower margins built in, and some of the materials hint at how many plans are in positive margin versus negative margin, but I didn't get a sense of this question of whether the competition between the plans actually attracts -- are beneficiaries in general moving towards plans with lower margins or towards plans with higher margins? Is there any evidence of competition working to keep margins down, or do we actually see the

reverse?

MR. ZARABOZO: That's a good question. We haven't looked at that, but it's a good thing to look at, I think.

DR. MILLER: I do just want to remind everybody. So I can't remember the year, but we did kind of go through and do some simulations of different ways of thinking about the MA baseline, whether you set it administratively this way or whether you set it competitively at the average or the 75th percentile or whatever it turned out to be.

And then also, we did some analysis where we were looking at -- and this is a couple of years ago now -- sort of thinking about doing that kind of a framework with both fee-for-service and MA and wrote that up in a chapter a couple of years ago. So there's been some of that going on, but the notion of returning to it, I don't have any objection to.

And I would also just take Kate's question and say for us to go back and talk about not just are they moving -- which is fine -- in direction of high-low margins, but what indicators are people moving in the direction of? Does the premium, does the -- you know, that type of thing. I would sort of broaden it a little bit.

DR. NERENZ: Well, this question may now follow Cori and Craig and Kate, so it's building.

If you could put Slide 7 up, please. I thought this was really interesting, particularly when combined with the information of Table 2 in the materials.

If I am interpreting Table 2 correctly, I guess it is not height of the bar. What do we call it? The width of the bar? The extent of the bar to the right is essentially a visual proxy for company size. It is not plan size. But just in looking at the detail in the table, the small companies tend to either not do very well or a few of them do extremely well. But the big companies do well, and I don't know if this is now directly a reflection of sort of not your dynamic, but the people seem to be in the plans that have the higher margins, at least in the big companies.

But it now is a special case of Cori's question. Is that because the big companies have better negotiating leverage and they use that kind of dynamic to get better margins? Are they better bidders, or is it the other way around?

MR. HACKBARTH: Are they in markets with high traditional Medicare costs --

DR. NERENZ: It could be that. It could be that.

MR. HACKBARTH: -- where the enrollment still tends to cluster and we have some evidence of higher margins in those places, as well?

DR. NERENZ: Or, since this is one year, is it just some random variation? That is, the small companies just are more variable in terms of their margin, and so they just happen to fall to the extremes, but in a different year, they look different.

So what's the message here about company size? Is there a message?

MR. ZARABOZO: There might be, and I think you might vary the smaller companies, smaller margins, part of -- I mean, economies of scale and so on, you may have in-house marketing people as opposed to having to pay brokers and potentially better ability to negotiate with providers, as you suggested.

We can look at it. It would be nice to look at it over time. I mean, part of the purpose of doing this is sort of have a baseline and look at over time what happened to -- like, for example, looking at this 2012's negative-margin people, what happened to those people?

MR. HACKBARTH: Okay. Let's see. I have Jack. Are you going in a new direction? Go ahead.

DR. HOADLEY: I mean, on this very specific point that you are mentioning, this is the company-level analysis. So, I mean, to Glenn's point, many of these companies, certainly the larger companies, are national. They are going to be in -- to the extent that they pick and choose, some obviously more and less, but they are going to be in a lot of different kinds of markets. So it gets to part of how we need to look at that.

To Kate's point, the other thing that seems like it's sitting out there is the start ratings. I mean, is there any correlation between star ratings and these margins? And the related question that we've asked before is whether people are drawn at all to the companies with higher star ratings, and the literature, what little there is, it seems to be maybe a little bit moving towards higher star ratings, but not real strong on that point.

Together, those create some interesting questions. If start ratings and margins have some particular relationship, even more reason to look at whether people are gravitating to ones that are high quality and operating

efficiently.

MR. HACKBARTH: If I was interpreting Slide 7 correctly, it really doesn't directly address company size. What it says is that the enrollment tends to be in places where the margins are high. That could be, in theory, smaller companies, just a lot of them, enrolling a lot of beneficiaries in places that are very profitable.

DR. NERENZ: Glenn, that's why I made reference to Table 2, because it refers to a number of companies --

MR. HACKBARTH: Oh, okay.

DR. NERENZ: -- and the number of enrollees, and it just turns out that there are significant number of companies in those upper bars, even though it's few enrollees.

MR. HACKBARTH: Yeah.

DR. NERENZ: So there are just a lot of small companies that are in the red-shaded area as well as the other extreme.

MR. HACKBARTH: Okay. I didn't look at Table 2. Yep.

MR. ZARABOZO: On that point, Jack, we did look at the stars for 2012, which was the first year of the bonus

program, and the highest margins were among the 3.5 star plans, which were bonus plans at that time.

But, of course, stars and benefits are tied together, so it's hard to say people are enrolling in a high-star plan, as Jon raised, because they are high-star plans. Well, they offer better benefits, so that may be why they seem to be migrating to the higher star plans.

MR. HACKBARTH: Yeah.

DR. REDBERG: I don't think people use the stars as much as the benefits, personally.

MR. HACKBARTH: So we're down to -- let's see. Actually, we've got about 15 minutes still left. So, Jay, do you want to go in a new direction? Okay.

DR. CROSSON: So I wanted to talk about the PSO issue a little bit, because I think we might be making an error if we just kind of dismiss it, because the waiver ran out and the like. In the way it was constructed originally, not a lot of organizations chose to go in that direction, but that was 10 years ago or more, and we have a different situation.

What?

MS. BUTO: More like 20.

DR. CROSSON: 20 years ago.

I think the reason it is potentially interesting to me -- and you may have been approaching that earlier -- is that it might create -- by reanimating it some way, legislatively. It could potentially create some positive -- it could help with some positive directions that we've talked about before. It could potentially make it easier for ACOs or provider organizations to assume risk, to engage in care coordination, without having to go through a plan.

Now, I have nothing against plans, having worked in a fully integrated organization my whole life, but I do know that it is one of the barriers to some of the larger integrated system trying to get into this business, because they can't necessarily find a plan that they're comfortable working with.

If they create one, a small one, that's a lot of work, but it also creates retaliation in some circumstances by other payers if they do that, and so they don't do that.

It seems to me that this could potentially obviate some of that barrier problem and speed along the development of these kinds of organizations, within the Medicare program for sure. It has the potential to solve the attribution

issue, which has been so troublesome, since it is an MA plan, to be able to be real attribution.

Having said that, it would seem to me that one of the problems -- I tried to read between the lines, Carlos, in what you've written -- that one of the problems with uptake was not only the regulatory requirements, but the fact that when this was being discussed in the past, the assumption was that Medicare would fully pass the risk to the provider organization. In other words, it would be full global capitation.

If you look at what's going on now, we almost have the opposite problem, at least with respect to the Medicare shared savings programs, where the transfer of risk or gain is so small that plans -- I mean provider organizations have had perhaps less than a robust incentive in order to sign up.

So I wonder whether or not there's some new thinking that we could get into which would be characterized by reanimating the MA PSO option, which is or is not still on the books, but certainly would require some legislative change. But constructing a different kind of shared risk assumption or a card or capitation or some process by which

over time perhaps, for certain types of services versus others, the provider organization would be accepting a lot of risk, but for others, Medicare would be carrying the risk. I know this model very well from my past experience.

And we could also deal with some of the risk assumption, positive, negative, downside kinds of barriers, which have gotten in the way of ACO development and uptake and maintenance.

Now, this is not a simple issue because, again, this would require some rethinking and passage of legislation, but it also struck me -- and I think there was a comment, at least in one of the articles that I read -- that depending on how you talk about it and how you frame it, there's a potential for bipartisan support for moving in this direction; that is, integrated systems with prospective payment in Medicare.

And I just wondered whether -- and I think we need -- I'd hope we could just think about it, whether or not moving in this potential direction as opposed to calling things what we have been traditionally been calling them would perhaps create a different political alignment around this direction.

Those are my points.

MR. HACKBARTH: The idea of opening up new options, different paths, is one that always appeals to me, just as a matter of principle.

I have wondered, though, about the PSO experience and why it never caught on. So, as I understand the PSO framework focused on, well, let's have a different way of establishing the financial ability of these organizations to bear risk, something that's different than traditional state insurance regulation.

DR. CROSSON: It was also full risk.

MR. HACKBARTH: Yeah.

DR. CROSSON: You take all the risk.

MR. HACKBARTH: Right.

DR. CROSSON: Medicare keeps no risk.

MR. HACKBARTH: Right. But insurance companies do other things besides bear financial risk. They do marketing, and they do claims and that sort of stuff. So if an organization, a PSO, is going to be competitive in the Medicare Advantage business, not only do they need to have a way to handle the risk, they also need to carry out these other insurer functions, because it is an enrollment

program, not an assignment program, the way ACOs are.

And those are functions that cost money, that even integrated health care systems don't generally know how to do, so it may be that some of the barrier to PSOs was that other stuff, as well.

MS. BUTO: Think back 20 years ago. There were so few new ideas on the table.

I think one of the issues, Glenn, was the -- correct me if I am wrong. You would remember this, but I think the BBA also substantially lowered the rates for tougher risk plans or the equivalent --

MR. HACKBARTH: It was a 2 percent rate of increase.

MS. BUTO: And there was a redistribution that happened between the high-cost areas, and so there was another kind of wave of nausea, if you will, around how predictable a partner the government was going to be on something this new that would require a lot of organization, capitalization, and so on and so forth. So that was certainly part of it, at least that was the feedback we got at the time.

The other thing that strikes me is that -- I

remember during the negotiation, we talked about the administrative functions and having to establish some kind of an administrative partner with the provider-sponsored organization. A number of organizations were already moving in that direction. Then a number of them have become Medicare Advantage plans.

I think Scott's point, which he made a while ago, was another issue, and that was how do you maintain a level playing field between state-licensed managed care plans and a federally sanctioned managed care organization. And that would have to be tackled again.

Now, maybe the ACOs raises at least the question of some kind of an off ramp into a more fully integrated managed care risk plan, and it could be more of the off ramp, that in-between thing rather than closer to risk, but not necessarily full risk. But we'd have to really look at it to see what has changed since then that we might want to consider, because I think all these things are still out there.

MR. HACKBARTH: Jay, I just want to underline the purpose was not to try to shut down the idea. In fact, in principle, I do think that the more flexibility we can offer

in terms of how providers offer themselves, assume financial risk, relate to insurance companies, in principle, that's a good thing to me, but there are a lot of different potential elements to it.

I have Jon and then Mary.

DR. CHRISTIANSON: Yeah, I like the comment, Jay. I like it. I think we should explore it, and I think one of the things that has changed is a larger percentage of employers are self-insured now, and we have a more robust market for reinsurance and for the sale of administrative services that might have existed. And I think that adds to the feasibility of sort of returning to this idea and exploring it a little more.

DR. NAYLOR: So I'm absolutely out of my league, but one of the things that intrigued me was that 18 percent of hospitals currently own insurance companies or programs, and an additional 28 percent are expected to launch. So it didn't sound, as I am reading that, that there are major barriers, at least at the hospital level, which is different than a community-based provider. So I was wondering if you could comment on what might be barriers that would lead or support movement around a federal PSO.

MR. ZARABOZO: Well, the only thing I can say is that there are number of provider-sponsored organizations, and there are several coming on in 2015, also. So this is happening that these provider groups are forming health plans that become Medicaid Advantage plans.

And I don't know. Maybe in particular states, there are larger barriers than in other states, but, again, as Mark points out, there's more to being a health plan than just, "I have a delivery network here," and so we'll see what develops with these kinds of organizations.

MR. HACKBARTH: Okay. We are at time. I have Jon and then Scott, and then we'll have to wrap it up.

DR. CHRISTIANSON: Yeah. Just very quickly, as I've said before, some of them are coming online by being offered as options within MA plans, so they're sort of like -- they don't know how big that demand is for accepting risk, but at least there are some provider organizations that are experiencing.

The sort of issues of managing care under ACOs, I think they're willing to accept more risk, and one way to do that is being offered as a capitated option under an MA plan.

MR. ARMSTRONG: Also very quickly, I just want to affirm that I think that this also is a topic really worthy of our closer attention. Really, I worry about it from both sides, as an advocate for the kind of policy agendas that Jay and others were talking about to promote integrated risk-bearing groups that engage patients in real relationships and are accountable for outcomes.

On the other hand, we do have to be really explicit about the expectations that we placed on insurance companies and the work that is required not only to comply with regulations, but to assure our beneficiaries are getting the care that they require.

In fact, I would argue there are too many restrictions, and there's this middle space in between that I think MedPAC could do an excellent job of trying to flesh some of the issues out and shed a little more light on.

MR. HACKBARTH: And, of course, at some point, we, I think, potentially bump into issues about federal and state responsibilities. Regulation of insurance companies has traditionally been the domain of the states, and we've made some -- sort of carved into that in some ways. The more we carve into it, the more potential for friction

between the federal and state governments.

So lots of interesting potential avenues here. Thank you, Carlos, for your work on this.

Let's now move to our last item for today -- or, no, next-to-last item for today. Excuse me. It's funny how I -- yeah.

So next to the last for today is payment for primary care, specifically converting the bonus for primary care into a per beneficiary per month payment.

So, Julie, Kevin, who's leading? Kevin.

DR. HAYES: Good afternoon. This session is for your continued discussion of issues surrounding this per beneficiary payment.

By way of a recap of your previous discussions, recall that there is today a Primary Care Incentive Payment program. The Commission recommended such a payment in its June 2008 report. It became law as part of PPACA. In a moment, I will go over the details of how the program works, but for now, it is important to note that the bonus equals a percentage of fee-for-service payments for primary care. The bonus program expires at the end of 2015.

I'll note here that, at the beginning of 2015, a

new payment for chronic care management will start. Its structure is very different from the primary care bonus, and it's different from the per beneficiary payment that is the subject of today's discussion. However, if you have questions about the payment for chronic care management, we will take those on question.

Specific to the primary care bonus, you considered several questions over the course of three meetings during the Commission's last report cycle. Should the bonus be replaced with a per beneficiary payment? If so, what are the important design issues for a such a payment? And how should the payment be funded?

One outcome of those meetings was a chapter in the June 2014 report. The chapter did not include recommendations. You did, however, direct us to develop a policy option for consideration this fall.

Our agenda for today begins with the Commission's rationale for replacing the primary care bonus with a per beneficiary payment. From there, we review your previous discussions on the topic as represented in the June report chapter.

First up, the payment amount for a per beneficiary

payment.

Second, the method of funding for the payment.

Third, whether receipt of the payment should be contingent on meeting practice requirements.

And, fourth, an approach to attributing beneficiaries to a practitioner.

We will conclude with the statement of a policy option for replacing the current primary care bonus. This will be a policy option that we believe includes the elements of a recommendation you could make on a per beneficiary payment.

Your discussions on this topic started from the position that primary care is undervalued in Medicare's fee schedule. Further, the fee schedule contributes to disparities in physician compensation. Average compensation for some specialties can be more than double the compensation of primary care practitioners, with compensation measured either in the aggregate or per hour worked.

The consensus you reached was that a per beneficiary payment could replace the expiring primary care bonus. Primary care is essential to delivery system reform.

A per beneficiary payment would be a step away from the unit-based payment of the fee schedule and toward a beneficiary-centered approach that encourages non-face-to-face activities critical to care coordination.

Replacing the primary bonus with a per beneficiary payment would require resolution of certain design issues: the amount of the payment, a funding source, whether practitioners and their practices would have to satisfy requirements to be eligible for the payment, and

how to attribute beneficiaries to a practitioner. Each of these issues was discussed in the June report chapter, and we will review them during our presentation today.

By this year's April meeting, your discussion was at a point where there was support among Commissioners for funding a per beneficiary payment at the same level of funding as the primary care bonus program, at least as an initial starting point. The current program provides a 10 percent bonus on primary care services furnished by primary care practitioners.

In 2012, bonus payments totaled about $664 million, with about 170,000 practitioners receiving the

bonus. Those practitioners accounted for about 20 percent of practitioners billing Medicare in that year. Bonus payments per practitioner averaged about $3,400. However, practitioners who provided more primary care services to a greater number of fee-for-service Medicare beneficiaries received much more than the average. For example, the average bonus for those in the top quartile of the bonus distribution was about $9,300.

To convert the primary care bonus to a per beneficiary payment, we start with the $664 million in bonus payments. The primary care practitioners receiving the bonus provided primary care services to about 21 million fee-for-service beneficiaries. Dividing $664 million by 21 million beneficiaries results in about $31 per beneficiary.

With a payment financed as a replacement for the primary care bonus, Medicare beneficiaries would not pay cost sharing. Medicare could make the payment on a periodic basis, say quarterly, which is how the primary care bonus is paid.

Turning now to possible sources of funding for the per beneficiary payment, your discussion to date has focused on: concerns about support for primary care,

recommendations the Commission has made about rebalancing the fee schedule, and redistributing payments within the fee schedule.

To redistribute payments, you have considered two strategies. One is to reduce payments for services not eligible for the current primary care bonus. I'll define those services in a moment. The alternative is to reduce payments for services identified as overpriced. This alternative is the one you discussed the most at previous meetings. Let me say a few things now about this alternative before coming back to the broader approach of reducing fees for services not eligible for the bonus.

In considering overpriced services as a funding source for the per beneficiary payment, two issues are worth noting.

First, after the June report chapter was drafted, the Congress used some of the savings from overpriced services to override the SGR. One question, therefore, is whether, going forward, savings from overpriced services will be used for other purposes.

A second issue is that the level of savings from overpriced services changes from year to year depending on

the overpriced services identified. This introduces some uncertainty in estimating savings.

Of course, if savings from overpriced services do prove to be identifiable and sufficient, overpriced services could be considered as a funding source. In the meantime, overpriced services are best viewed as an alternative funding source for the per beneficiary payment rather than the funding source to use when the payment is initiated.

Let's return now to services not eligible for the current primary care bonus and whether they could serve as a source of funding for the per beneficiary payment.

This alternative would protect the services eligible for the primary care bonus but reduce the payments for all other services in the fee schedule. The savings would then be redistributed as the per beneficiary payment.

Before getting into the specifics of how this funding method would work, let's review how the current bonus works.

The requirements for receipt of the bonus are as follows: It's applied to the payments for a subset of evaluation and management services, such as office visits. The bonus is available to family medicine physicians,

general internists, geriatricians, nurse practitioners, and others. And it's available to those for whom primary care services account for at least 60 percent of total allowed charges.

Given the specifics of how the current bonus works, we are now ready to talk about a fee schedule reduction as the source of funding for the per beneficiary payment. The intention here is to have a per beneficiary payment that's comparable to the current bonus. Total monies would be the same and going to the same practitioners.

Looking at this graphic, there are two ways to accomplish this. First, it's possible to protect the primary care services eligible for the bonus and then reduce the payments for everything in the fee schedule -- services and practitioners -- not eligible. This is the option shown on the left side of the graphic.

Funding for the per beneficiary payment would come from about 90 percent of the fee schedule. It would require a reduction in payment for those services of about 1.1 percent.

A variant on this option is to protect all bonus-

eligible E&M services, regardless of specialty and regardless of whether primary care services account for at least 60 percent of a practitioner's allowed charges.

Going from left to right, this is the option shown on the right side of the graphic. In this case, funding would come from about 75 percent of the fee schedule. Because the funding would be coming from a smaller portion than the earlier option, the reduction would be a bit larger: 1.4 percent.

So that's where things stand with your discussion of funding the per beneficiary payment. Julie will now review your discussion of the two remaining design issues.

DR. SOMERS: Our third design issue concerns whether receipt of a per beneficiary payment should be contingent upon fulfilling practice requirements such as extended office hours or opportunities for patients to communicate with their practitioner through e-mail.

Over the course of its discussions, the Commission appeared to reach a consensus on having no practice requirements. That decision was favored for two main reasons:

First, a payment amount at the current primary

care bonus level may not be enough for practitioners to make substantial practice investments.

And, second, regardless of the funding level, evidence concerning the effect of practice requirements on improving quality and reducing health care spending has been mixed.

However, the issue of practice requirements could be revisited in the future. Some of you indicated the sentiment that the initial implementation of a per beneficiary payment should be viewed as a starting point that could be built upon going forward. So in the future, the Commission may recommend practice requirements, if the per beneficiary payment amount were to increase and if new evidence were to show that certain practice requirements are effective at increasing quality and lowering costs.

Our fourth and last design issue is how to attribute beneficiaries to practitioners. Unlike the service-based primary care bonus, a per beneficiary payment necessitates attributing a beneficiary to a practitioner to ensure that the right practitioner gets paid and that Medicare does not make payments to multiple practitioners on behalf of the same beneficiary.

Among other options the Commission considered were prospective attribution and retrospective attribution. In prospective attribution, beneficiaries are attributed to eligible practitioners at the beginning of the performance year based on the plurality of eligible primary care services furnished in the previous year.

In retrospective attribution, beneficiaries are attributed to eligible practitioners at the end of the performance year based on the plurality of eligible primary care services furnished in the actual performance year.

While there are pros and cons to both methods of attribution, the Commission appeared to favor prospective attribution. Advantages of doing so include the ease with which it could be administered. Like the primary care bonus payment, the practitioner would receive payment automatically without extra paperwork requirements on behalf of practitioners and beneficiaries.

The practitioner could also be paid throughout the year and may be better positioned to make front-end investments in infrastructure and staffing that facilitate care coordination.

However, under prospective attribution, if

beneficiaries do not stay with the same practitioner throughout the year, or if they switch practitioners from year-to-year, practitioners would be paid for beneficiaries no longer under their care.

At the April meeting, Commissioners asked staff to look into this issue. We did, and here's what we found:

An overwhelming majority of beneficiaries (69 percent) stayed with the same practitioner within a year. And a smaller majority (60 percent) stayed with their practitioner from year to year.

We also found that, from a practitioner's perspective, some beneficiaries switch out of the practitioner's practice and go to other practices, while other beneficiaries switch in from other practices. So, on net, practitioner panel sizes are relatively stable from year to year.

And, finally, even for those practitioners whose panel sizes do increase or decrease from year to year, those changes will be reflected in the attribution for the next performance year. So per beneficiary payments in the next performance year will move up or down according to the changes in panel size.

So to wrap up, at the end of your discussions in the spring, you asked us to formulate a policy option. e did so, and it is presented here on this slide for your review. It is our best effort at representing the views of the Commission to date.

Stepping through the bullet points, there appeared to be clear consensus on replacing the expiring primary care bonus with a per beneficiary payment at a payment amount set at the level of the current bonus.

On source of funding, last spring there was an interest in using savings from reducing the fees of overpriced services. But since then, as Kevin just explained, the Congress has used some of the savings from overpriced services to override the SGR, and the Congress could continue to use those savings for other purposes going forward.

Due to those circumstances, we put up here for your consideration the other funding method Kevin outlined: to reduce fees for all services that are not eligible for the current bonus. But we'll leave that for your discussion today.

On attribution, the Commission appeared to favor

attributing beneficiaries to practitioners prospectively. And finally, on practice requirements, the Commission favored no practice requirements at this time.

So, in summary, we think the main issue left for discussion today is how to fund the per beneficiary payment.

With that we conclude, and we look forward to your discussion.

Thank you.

MR. HACKBARTH: Okay. Thank you, Julie and Kevin.

I want to say a couple things at the outset, one about where we are in the process, and the other a little bit of context, in particular for Kathy and Warner.

The process piece is simple. My hope is that, after today's discussion, we will have the raw material for a draft recommendation to be discussed next month, hopefully working towards a final recommendation in January that would be included in the March report.

In terms of the context for this, this issue ha a fairly long history in MedPAC, really going back to 2008-2009. And it was back in that time frame that we first recommended the primary care bonus that is in current law. It was enacted as part of the Affordable Care Act in 2010.

As you know, that is expiring, and that is why we're now revisiting this issue.

You know, our feeling in 2008 and 2009 was that it made sense to make this adjustment and payment outside the framework of the resource-based relative value scale for a combination of reasons having to do with the perceived high value and importance of primary care and concerns about the economics, the viability of primary care practice. But it is decidedly something that, you know, is happening outside the normal construct of resource-based relative values.

I do think it's important to emphasize that we've done a lot of work also within the confines of the fee schedule to try to improve the measurement of relative values, and over years work encouraged by us and some done by others has led to a series of adjustments in payment for our evaluation and management services that have pretty significantly increased E&M relative to other services.

The last time we talked about it, Kevin, it was, you know, 28 percent or something like that, cumulative --

DR. HAYES: [off microphone].

MR. HACKBARTH: Yeah, adjustment in E&M services from a series of changes in both -- various parts of the

system. So that's important work. We will continue that work. This isn't in lieu of that but, rather, in addition. And I'd highlight that that's also E&M services, and E&M services are provided not just by primary care clinicians but also by various specialists. This is targeted, as you well know, to primary care in particular.

The other thing going on in this history, of course, is the notion of a medical home, which would also include a per beneficiary payment as part of the structure. Back in the same time window, 2008-2009, we recommended that there be pilots of medical. For a variety of reasons, those were delayed for a while. The Affordable Care Act sort of reinstituted the legislative authorization for those pilots, and they are underway as we speak. And off the top of my head, I couldn't say when we're going to get definitive results from those, but it's still a ways down the road. So this is something that we thought could be done while medical home pilots are underway and evaluated and all of that that would be simpler to institute.

Now, the bonus is an add-on to individual fees, not a per beneficiary per month payment, and the bonus is expiring. So when we first addressed the question about

what should we do about the expiration of the bonus, we said should we just repeat the same thing and say it just be extended, or maybe a different form of payment might be a better way to support primary care. And that's what brought us to this point.

I think it's safe to say that none of us who have been involved in this have any illusions that, A, this is the perfect way to construct the payment and it's going to be targeted perfectly or, B, that it's going to make all the difference for primary care practices. When we talked about this -- I think it was back in the spring -- there was a very strong point of view that even if this isn't a huge amount of money, it's important to continue it and not allow it to expire and for Medicare to backslide on this issue.

So, with that guidance from the Commission, we set about to try to figure out how it might be extended at expiration, which leads us to the point where we are today.

You know, the issue in this series that we've discussed least is probably the second bullet. We did talk about funding, as either Kevin or Julie said in the presentation. There was seemingly a lot of interest in using overpriced procedures as the funding source, but then

we did have this intervening action by the Congress where they wanted to use some of that money for SGR extensions. And so we need to really consider the funding source in this somewhat altered context.

So that's a brief recitation of the history that brings us here. Round 1 clarifying questions?

DR. CROSSON: Yes, Kevin. Thank you. Very clear and concise, as always.

Could I ask you if you have thought about how the policy would or would not integrate with the care coordination payments, particularly as specified in the CMS rule that you probably haven't had a chance to fully read yet?

DR. HAYES: We did anticipate this, and we've got a slide here, which just to begin with would summarize how the chronic care management code works, and then we can speak to your question. Is that okay?

Why don't you go ahead.

DR. SOMERS: Sure. I'll summarize the slide here.

So that's right. Separately, CMS has developed a new code for chronic care management services set to begin with a 2015 fee schedule. The code will be billable by

practitioners of any specialty who furnish non-face-to-face chronic care management services to beneficiaries with two or more significant chronic conditions.

The beneficiary must provide written consent and will be charged cost sharing.

In its final rule, issued last week, CMS proposed a payment rate of $40.39 for the code, which can be billed no more frequently than once per month per qualified beneficiary.

According to its proposed rule, issued in July of this year, CMS is projecting annual allowed charges from the code of $107 million. That relatively small projected total suggests that CMS is expecting low use of the code.

While the Commission has supported this effort, the chronic care management code differs in design from the per-beneficiary payment under consideration today, largely due to different goals of the two initiatives. So, specifically, the per-beneficiary payment would be paid only to primary care practitioners. It would be paid automatically, and beneficiaries would not provide written consent, nor would they pay cost sharing.

Do you have something to add, Kevin?

DR. HAYES: No, that's good.

MR. HACKBARTH: Go ahead.

DR. CROSSON: Right. Again, there's a number of moving pieces here. I mean, it is what it is.

It did strike me as interesting in looking at what I read, anyway, about the rule that this is a lot more money per beneficiary than what we have proposed in this policy, and yet, as you mention, it's expected to produce, what, about less than 20 percent of the total expenditures by Medicare? So the expectation is, for some reason, that it is not going to be taken advantage of.

I don't know what to say about that, except that it strikes me as odd, because I would imagine for this amount of money, per beneficiary per month, it would be a lot of physicians and different specialties interested in pursuing that. So whether that's the right number or not, I don't know.

What we would be proposing then would be additive to this. As you point out, because we have a different set of goals here, it's not, per se, about coordination; it's about the fact that we believe that primary care physicians (a) have a particular role in advancing care coordination,

but in addition, they are underpaid, right?

I don't see a conflict here, per se, except that as we bring this policy forward, the policy recommendation forward, I think we need to be ready to answer people who say, well, you know, we've already done that with this rule. What's different about it? Do you really want to have two? Or more now with the medical home and everything, but do we really want to add yet another one? And so we need to be very thoughtful in communicating the new policy that it in fact is fully justified, perhaps creates slightly different incentives than we have here, so that we don't -- it doesn't end up getting just shelved on the face of it.

MR. HACKBARTH: For me on this list, the things I would highlight are billable by any specialty, which I think is a really important distinction. I don't know what the share of the dollars is here that's going to go to subspecialist, but I would think it's a pretty big hunk of that, that money. Is that actually in the CMS proposal?

DR. SOMERS: The projections are that most of it will go to the types of primary care specialties, but there are -- for example, cardiologists are another group --

MR. HACKBARTH: Right.

DR. SOMERS: -- that's projected to bill.

MR. HACKBARTH: That's what I would have -- yeah, I would have thought cardiology, endocrinology, a variety of subspecialties might get a lot.

But you say that CMS's projection is that most of it goes to primary care?

DR. SOMERS: Right.

MR. HACKBARTH: The other thing that is different here is that -- of course, this is limited to patients with two or more chronic conditions; whereas, our bonus is for all primary care services.

Now, given the fact that so many Medicare beneficiaries have two or more, I, too, was surprised at the price tag here, the magnitude of the payment. That not very restrictive condition on the patients eligible -- I don't know. There seems to be a disconnect for me between that and the price tag, but maybe you have some insight on that, Julie.

DR. SOMERS: In the final rule, there was a lot of commentary about the written consent and the pay and cost sharing.

MR. HACKBARTH: Yeah.

DR. SOMERS: So it would be $8 cost sharing the practitioner needs to bill each time. CMS doesn't have the authority to have a recurring payment go out to practitioners. So they didn't say it explicitly, but perhaps it's the cost sharing and the fact that --

MR. HACKBARTH: So the implicit is patients won't want to do it.

DR. SOMERS: Right, right.

DR. CHRISTIANSON: But the billing -- [off microphone].

DR. NAYLOR: There's also, in the final rule, the explicit practice requirements, which are onerous, meaning may be perceived by practitioners on completing medication reconciliation, making sure there's connection with all other health professionals, so they are very specific, and all of that being documented.

You pointed all that out in the terrific report. Those, I think, make this, as the transitional care payment codes, a question about whether people will really use this tool because of pretty substantial practice requirements.

DR. CROSSON: Can I just make one point? Let's just take the care of an internist managing a panel of

2,000. Let's say on average, 10 percent of those are Medicare beneficiaries. It is probably greater than that. Even for 200 patients times $40 a month, that's $8,000 a month or $100,000 a year.

I mean, for many physicians, particularly primary care physicians that are struggling financially, I would imagine a lot of them would overcome these potential barriers in terms of the practice requirements, for that amount of money.

MR. HACKBARTH: How does the $40 compare to what's in the medical home pilot?

DR. HAYES: Those medical home pilots span a wide range. I'd be hesitant to try and pin a dollar average on those.

Some of them are in this area of $40, some of them are a bit higher, but some of them are quite a bit lower, too.

The thing about those pilots is that they take a variety of forms. They involve -- in a number of cases involve collaborations with the states. There is an expectation that they are multi-payer in nature, and the states are playing a big role in the design of them. So

they just cover such a wide range that I'd be reluctant to try to characterize what those are.

MR. HACKBARTH: I understand.

DR. HOADLEY: Do those have copays, the medical home pilots? Do they have copays associated with those?

DR. SOMERS: I don't believe they do for the --

DR. HAYES: [Off microphone.]

DR. SOMERS: Yeah.

MR. HACKBARTH: Okay. So we're in clarifying questions. Who else wants to jump in here? Dave.

DR. NERENZ: Just a quick question on the arithmetic here. It looks straightforward. This assumes that every single beneficiary is going to be attributed to a primary care physician. Would that be correct?

DR. SOMERS: Not all. There's around 35 million fee-for-service beneficiaries.

DR. NERENZ: Okay. That's what I wanted to ask.

DR. SOMERS: Okay.

DR. NERENZ: So the 21 is the subset of all.

DR. SOMERS: Right.

DR. NERENZ: And how do you get from the 35 to the 21?

DR. SOMERS: So those are the beneficiaries that received an eligible primary care service from an eligible primary care practitioner.

DR. NERENZ: One service?

DR. SOMERS: At least one.

DR. NERENZ: Okay, good.

DR. NAYLOR: So I think you've answered this before, but remind me. How will nurse practitioners or other qualified health professionals who operate on --

MR. HACKBARTH: Incident.

DR. NAYLOR: Incident 2. Yes. Sorry. -- Incident 2 be eligible for this. They are eligible for the bonuses, but I'm just asking what's the strategy here.

DR. HAYES: Well, let's first just kind of get consistent on the issue of what Incident 2 billing involved. So, as most of you know, there are two ways by which services furnished by nurse practitioners can be billed. One way would be if they are practicing independently and have the own provider number and submit a claim and so forth, and they're paid for their services.

The other way would be if they are furnishing services and billing for services, Incident 2, the services

furnished by a physician. In that case, then the billing occurs under the practice -- under the providing physician's provider number, and so the payment is going back that way.

Now, with respect to this payment, we have a question of who would be eligible for the payment, and the way that we are contemplating this, the rules would work in a similar fashion to the way the primary care bonus works, and that we're talking about physicians who are in certain specialty designations.

So, in that case, the question would be whether a nurse practitioner billing Incident 2 is billing -- whether her services are being billed by a physician who is in the specialty designation that we have in mind for this particular type of payment, and so there's a potential in that kind of case for a nurse practitioner not billing under his or her provider number to be billing -- having instead their services billed by someone in a specialty not eligible for this payment. That would be a possibility.

Otherwise, we anticipate that if a nurse practitioner is practicing independently, they would be one of the specialties that would be eligible for this payment, and for patients attributed to them, they would be receiving

the payment.

DR. NAYLOR: Just a brief follow-up. Is there potential for coding adjustment that would allow advanced practice nurses, nurse practitioners, and other health professionals who are delivering 100 percent of the primary care services to be eligible for the bonus.

DR. HAYES: What it would take from a coding standpoint would be -- as long as there would not be any -- well, the only way that I could see for a coding adjustment to occur would be if, say, there were a payment modifier identified on the claim, which said, well, okay, this is a service that's, say, a primary care service, and we're going to put essentially a flag in the claim to indicate that while it was furnished by a nurse practitioner, Incident 2, the service otherwise billed by the physician.

MR. HACKBARTH: So, Mary, I just want to be sure I understand the case you are talking about. Say a cardiologist, the physician doing the billing is not eligible for the primary care bonus. A nurse practitioner is doing work, Incident 2, that is primary care work, and you are trying to figure out how the primary care bonus could be paid for the work of that nurse practitioner.

DR. NAYLOR: It also exists in primary care practices.

MR. HACKBARTH: Okay.

Go ahead, Kevin.

DR. HAYES: When you say it exists in primary care practices, what do you --

DR. MILLER: I think the way I think about it, there's three potential cases that we're talking about here. If the advanced practice nurse has a separate ID, they get it. It's all straightforward. They submit a bill.

If the advanced practice nurse is billing Incident 2 for a primary care physician who qualifies, then the two of them sort the money out, just like they do now, right? The physician gets paid and has some kind of financial arrangement.

The third case is the advanced practice nurses practicing with somebody who doesn't qualify, whether it's a primary care physician or whether it's a cardiologist, and I think that is the case.

And I think that almost implicates kind of the basic question. If the person whose billing is not falling into the category, one question is should the --

DR. NAYLOR: [Off microphone.]

DR. MILLER: Well, no, not reimburse, but should the advanced practice nurse get the bonus, because to his point or to his example, that's a person providing cardiology. Then I guess the question is how would you know for sure that the advanced practice nurse was providing primary care or whether providing something related to cardiology follow-up.

Now, I'm not trying to shoot this out of the -- but I want --

DR. NAYLOR: I don't want to -- honestly, we can talk about it. I fully support this proposal and policy. I just wanted to make sure that attribution, that we had considered all of the people who are delivering primary care services, and so that was --

DR. MILLER: And if I could. I just want to be really clear. I'm not trying to blow it out of the water, but I wanted the conversation to kind of zero in on that thing that I think you are trying to talk to each other about.

MR. HACKBARTH: So, in Mark's three-part framework, I think the first two cases are straightforward.

An advanced practice nurse gets compensated, gets the bonus for primary care work done either directly or through the physician who is doing the billing.

For me, the third case is really problematic, and the essence to me of Incident 2 billing is the advanced practice work is Incident 2, the specialist work in that third case, and so it wouldn't qualify for the primary care bonus. But the first two cases, independent practice or Incident 2 practice in primary care, I think are very straightforward. Does that make sense?

[No response.]

MR. HACKBARTH: Alice and then Jon.

DR. COOMBS: So, on Slide 11, I have a number of friends who do both primary care and they practice their specialty, a rheumatologist who does probably somewhere between 60 and 70 percent primary care. Where do they fall out in this diagram?

MR. HACKBARTH: Kevin -- [Off microphone.]

DR. HAYES: Right.

MR. HACKBARTH: [Off microphone.]

DR. HAYES: All right. So they would not be in the gray portion at the top of the bar, okay, because they

would not be in a specialty that qualifies for the current primary care bonus.

DR. COOMBS: But, technically, they are, because they are doing primary care, probably have seen many patients. Their panels are large. If you look at absolute numbers, they might be actually seeing more primary care patients than some internists.

DR. HAYES: This is a point that came up when the Commission made its initial recommendation about the primary care bonus in 2008, and the intention, I believe, of the group was that there was a need to address issues of compensation differences among specialties and a need to support primary care. And then it becomes a question of how do you best target those dollars, and within the tools available, it's specialty designation and it's an ability to identify the extent to which a practitioner furnishes primary care as a percentage of their total allowed charges.

And so the conclusion reached was that, well, for purposes of what the Commission was trying to do of supporting primary care, that was the best way to do it. It wasn't perfect, but it was viewed as the best way, to go the best way to target the dollars.

There are going to be -- and we hear about it all the time in the office, as groups come in to speak with us, about, well, what about neurology, what about rheumatology, whatever the specialty would be, and it becomes a question of, well, where do you put your first dollar, and that was it.

MR. HACKBARTH: I would just underline what Kevin said about realizing that this approach, the twin standard of both a specialty and confirmed by a pattern of practice was imperfect, especially the specialty piece of it, but one of the implications of not having a restrictive specialty limit is that then the potential number of qualifying people is greatly expanded, and the amount of money goes up by a lot. And you are almost to the point where you are starting to talk about non-hospital-based E&M services as where the money is going to go, and that's a big, big number.

Kathy.

MS. BUTO: Yeah, I just wanted to -- Alice was pointing to this particular chart, but this one is about the funding. So as I read it -- and I think this is something we should talk about -- the question is: Where do you get the money to pay the bonus to this designated group of

practitioners who are providing, you know, 60 percent primary care? And I think we should talk about it because one option that you've laid out is only E&M services provided by those same primary care practitioners would be exempt from the reduction, even if --

DR. COOMBS: If they don't get the bonus [off microphone].

MS. BUTO: Even if specialists are providing those kinds of basic primary care services, those services, when provided by a specialist, would be subject to a reduction in order to fund the bonus. And I think that is -- my own perspective is that's not really fair if we want to promote more primary care, if indeed those are the same primary care services, even when they're provided by a specialist. You're not giving the bonus to the specialist, but it's a matter of whether you're reducing their fees in order to pay for the bonus.

So I think we should just not get too confused about the two issues, but they are --

MR. HACKBARTH: Yeah, and as I said earlier, sort of on a separate track, we believe that in E&M services are undervalued, and we've undertaken a lot of work to try to

get E&M services increased in value. And so one argument for excluding the specialty-provided E&M is that it sort of undercuts other things that we've tried to do.

DR. MILLER: So can we just put a sharper point on this? Since we are trying to figure out what the recommendation would look like -- and I don't want to put words in your mouth -- you're saying so given the concerns she's raised and the exchange you just had with Glenn, you would fall on the right-hand side of this chart. And I think just to put a fine point on it, that's what Kathy is saying here.

DR. CHRISTIANSON: I fall on the right-hand side of the chart, too, but I had a different comment.

So I think we need to -- I've said this last time, so you can throw your water glasses at me if you don't want to hear it again. But I think we have to keep in mind in our language in how we talk about this that there are an increasing number of physicians and nurse practitioners working for health care organizations, and especially younger physicians and practitioners. And we don't know -- okay. So the bonus does not go to the practitioner. We talk about, oh, the nurse practitioner gets the bonus, or

we're doing this to improve primary care. We don't know. The bonus goes to organizations that have people work for them that bill on our primary care codes.

So when the organization gets this new revenue, it's new revenue, and they should do whatever they think is best for the organization in how that revenue is spent. Now, if it's to pass it on to the primary care physicians and change their compensation schedule, great. They don't have to do that. They don't have to invest in primary care. If the best thing for the organization is to buy that piece of equipment that will generate more revenue and keep it afloat, they can do that with the money. So we're not tying it to any kind of practice requirement.

So my only point is, as we write this up -- and there are several places in the chapter and a couple places in the presentation where the implication was if we had this bonus payment, somehow it just sort of directly flows through to the primary care physician or the nurse practitioner and they are better off and it's going to be invested in primary care. That may occur. As Glenn tells me and reminds me, there are a lot of places where there are one or two or three physicians practices, and that would be

the case. But we need to keep in mind that there are other models of care where that's not the case, and so let's not write this up in a way that we appear too naive about, you know, what's going to happen with this bonus payment. We can't guarantee anything for when large organizations get this bonus payment. Okay?

MR. HACKBARTH: And I concur with Jon's point. We've talked about this a number of times. The only thing I would say in addition is that when you're running a multi-specialty group, and if you have the objective of improving payment for primary care relative to some of the subspecialties, and you get bonus dollars, that makes it easier to narrow that gap. Otherwise, you're saying I've got to tax the subspecialist for whatever I give to primary care, and so a new -- an increase in primary care payment could ease some of the internal dynamics that I've suffered with within multi-specialty practices.

DR. CHRISTIANSON: And I support the recommendation, don't get me wrong. It's just when we talk about it, let's not -- let's be careful how we talk about it.

MR. HACKBARTH: I agree with your point Jon. So

we're still on clarifying questions, it seems.

[Laughter.]

MR. HACKBARTH: Somewhere I think we crossed the border into Number 2 land. But any final clarifying questions?

[No response.]

MR. HACKBARTH: I am going to reserve a few minutes at the end to sort of -- put up the final slide, Julie, with the elements and sort of walk through those and do a straw poll, no final commitments, on what people think. But before I do that, I want to give an opportunity for other Round 2 comments.

DR. COOMBS: So with the last discussion, what Kathy said, one of the considerations is if you do number two, is it possible to do what we just proposed in terms of looking -- you could actually look at the size of the panel and then go from there, because some of the panels might be -- in this particular situation, my colleague's panel is probably close to 2,000, she's burning the candle at both ends. And like I said, if you took out the primary care patients in her panel, you would say, wow, she's taking care of more primary care patients than the average internist in

the area. And is there some sort of way that we could -- I don't know -- not necessarily give the bonus but, again, keep them from getting the decrease as an overall impact? And maybe there's something that could be done in terms of the absolute number of patients, because I think that's another issue, too. You can have a very teeny-weeny practice where someone sees, you know, 500 patients and they are seeing a very small number of patients to start with. So it's not like they're a major work horse in the area of primary care, but I think if someone is doing some sort of measure of considerable primary care work, there ought to be a way in which we can encourage them and incentivize them to continue doing that work.

MR. HACKBARTH: I'm sorry, Alice. My mind was focused on process steps. I sort of missed the first part. I apologize.

DR. MILLER: I can pick it up. In some ways, I thought that your exchange with Kathy and what I was trying to point to is if you can give me the 1114, I think this can in some ways give you some rough justice if you end up on the right-hand side of that -- okay. Right.

MR. HACKBARTH: Okay.

DR. HALL: This is for Round 2?

MR. HACKBARTH: Yep. Go.

DR. HALL: Jon, you mentioned that what you see at the additional bonus money could go into a practice and be used for whatever the practice deemed was an important use of the money. So how does this enhance the delivery of primary care? One of the things we talked about in the description here is that one of the barriers in the salary differentials between current primary care providers and specialists.

So I'm a cardiologist, and I want to do some of these services, and I want to invest in a new technology for imaging or something. The service is probably provided in a competent way, but it certainly doesn't promote a career in primary care. It seems that we're talking out of both ends of --

DR. CHRISTIANSON: Well, Glenn argues two things. One is there are lots of practices that are small, small primary care practices, and they will get the bonus, and that should directly improve their practice. Also, he's saying that it gives some more flexibility to people around large organizations when they have money coming in that says

this is for primary care to actually use it for primary care.

I think the salaries that are paid in organizations are pretty much market driven. It's what you have to pay to get this specialist or that specialist. So I don't think this is necessarily going to change that in any way.

MR. HACKBARTH: I would add -- and there are people around the table better qualified to talk to this than I am, but making primary care more attractive is, yes, in part a function of salary and income. But it also can include practice supports and, you know, more medical assistants or higher-quality medical assistants that are better trained that make the daily work life better. And so that multi-specialty practice that has more income, it may not give it in primary care salaries, but it may spend it on other things that could help primary care.

The bottom line is when it goes into the multi-specialty practice, there is no guarantee on how it's going to be used.

DR. HALL: Right.

MR. HACKBARTH: And that's the point on which Jon

and I completely agree. But, you know, that's sort of the state of the world.

DR. CHRISTIANSON: That's where we are. We're not willing to say here are practice requirements, if you meet them you get the money. So since we can't say that, we can't know what we're getting for the money.

MR. HACKBARTH: Yeah. And the reason that we didn't go so far as to attach practice requirements is the amount of money is relatively small. And, in fact, Mary was pointing out, even with 40 bucks per month, it's easy to get to the point where people say, you know, the requirements are just too onerous to make it worthwhile.

DR. CHRISTIANSON: And we're not quite sure what those requirements would be, even if we thought the money was large enough at this point.

DR. HALL: So is that compatible with what we said, that the practices that are eligible for this have to have -- what was it? -- 60 percent of their billings in primary care services?

MR. HACKBARTH: Right [off microphone].

DR. HALL: But how do those two come together? That's what --

MR. HACKBARTH: There's a specialty test. You need to be in one of the designated specialties.

DR. HALL: Right.

MR. HACKBARTH: And then 60 percent of the billings need to be for primary care services, as --

DR. HALL: So I'm in my cardiology practice, but I'm, say, doing 20 percent.

MR. HACKBARTH: Cardiology, you don't make the specialty --

DR. HALL: You don't the specialty cuts. Okay, yeah, got it.

MR. ARMSTRONG: So I just would reinforce the point of view we've taken on this topic quite a few times in the four-plus years I've been on the Commission and support this. I do believe -- and, by the way, I like the right-hand side of the funding source for many of the arguments people were just making.

I do believe part of what we're doing here is responding to the fact that this bonus program is expiring rather than, you know, what I hope will help us as we go forward, and that is kind of reconnecting on so what's really the primary care goal that we're trying to solve to

or problem we're trying to address, and that when we go through the rest of our schedule this year and access to primary care and some of those things will create some of that context for us. I think it will affirm that this is a good step, but generally speaking, I think while a good step, probably not sufficient to achieve some of the broader goals that we're really talking about.

MR. HACKBARTH: That raises an interesting idea. My thinking about this has been it's a stopgap, and let's say for the sake of argument that it turns out that the results from the medical home pilots are very good, and the Secretary makes the decision to implement nationwide the medical home pilot. Then I think that this, you know -- you may want to say, okay, it's time to scrap the imperfect bonus, we've got a more robust system in place for supporting the development of primary care. And maybe we want to include in our recommendation language that says, you know, that's what this is about, and you know, pending results from medical home pilots, you know, this is a stopgap, and we don't envision it existing in perpetuity necessarily. That may make our thinking about this clearer.

And then medical home pilots, you do have a very

specific list of requirements, here's what you got to do to get the money, et cetera.

DR. SAMITT: I think my comments are very similar to Scott's. I see this as a positive change, although it's kind of a first generation change. It's a step, but it's a very small baby step. As we've discussed in many prior meetings, we've talked about the imperative to, A, pay primary care providers more and, B, pay primary care providers differently. This does that a little bit, but not enough to really drive the necessary transformation to a value-based model of care. But it's certainly better than the alternative, which would be to not renew the bonus payment at all, which just moves us in the opposite direction.

So I certainly would endorse it, but I think we need to quickly get to the next generation, which would be to think about, you know, do we begin to think about, you know, especially for primary care groups that want it, a full-scale PMPM reimbursement option for primary care to replace an RVU-based model, to say we're going to be accountable and at risk for population health reimbursement just for primary care, which is more than just -- this

amounts to about 2 percent of any primary care provider's salary. Is that sufficient incentive to change practice patterns? I would argue no. So it needs to be a whole lot bigger and better than that in the next generation.

MR. HACKBARTH: I agree with all of that, though, you know, I know that I sometimes lose sight of the fact that we're talking about a small amount here, but it's only one payer for a subset of patients. And to the extent that other payers are also increasing their payments for primary care, the aggregate across the full 2,000-patient panel, the aggregate dollar effect could be quite a bit more.

DR. HOADLEY: Just a quick follow-up to your previous comment. The only thing I would worry about with the way that sort of caveat would be phrased is that we don't sort of open up the door in terms of the way this is read to say we want this to be a temporary change. I mean, we're dealing now with the expiration of a previous thing, and Congress may well want to make it temporary for scoring reasons or whatever, but we should -- I would think we should say, you know, we see this even though all those other things you said, you know, could be true later.

MR. HACKBARTH: What I'd like to do is switch

gears in our last ten minutes and go through that final slide and the four basic elements and get a sense of where people are.

Based on the discussion to this point, I think the second bullet is probably the one that we really need to focus on, but let me just go through them one by one.

So the first element is continue the bonus at the current dollar level. Let me just ask, is there anybody who's really uncomfortable with that as part of a final recommendation?

[No response.]

MR. HACKBARTH: Now, the second issue, and why don't you put up the other graph, Kevin? And this is about the funding. So a number of people have said, led by Alice, that they prefer funding this bonus without going into E&M services provided by specialty physicians. The right hand. So that would mean a 1.4 percent reduction in the conversion factor. Let me see a show of hands of people who favor exempting the specialty E&M from the cut. So I see Warner and Craig. Do you want to speak to it?

Again, let me emphasize that these aren't final votes, and nobody's going to be held to this. I'm just

trying to figure out how to formulate the draft recommendation. Warner, what are your thoughts?

MR. THOMAS: Yeah, my question is just what is the -- do we understand the materiality, you know, for specialists? It's just hard to understand that. And once again, this is the first time I've been in the discussion. I know it's been several times with the Commission.

DR. SAMITT: And to tag onto that, my question is: To what degree have we studied what percentage of specialists are providing primary care? And would a better alternative be that the prospective attribution methodology is much more similar to the ACO methodology, to say that some of these bonuses could be attributed to specialists if they were the primary primary care provider for any particular beneficiary? So the question is: Which is more material? Would we include certain specialists in the attribution? Or should we actually only focus on the 1.4 percent as the alternative? So I'm torn without more information as to which would be preferred.

MR. HACKBARTH: And how would you determine the specialists who are doing primary care?

DR. SAMITT: The ACO experts may be able to

comment, but there is an attribution methodology, right, that first starts with primary care and then cascades to specialists if there isn't a primacy of visits.

DR. MILLER: The awkwardness of that is when we commented on the ACO rules, we sort of said you should do away with that because it created some complications I'm going to pass over for the moment, but I'll go through them if everybody has the stomach. And we said ACOs should be allowed to designate certain specialties even those their specialist is providing primary care, like your cardiologist, like your endocrinologist, that type of thing, and the difference being that there's an entity there who says this is the group of people I'd like you to count because they're in the club. Here you'd be out in fee-for-service land trying to do something like that.

DR. SAMITT: Well, if that goes against the grain of what we've recommended previously, then I'm with the rest of the crowd in terms of focusing on the 1.4 instead of the 1.1.

MR. HACKBARTH: Okay. I'm going to press ahead because we are almost out of time here. Could you put up the last slide again?

And so the third bullet I won't read. You can read it for yourselves. But this is the prospective attribution, recognizing that there, in fact, will be some changes and some patients that formerly received primary care from A will move on to B and some of that from B will move to A. So it's not perfect, but we thought that the benefits of prospective attribution outweighed the harm of having some churning. People comfortable with that?

And then, finally -- we touched on this a minute ago -- we opted -- and this was really a discussion back in the spring -- not to attach lots of practice requirements because we didn't think that the payment was high enough to carry a lot of additional burden. People okay with that judgment?

DR. MILLER: And then I hear you saying perhaps try and work something into the recommendation, recognizing what you said, that, you know, in an ideal world, if we have evidence and all the rest of it, and we'll try and figure out how to work around that without implicating what you said.

MR. HACKBARTH: Are we close to there? So we'll put together a draft recommendation for discussion next

month and hopefully move one step closer to finishing this.

Thanks, Julie and Kevin. Good work.

Our last item now is 340B drug pricing program.

[Pause.]

MR. HACKBARTH: So let me just say a word of introduction about this topic.

The 340B drug pricing program is, of course, not part of the Medicare program. And we've been asked to do some work on this and sort of package some information, do some descriptive fact-finding work, by the committees that have jurisdiction over Medicare, the committees that we regularly work with, recognizing that it is itself not a Medicare program.

And so we will be making no recommendations related to 340B. This is more descriptive work to assist those committees.

With that, Ariel.

MR. WINTER: Good afternoon.

Here's the outline for our presentation today. We'll start by talking about some background on the 340B program. We'll discuss how it has grown substantially in recent years. We'll then go over some issues with the 340B

statute and describe concerns with HRSA's oversight of the program. And we'll conclude by summarizing the current debate over the scope of the program.

The 340B program allows certain hospitals and other health care providers, known as covered entities, to obtain discounted prices on covered outpatient drugs from manufacturers.

Covered outpatient drugs include prescription drugs and biologicals other than vaccines.

Manufacturers must offer 340B discounts to covered entities in order to have their drugs covered under state Medicaid programs.

The discounts available through the program for outpatient drugs are substantial. Savings range from 25 to 50 percent of a drug's average wholesale price.

These discounts apply to drugs used for uninsured patients, patients with Medicare and commercial insurance and, in some cases, Medicaid patients.

The program is managed by the Health Resources and Services Administration.

Although the program is not part of Medicare, as Glenn was saying, there may be implications for Medicare,

which we'll touch on during this discussion.

This table lists the types of providers that are eligible to participate in 340B according to the statute, and in a few more slides down, we'll be showing you some of the numbers of providers for each of these categories.

So the first row refers to clinics that receive federal grants from HHS, such as Federally Qualified Health Centers.

Several types of hospitals are also eligible, and we'll spend the bulk of the presentation focusing on hospitals.

The two biggest hospital categories are disproportionate share hospitals, which have a DSH percentage greater than 11.75, and critical access hospitals, which do not have a DSH requirement.

Other types of eligible hospitals include freestanding cancer hospitals, children's hospitals and rural referral centers.

To be eligible, hospitals must be owned by a state or local government, or be a public or nonprofit hospital that is formally delegated governmental powers by a state or local government, or be a nonprofit hospital under contract

with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.

Medicare pays for 340B drugs provided by covered entities to beneficiaries.

Part B pays hospitals for outpatient drugs that are provided incident to a physician service, such as infusion drugs used to treat cancer and rheumatoid arthritis.

Under the outpatient PPS, Medicare pays the same rates for drugs to 340B and non-340B hospitals even though 340B hospitals can buy outpatient drugs at a steep discount.

Part D plans may also pay for 340B drugs that are covered under Part D when they're provided to patients of a covered entity.

And Dan will talk now about the growth of the 340B program.

MR. ZABINSKI: One reason the 340B program has become a point of interest is that it's been growing rapidly.

Over the 2005 to 2014 period, the number of sites providing 340B drugs increased by 9.6 percent per year, and

the number of participating hospital organizations increased by 15.5 percent per year.

Also, spending by 340B providers to purchase drugs increased by 14.7 percent per year over 2005 through 2013, and Medicare spending at 340B DSH hospitals for drugs covered under Part B of Medicare increased by 22.6 percent per year from 2004 to 2013.

On this slide, we show the growth in the number of sites that provide 340B drugs.

Hospitals can, and often do, have multiple sites. For example, a hospital with five affiliates would count as six sites. For hospitals, sites can be the hospital itself, clinics and physicians' offices that have been purchased and converted to hospital-based clinics.

We break sites into hospitals and their affiliates, which are the yellow parts of the bars in the diagram, and all other entities and their affiliated sites that are the green parts of the bar.

The number of total sites increased from about 12,000 in 2005 to about 28,000 in 2014.

We see especially strong growth over the 2010 to 2014 period. Some of the growth over that period is due to

a change that HRSA made in 2012 about hospitals having to register all off-site facilities that purchase and/or provide 340B drugs, but we can't tell exactly how much of the growth is due to that rule change.

And, as you can see, much of the growth in the number of sites is due to the growth in the number of hospital sites. In 2005, hospital sites accounted for just 11 percent of all sites while, in 2014, hospital sites were about half of all sites.

Because of the rule change in 2012 that requires hospitals to register all off-site facilities makes it unclear how much of the reported site growth is due to actual site growth, here we examine the change in the number of unique hospital organizations participating in 340B, where a hospital organization is a hospital with its affiliated sites counted as 1.

This chart shows that the number of hospital organizations grew strongly by 18.5 percent per year from 2005 to 2010 and by 11.9 percent per year from 2010 to 2014.

The growth from 2005 to 2010 was largely from DSH hospitals, which increased the number from 583 to 1,001.

In contrast, the growth from 2010 to 2014 was

largely in CAHs and other hospitals that became eligible in 2010 through the Affordable Care Act. Over this period, the number of DSH hospitals actually declined slightly.

And currently, about 45 percent of Medicare acute care hospitals are in the 340B program.

In addition to strong growth in the number of 340B hospital organizations, the amount hospitals spend to obtain drugs has increased. Among DSH hospitals in the 340B program, the amount they spent to obtain 340B drugs increased from $2.4 billion in 2005 to $7.1 billion in 2013.

One thing we don't want you to confuse is that these numbers are not what Medicare or other payers are spending to cover these drugs.

These numbers indicate how much hospitals are spending to obtain drugs for both Medicare and non-Medicare patients.

And then to give you an idea of how the 340B program is growing within the Medicare program, we compared how Medicare spending on Part B drugs in the outpatient PPS has grown for 340B DSH hospitals to how it has grown for all hospitals. In this case, Medicare spending means what the program paid plus beneficiaries' cost-sharing.

Among the 340B DSH hospitals, Medicare's spending on separately paid drugs in the outpatient PPS increased from $0.5 billion in 2004 to $3.4 billion in 2013, which is an increase of 22.6 percent per year.

Among all hospitals, Medicare spending increased from $2.5 billion in 2004 to $7.2 billion in 2013, an increase of 12.7 percent per year.

And although 340B DSH hospitals are 20 percent of Medicare acute care hospitals, they account for 46 percent of Medicare spending on Part B drugs that goes to all hospitals, which is up from 22 percent in 2004.

And now Ariel will discuss the 340B statute and related issues.

MR. WINTER: The 340B statute does not set clear parameters around the program, which has played a role in its rapid growth and has made it difficult for HRSA to manage it.

As an example, covered entities are only allowed to provide 340B drugs to individuals who are patients of the entity, but the statute does not define who is considered a patient of the entity.

As a result, HRSA has struggled to establish a

clear definition of this term, which makes it possible for covered entities to interpret it broadly.

In terms of 340B hospitals, HRSA's definition currently states that an eligible patient is an individual with whom the hospital has a relationship, which means that the hospital maintains the individual's health care records and the individual must receive health care services from a health care professional who is employed by the hospital or who provides care under contractual or other arrangements, e.g., referral for consultation, such that responsibility for the individual's care remains with the hospital.

HRSA has not clarified the meaning of other arrangements or responsibility for the individual's care.

And HRSA has expressed concern that some covered entities may be including individuals seen by providers who only have a loose affiliation with the entity, and thus, the entity does not have actual responsibility for their care.

The statute has broad criteria for hospitals to qualify for the program, which has enabled many hospitals to participate.

In 2012, 65 percent of hospitals paid under the inpatient PPS had a DSH percentage greater than 11.75 and

were government-owned or nonprofit. This means that they can qualify for 340B if they were formally delegated governmental powers by a state or local government, or if they had a contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.

In the case of a hospital that has a contract with a state or local government to provide care to low-income patients, the statute does not specify the amount of care that must be provided. Thus, hospitals with contracts to provide a relatively small amount of care to low-income patients could be eligible for 340B.

In addition, the statute does not require CAHs to have a minimum DSH percentage to qualify for 340B. Ninety-four percent of CAHs are government-owned or nonprofit, which means they're potentially eligible to participate in the program.

Hospitals and other covered entities can purchase 340B drugs for all eligible patients, including those covered by Medicare and commercial insurance, and generate revenue if the payments they receive for the drugs exceed the discounted prices they pay for the drugs.

Because the 340B statute does not restrict how revenue generated through the program can be used, hospitals can use the revenue for any purpose, such as expanding the number of patients served, increasing the scope of services, investing in capital or covering administrative costs.

GAO and OIG have raised concerns about HRSA's oversight of the program. They have questioned HRSA's ability to verify that covered entities and manufacturers are complying with program rules. They've noted that it's difficult to enforce the rules when key terms, such as eligible patient, are unclear.

HRSA primarily relies on participants in the program to ensure their own compliance.

In 2012, HRSA began auditing a small number of providers but has not yet audited manufacturers to ensure that they're selling 340B drugs at the discounted prices.

HRSA has been working on a proposed rule to address several issues in the program, such as the definition of an eligible patient, but the proposal has not yet been released.

We note that it may be challenging for HRSA to develop more specific guidelines when the statute itself is

vague about important parts of the program.

Another important issue is the use of outside pharmacies to provide 340B drugs.

HRSA allows covered entities to provide 340B drugs through in-house pharmacies and also to contract with outside pharmacies to dispense these drugs. According to HRSA, 82 percent of entities dispense 340B drugs through an in-house pharmacy and 18 percent use outside contract pharmacies.

Since HRSA began allowing entities to use multiple contract pharmacies in 2010, the number of contract pharmacy arrangements has grown rapidly.

HRSA's audits and an OIG study have identified concerns with the use of contract pharmacies.

HRSA found that some contract pharmacy arrangements provided 340B drugs to individual who are not patients of the entity.

OIG found that there was a lack of consistency in how entities identify eligible patients for their contract pharmacies, which leads some entities to identify more patients as eligible than others.

There is a debate between drug manufacturers and

340B hospitals over the proper scope of the program.

Manufacturers have urged policymakers to reconsider the eligibility criteria for hospitals and to limit the use of contract pharmacy arrangements. They argue that the program should be focused on helping patients who are poor and uninsured to gain access to outpatient drugs.

On the other hand, 340B hospitals seek to preserve the current rules for hospital eligibility and hospitals' ability to use revenue generated through the program for any purpose. They argue that the program is essential for maintaining their services and their mission.

To support their position, 340B hospitals cite the following language from the conference report that accompanied the 340B legislation, which reads: "The Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

As we mentioned earlier, under the outpatient PPS, Medicare pays the same rates for Part B drugs to 340B hospitals and non-340B hospitals even though 340B hospitals are able to purchase outpatient drugs at significant discounts.

An issue the Commission could discuss in the future is whether Medicare beneficiaries should pay less for outpatient drugs provided by 340B hospitals. This would save money for the program and beneficiaries, but it would reduce the revenue that hospitals could generate from the 340B program.

The OIG is currently researching this option and expects to issue a report in FY 2015.

We could look at this idea in our future work, but we are not prepared to discuss it today.

So, to conclude, here are some questions for your discussion: Is there anything that we can clarify of what we presented today, and is there additional information you'd like to see reflected in the paper?

Thank you.

MR. HACKBARTH: Okay. Thank you very much.

Could you put up -- I think it's slide seven, yeah.

DR. MILLER: The hospital one or the sites?

MR. HACKBARTH: Yeah, the sites one. I think it's seven.

When I read the chapter, it's Figure 1 in the

chapter. And I thought it matched up with one of the slides, but I'm not sure that it does.

Yeah, it does. It matches this one.

So, if I read the note correctly in the chapter, the way the count is done is different in 2010-2014 because HRSA changed the rules on how you report in 2012.

And, if I understand it correctly, in 2010, if there was a hospital that had no affiliated sites -- it was just the hospital -- that counted as 1. If there was a hospital that had several affiliated sites, it still counted as 1 in 2010.

But now after a change in the counting rules in 2012, in '14, it counts all the affiliates -- affiliated sites; each count separately.

And so we've got sort of an apples and oranges comparison here that distorts, potentially, the growth rate.

Do I understand the note correctly?

MR. WINTER: So, prior to 2012, hospitals were not required to register all of their -- each of their off-site facilities that purchased or used 340B drugs.

But they might have been doing so, and we don't know. To some extent, they might have been doing so prior

to 2012 when the rules were clarified.

So it's unclear whether your statement is -- reflects what was happening, but we can check with HRSA about that.

MR. HACKBARTH: Yeah.

MR. ZABINSKI: And I'll add that looking at the data and the list of registered sites that hospitals were definitely, to some extent, recording their off-site facilities, but they weren't necessarily recording all of them.

MR. HACKBARTH: Yeah. Well, it's not a big point.

But to the extent that part of the issue here has to do with how rapidly this has grown, if, in fact, we're comparing numbers that aren't really the same in this site count, it may not be shedding light.

The dollar count seems more relevant than the site count, and it may be good just to focus on the rapid growth in dollars as opposed to site counts that are really not the same.

So that's just my thought.

Clarifying questions?

Kate.

DR. BAICKER: Just following up on that discussion about the dollar amounts, there's a figure in the readings that shows Medicare spending on Part B drugs at these entities, and there's some discussion about the average discount off of AWP.

I may have just missed it, but do we know the excess?

How much less are the 340B hospitals and entities paying for the drugs than Medicare is paying them, in the aggregate?

DR. ZABINSKI: Yeah. Let's see. If you compare non-340B to 340B -- just because of the limitations on the day we're working with, this is a little bit of a gray area -- maybe 13 percent, in that territory.

DR. BAICKER: So they are taking in 13 percent more than they are paying in payment.

DR. ZABINSKI: Well, I would say --

DR. BAICKER: So Medicare payments to them are 13 percent more than their payment for the drugs, 340B entities, and how does that compare to non-340B?

DR. ZABINSKI: That's what I'm saying. I'm comparing the 340B to non-340B.

MR. WINTER: Their costs are lower.

DR. ZABINSKI: Yeah. Because the costs are lower -- you know, the payments are the same for both types of hospitals. The costs are lower for the 340B, and relative to 340B, relative to non-340B, you've got about a 13 percent advantage.

MR. WINTER: We had to estimate that, because we don't know the actual acquisition cost for the drug at each hospital. That's information we don't have.

And the discounted, so-called "ceiling prices," which are the prices that manufacturers have to offer, that's proprietary information. HSRA maintains that, and it's available to covered entities, but not to the public and not to us.

DR. BAICKER: So you're estimating on both -- for the 13 percent delta between the 340B and the non-340B, you are estimating both of those numbers, the 340B number and the non-340B number --

DR. ZABINSKI: Correct.

DR. BAICKER: -- and therefore the difference?

DR. ZABINSKI: Correct.

DR. BAICKER: So that is 13 percent difference,

and then how does that compare to what Medicare is paying?

DR. ZABINSKI: Well, okay. Should I proceed on that, Mark?

DR. BAICKER: Am I asking --

DR. MILLER: I'll take it.

DR. BAICKER: [Off microphone.]

DR. MILLER: What I hear, what we're trying to say is the payments in 340B and non-340B are the same. So to approximate -- because we don't know exactly the discount and what they purchase the drug for. They are looking at the cost reported to those drugs for the 340B and finding that they are 13 percent lower.

DR. BAICKER: So then how does that -- [Off microphone].

DR. MILLER: Paying the same on both sides. All right.

DR. BAICKER: So we're paying the same. They're buying for a price that is 13 percent different from each other, but how does that compare to what we are paying? Say we pay 100 bucks. They are buying it for something and 1.13-something. What's the something?

DR. MILLER: I have a rule about doing math out

loud with about 100 people in the room.

[Laughter.]

DR. MILLER: Unless you have actually done this calculation, this we'll take back as an additional information point to run through.

Have you done this calculation?

DR. ZABINSKI: Yes.

DR. MILLER: Okay.

DR. ZABINSKI: Okay. We'll do a payment-to-cost ratio. It is about 1.13 for the non-340B and about even-1 for -- let me try that again. 1.13 for the 340B and about a 1 for the non-340B.

MR. HACKBARTH: So can you tell me again, Dan, how you're getting the cost in this when we don't know the cost for the others?

DR. ZABINSKI: Let's see. Well, we have the charges on the claims multiplied by a cost-to-charge ratio from the cost reports that matches to the revenue center on the claims.

MR. HACKBARTH: Yeah. I don't know enough --

DR. BAICKER: I would love to hear this in the future. I just want to know how much money they are making

on this.

MR. HACKBARTH: You just cause so much trouble here, Kate.

DR. MILLER: Yeah. Let's go ahead, and we will go through our methods and then our language, and we'll come back to these folks.

DR. CROSSON: Can I just compound it?

MR. HACKBARTH: Sure.

[Laughter.]

DR. CROSSON: I am obviously missing something here. If you go back to Slides 9 and 10 -- what? Yeah, right.

MS. BUTO: Yeah, that's the one.

DR. CROSSON: So Slide No. 9 says that in 2013, the 340B providers were spending 7.1 billion.

MR. BUTO: Or Medicare was spending. Is that Medicare?

DR. CROSSON: No. It says by providers, and the next slide, it says -- and I assume this is all 340B-eligible hospitals.

MR. WINTER: DSH.

DR. CROSSON: Or DSH.

MR. BUTO: Or is it all hospitals --

DR. CROSSON: No, no. The second line, where it says all hospitals. In 2013, Medicare was spending 7.2 billion, which is almost the same number. So what am I -- I'm missing something.

DR. ZABINSKI: Okay. Go back to 9, 9 is all patients, Medicare, non-Medicare.

DR. CROSSON: Ah, ah, ah.

DR. ZABINSKI: 10 is Medicare only.

MR. WINTER: A little more distinction is Slide 9 includes all covered entities; that is, hospitals and FQHCs and other grantee clinics. It's not just hospitals; whereas, Slide 10 is just hospitals.

DR. CROSSON: See, I simplified it.

DR. MILLER: Certainly, a clarification will carry into the paper.

DR. REDBERG: I just want to make sure I understand. They don't release the prices of what they're actually paying because they're not allowed to? So Medicare pays the 340B hospitals' set price, but Medicare is not allowed to know what the hospitals paid for the drug?

MR. WINTER: I'm not sure about the latter.

The information about what the hospitals pay, it's not publicly available. I don't know of CMS has legal authority to get the data on the actual acquisition cost --

DR. REDBERG: Jack is saying it doesn't.

DR. HOADLEY: Well, it doesn't.

MR. WINTER: -- for each drug.

DR. HOADLEY: In a sense, it doesn't matter because Medicare by statute is paying average sales price. I mean, Medicare could be interested in that to do an analysis, but it doesn't matter for payment purposes, because Medicare is going to reimburse that drug by ASP, regardless of what the acquisition. That's kind of your point in all this.

MS. BUTO: But I think that Medicare does know what the 340B price is for these drugs.

MR. WINTER: We don't think so.

MS. BUTO: You don't think so.

MR. WINTER: HRSA knows.

MS. BUTO: So only HRSA knows.

MR. WINTER: HRSA knows, and their contractor --

MS. BUTO: So it's a right-hand/left-hand issue.

MR. WINTER: -- their prime vendor contractor

knows, and the entities know.

DR. HOADLEY: In part, because it doesn't matter for CMS to know that.

MS. BUTO: Well, except it's fairly similar to the Medicaid payment, right?

DR. HOADLEY: I mean, anybody can estimate what this is, right.

MR. WINTER: And there are state Medicaid programs who would know if they choose to reimburse for 340B drugs, the actual acquisition cost plus a dispensing fee.

MR. HACKBARTH: Warner.

MR. THOMAS: On Slide 10, you talk about the escalation in growth rate. How does that compare to the overall escalation in total pharmaceutical cost in general? Because I think we've seen, obviously, a continued escalation in just pharmaceuticals in general.

MR. WINTER: So the better reference point -- I have not calculated on what percent the Medicare spending for 340B drugs, DHS hospitals would represent as a share of total, but if you look at the prior slide, in 2013 this is about 2.2 percent of total U.S. spending on drugs, according to IMS Health, and 2005 or 2004, it was about 1 percent. So

it's increased as a share, but it's still about 2 percent of the total. It's still 2 percent.

MR. THOMAS: Okay, let me just understand. So the 7.1 billion of all drugs expenditures, that's only 2 percent of total drug expenditures in the country?

MR. WINTER: Yes.

MR. THOMAS: So it's pretty small. I mean, materially --

DR. REDBERG: [Off microphone.]

MR. THOMAS: No, but as a percentage, it's 2 percent. It's 2 percent.

DR. REDBERG: I'll take it.

[Laughter.]

MR. THOMAS: So what's the total? What's the total expense, total expenditures?

MR. WINTER: I don't have that here -- oh, I do have it here. 329-billion-200-million. That's for 2013.

And the number, the 1 percent, it was 1 percent of -- this number was 1 percent of the total in 2005. I said 2004. I was wrong.

MR. HACKBARTH: Warner, your initial question was how does the 340B growth rate compare to sort of the general

growth rate in drugs, right?

MR. THOMAS: Actually, I had two questions. I mean, he actually answered the second question first.

My first question was really trying to look at -- if you look at -- at least our experience has been, with the addition of specialty drugs, injectables at the acceleration rate of drug expenditures, it's been pretty significant over the past several years, so just trying to understand how that trend compares to the growth rates that are shown on page 10. I just didn't know how it compares to the overall expenditures.

MR. HACKBARTH: Put up Slide 10 for a second. I want to make sure I am interpreting this correctly.

So the second row is Medicare spending for Part B drugs in all hospitals.

MR. WINTER: Yes.

MR. HACKBARTH: And there, the rate of growth is 12.7 percent. So that's sort of one measure of what the baseline rate of growth is.

Then the top row, it includes that plus growth in a number of 340B sites and patients covered, and that's why it's twice as large, right?

MR. WINTER: Yes.

MR. HACKBARTH: So I think 10 gives you sort of the comparison that you're looking for Medicare.

MR. WINTER: Although I guess what I was thinking about is excluding, excluded from hospitals, just in general, what does the pharmaceutical trend in general look like?

MR. HACKBARTH: [Off microphone.]

DR. NERENZ: If I go just directly on this point -- I didn't think of this before. This is not a so-called "same-store comparison," right, because over the two, people are moving from one category to another, and that's part of why the trends or different -- or hospitals are moving?

MR. WINTER: That's part of it, and we can try to calculate the same-store growth as well for the future.

DR. NERENZ: No, no, that's okay. I just wanted to know what we're looking at.

MR. WINTER: Sure.

DR. REDBERG: Do you have a feeling, because this says 10 years, is it a flat curve, or has it increased in the last few years, so that the growth rates are higher in the more recent years?

MR. WINTER: In terms of the 340B DSH hospitals or all?

DR. REDBERG: Both.

MR. WINTER: So if you look at page 21 in the briefing paper, we have more years of data. We also talk about the growth. So there was a steep increase between 2010, 2011. I mean, it's growing at a rate about -- it is growing by about 5- to 600 million per year, from 2010 to 2013. I don't have the actual rates, though, in the chapter. We'd have to add those.

MS. BUTO: I think that was post the ACA liberalization of the criteria, right, for 340B provider?

DR. ZABINSKI: Yeah. That's going to be part of it.

MR. WINTER: Yep.

MS. BUTO: I wondered whether you could clarify. On page 14 of the paper, we say that the increase was driven by growth in the number of critical access hospitals and other hospitals that became eligible for 340B in 2010, and I am wondering if you could give us a little more specificity. Was that cancer hospitals specifically? Were there certain types of hospitals that have contributed to this real growth

rate that Rita was mentioning earlier?

MR. WINTER: It's primarily CAHs. If you look at Slide 8, you can see the big increase in CAHs.

In 2010, that's the third quarter of 2010, actually third quarter of each year. So when CAHs became eligible and when the ACA was passed in March 2010, between March and the end of September, there were 292 in the program, that entered the program, and then by 2014, it was 940.

And then the yellow category includes other hospitals, which would be freestanding cancer hospitals, children's, rural referral centers, and sole community hospitals. And it's really not cancer hospitals, because there are only three in the program.

MS. BUTO: Okay.

MR. WINTER: So it's really going to be the last two categories, the SCHs and RRCs, that small yellow bar at the bottom.

MS. BUTO: I think I saw elsewhere in the paper -- and now I'm looking for it -- some reference to the growth in oncology drugs that are covered under 340B?

MR. WINTER: Yes.

MS. BUTO: Is that a category that's grown, notwithstanding what type of hospital is involved?

MR. WINTER: Yes. There is a category that has grown, as we talk about in the paper, and that is looking across all 340B hospitals, so it's going to be DHS, CAH. It's probably mainly DSH, because that's where most of the Medicare dollars are, but we can disentangle that further, if you'd like.

MS. BUTO: Thanks.

MR. HACKBARTH: Okay. In fact, I think really our role here is sort of Round 1 questions. Congress is not looking to us to provide advice on this, hopefully just some good information, and so we're sort of a focus group that has reasonably intelligent and informed people asking questions that help the staff refine the work.

Jack, clarifying questions?

DR. HOADLEY: So this is sort of clarifying to the previous clarifying discussion. I guess it was really Warner's question on Slide 10 versus Slide 9, for example, and I want to make sure I'm reading this correctly, but Slide 10, because we are talking about Medicaid spending, we are talking only about Part B drug, which means only

physician-administered drugs, and that's had a high-growth rate, whether we are looking at all hospitals or even higher with the 340B.

But when we're back on the previous slide, Slide 9, we are changing the frame in at least two or three different ways. We are now looking at 340B drugs, any kind of 340B providers, Medicare, non-Medicare, but all kinds of drugs, as well.

So, here, we're talking about blood pressure drugs, all the kinds of oral meds, not just the physician-administered drugs that show up in 10. So if you talk about what the overall growth rate was, sort of underneath Slide 9, it is much, much lower, and so this is heavily driven by more entities and that kind of thing.

Am I reading all of those --

MR. WINTER: And just one other distinction between the two slides, Slide 9 is what the 340B entities paid to acquire the drugs as the purchase price, rather than Slide 10 is what Medicare spent, Medicare paid for these drugs, the payer's price.

DR. HOADLEY: And so it is important to just keep in mind, because when we bring our Medicare lens to it, we

think of 340B relative to the physician-administered drugs, but 340B as a whole is all kinds of drugs, and so we're getting different universes when we're sort of inside the Medicare world versus not.

Then my next comment, on Slide 3, it kind of goes to the discussion of the different kinds of discounts. Here, you cite 25 to 50 percent of AWP, and it's important, I think, to note that AWP is not the usual sales price for a drug. So most insurers not benefitting from 340B are getting something like 13 percent, plus or minus, kind of discount from AWP.

So framing this from AWP is the way everybody does it, but the sort of normal paid price by insurer is lower than AWP.

And then my question --

DR. MILLER: So, on that point, you'd like us in the paper to point out that? That's what you're driving at?

DR. HOADLEY: Yeah. You could say typical commercial plan, this AWP --

DR. MILLER: I just want to pin these down as we go, so that we all follow.

DR. HOADLEY: I mean, CBO, some years ago, did a

nice chart that shows where various payers line up relative to AWP. You could go back to that.

And then this isn't on any particular slide, but I'm trying to remember and ask whether you know. Are the 340B purchases included in the ASP calculation?

MR. WINTER: No, they are not. We've confirmed that.

DR. HOADLEY: Okay, good. So, if they were, then you would say that one of the effects of some of the buyers buying 340B drugs at this now-greater level would be that it would gradually bring the ASP down, and you'd have that sort of averaging game that we often get. Because they're excluded, it keeps that gap between what Medicare pay and what others pay.

MR. WINTER: Right.

MR. HACKBARTH: Other clarifying questions? Craig.

DR. SAMITT: SO just help me to understand. On Slide 4, I am trying to get my head around sort of this notion of affiliation. If I am a hospital that meets one of these criteria, but I've got seven other hospitals in my system that don't meet the criteria, can my 340B program

still apply to all the other hospitals even though they don't meet the criteria individually?

MR. WINTER: These questions apply to the entire entity, and if the entity has sites that it wants to enroll and that can follow the rules of the program, then they can enroll those sites.

DR. SAMITT: But the assessment of the entity is the entity collectively with all of its parts?

MR. WINTER: I believe so. That is a really good question, and we should track that down with HRSA and try to confirm that. That is my understanding.

DR. NERENZ: Well, just as a guess, I think talking a little bit of cross-purposes, I think you are talking about a hospital with multiple sites. Craig is talking about a system with lots of hospitals.

MR. WINTER: I'm sorry. Yes.

DR. ZABINSKI: I think it is like each individual hospital has got to be considered distinctly, even if they are in the same system.

DR. NERENZ: Okay.

MR. HACKBARTH: Dave's point and Dan's point is it that it matters whether it is a multi-hospital system as

opposed to a single-hospital system with a network of ambulatory clinics, and that the rules apply differently.

DR. SAMITT: So an entity is defined as a single hospital, not a hospital system with multiple facilities?

MR. WINTER: I believe it's defined as a single hospital.

MR. THOMAS: It's probably by provider number. Wouldn't you think?

MS. BUTO: But if the hospitals share a pharmacy, it would be very hard for the pharmacy to distinguish if a patient is somewhere in that system, so I think it's -- you know, that's one of those fuzzy areas that the paper points out.

DR. SAMITT: And then my second question is on Slide 12, in terms of the 65 percent of hospitals that have a DSH greater than 11.75. Do we envision that will evolve over time and that there would be those that will fall below that threshold? And when they fall below that threshold, do they lose their 340B status or do they maintain it into perpetuity?

MR. WINTER: If they fall below the threshold, then they are supposed to --

DR. SAMITT: Self-report?

MR. WINTER: Yes. Because they're supposed to recertify every year that they meet the requirements. So if they fall below the threshold, they've got to report that, you know, "We no longer meet the requirements, and therefore, we're going to be out of the program."

We do expect that over time more hospitals will have -- will exceed this percentage because of the expansion of Medicaid in many states, and that's a key part of the DSH percentage calculation.

DR. NERENZ: And also just back to our earlier discussion, a DSH percentage is a characteristic of a hospital not of a system, right?

MR. WINTER: I believe it's calculated at the hospital level, but I'm not --

DR. MILLER: Yeah, that's right.

MR. WINTER: -- the hospital expert here, so I'm going to look at --

DR. NERENZ: Yeah, that would have been my presumption. It just reinforces the idea that this is a hospital program, not a system program.

DR. MILLER: And we'll go back through your -- you

know, David's and Craig's questions about hospital versus site, separate question, what about system. We'll check all of our facts. Take everything that we've said as this is our best take given what we understand, and yes to your question, DSH is calculated at a hospital level.

DR. REDBERG: Can you explain why a DSH percentage is not a good proxy for the amount of uncompensated care?

MR. WINTER: So we did a study, and Jeff I think was the lead on this. It was published in our 2007 report, and that was the conclusion of the analysis, that the DHS -- what we said in the paper. And if you want more detail, I would ask Jeff if he would come up and --

DR. MILLER: I'll give you a little shot on it. So the DSH percentage is two things: the percentage of SSI -- Medicare patients that are -- or days, I guess, that are SSI Medicare, so it's poorer Medicare, and Medicaid. And so it doesn't actually measure uncompensated care, and we did some work awhile back, and I think we even looked at it even more recently given the change in the law. And when you look at the hospitals who qualify for DSH, it's not the same hospitals who have the highest percentage of uncompensated care when you think of it as charity care, bad debt, that

type of thing. So they don't exactly line up. And I got a nod, so we're going to stand there. I'm going to stay on this base.

DR. COOMBS: I just have a question. I didn't see it. Are the 340B sites in a particular area geographically? And is there a clustering? Is there a way that we could get our arms around that? Or does it make a difference?

DR. ZABINSKI: It's pretty national. If you exclude the CAHs, it's more urban than rural. But beyond that, I don't think there's any real type of, you know, hospital location or characteristics that --

DR. REDBERG: So I was wondering if there's --

DR. ZABINSKI: -- really distinguish --

DR. REDBERG: -- like 340B deserts? Are there places where they're not?

DR. ZABINSKI: Not really. You know, they're going to tend to be in, you know, poorer areas just by their nature, but even -- but that said, the 11.75 percent threshold is not a high one to meet. So it's, you know -- even, you know, going by income level is not really a strong indicator. So like I said, I guess the only thing that really distinguishes, you know, hospitals is basically urban

-- it's just more of an urban-focused situation, once again, if you exclude the critical access hospitals.

DR. MILLER: For the critical access hospitals, there's 900-plus of them, right? And there's about 1,200 or 1,300 of --

DR. ZABINSKI: Yeah.

DR. MILLER: So, I mean, I know -- your statement is true if you take them out. It's much more of an urban phenomenon. But a lot of this action is the critical access hospitals, and a lot of the growth --

DR. ZABINSKI: I mean, I guess I should have said why I was, you know, throwing out the idea of taking out the critical access hospitals, is that, you know, in terms of money in the program, it's in the DSH hospitals.

DR. MILLER: Absolutely. If you're counting the units, there's a lot of them. If you're counting the money, then it's definitely DSH. Because she was asking about -- you know, looking across the country, and it's pretty much out there.

DR. CHRISTIANSON: In one of your slides -- or I think in one of your slides, certainly in the paper, I think there was some mention that HRSA is continuing to work on

clarifying some of -- yeah, so do you know the direction that this would likely take us in terms of affecting the dollars that are flowing here, or too early tell, or what?

MR. WINTER: They have not signaled what direction they're moving in terms of the reg, and the target date for issuing it -- the original target date was June, and that was -- it did not come out in June, and they have not issued a new target date. And we know it was sent to OMB for review sometime in the spring, and that's all we know. And they have not signaled -- they have said what kinds of issues they plan to address, and they have mentioned three or four things: the definition of an eligible patient, contract pharmacy arrangements, the criteria for hospital eligibility, and off-site families. They have not --

DR. CHRISTIANSON: Have they been asked to address these issues by OIG or some other body?

MR. WINTER: Both OIG and GAO have flagged these issues, particularly the definition of patient eligibility and contract pharmacy arrangements, and even the hospital eligibility criteria, as things that HRSA should address.

DR. CHRISTIANSON: So based on that, would it be reasonable to assume that if they do follow through with

those suggestions that we would have a restriction in terms of eligibility? They're identifying areas that they don't like, that need tightening up. Right?

DR. MILLER: I just don't think Ariel wants to speak on behalf of HRSA.

[Laughter.]

DR. MILLER: How do I put this delicately.

DR. CHRISTIANSON: There was something more public about the direction they were going.

DR. MILLER: We really don't have a lot here, and I think we'd be filling in gaps that we don't really have.

MR. WINTER: The one thing we can say is that in 2007 HRSA issued a proposed notice which would have tightened the definition of an eligible patient, and that was never -- we understand that there were a lot of concerns expressed about that proposal, and it was never finalized. But we can't use that to predict what direction they're going to head in.

MS. BUTO: Ariel or Dan, do we know the extent to which the program is -- you know, has a benefit to low-income patients? I know that's a vague question, but that was the original intent, was to benefit hospitals and other

entities that were serving lower-income -- do we have any sense of that, or is that anything that the OIG, GAO, or HRSA are looking at?

MR. WINTER: We don't have data on that because the covered entities are not required to track the savings or revenue or how they're using them, you know, what purposes they're using them for. There are no requirements for that, and they're not required to track it, and HRSA doesn't collect the information. So we don't have data for which to answer your question.

This is something that I know that OIG did look at a little bit in their report from this year on the use of contract pharmacies, contract pharmacy arrangements, and they did find evidence that some of the contract pharmacies were not providing discounted drugs to uninsured patients. But we should keep in mind that this was a pretty small sample. It was 30, I believe, covered entities and their contract pharmacy arrangements. So it's pretty -- you know, that's the best I can do to answer that question.

MR. HACKBARTH: And in a way, Kathy, it seems to me your question goes to one of the central issues here. Is the objective to benefit low-income patients or is to

benefit the institutions that serve them? And there seems to be some ambivalence, and that's why the program is complicated.

DR. MILLER: And just to complicate this a little bit further, you could think about that question two different ways. You can think -- in a sense, you guys almost indirectly touched on the two different ways, but just to tease it out, you could almost also the question of when the drug is dispensed and the definition of what qualifies for the discount, do you make a decision there? Or, two, once you have the revenue, should the revenue be devoted to, you know, some -- whatever the case may be. So in a sense you could ask questions about when you generate the discount, who should qualify for that and/or, two, when you have the dollar, what you devote it to. Those could both be ways of satisfying -- but I also think I have to say this: I think there are very strong differences of opinion on this between the two protagonists, you know, the drug manufacturers and the hospitals. The hospitals point to that language that Ariel was putting up and the legislation and say this is about benefiting the institution and stand pretty firmly on that.

DR. HOADLEY: And if we were -- which we're not. If we were studying this further --

[Inaudible comment/laughter.]

DR. HOADLEY: You would also want to think about the different provider types, because we're mostly talking about hospitals, but there's an awful lot of this program that's the federally qualified health centers, and there might or might not be different answers to the different questions you just asked in those different settings.

MR. THOMAS: Have we looked at any of the margin comparisons of organizations that are in this 340B program kind of compared to others that are not? Have we looked at any impact on the margins of the pharmaceutical companies from '05 through '13 to see if the rise in the 340B drug purchases, you know, from 2.4 to 7 billion have had an impact on margins there?

DR. ZABINSKI: Not --

MR. WINTER: The question is about whether we've looked at overall hospital margins for 340B hospitals or for the drugs themselves?

MR. THOMAS: The second question is the manufacturer. The first question was just in general. Not

on the specific drugs themselves, just on the overall margin of these facilities, the critical access hospitals, the DHS hospitals.

MR. WINTER: Right.

MR. THOMAS: I mean, do we understand -- I know we've just recently looked at margins kind of generally for hospitals. Do we understand what that looks like for 340B hospitals? And then, separately, a different question, do we understand what the margins in the pharmaceutical industry look like, you know, comparatively from '05 through '13? Has there been a difference, has there been an escalation in the 340B drug purchases.

MR. WINTER: We have not looked at either, to answer your question.

MR. HACKBARTH: So many other things going on in both the hospital margins and the drug company margins, both over time, a time series, and on a cross-sectional basis. I don't know what you'd really figure out.

Any other clarifying questions?

[No response.]

MR. HACKBARTH: Okay. Thank you very much.

MS. BUTO: You're not doing a part two for this

[off microphone]?

MR. HACKBARTH: No. For the reasons I said earlier, you know, the request here from the Congress is not that we provide commentary on the program or advice on how to reform it or anything else but, rather, just help them with some organized information about how it works and some of its -- how it plays out.

MS. BUTO: Glenn, does that apply also to giving them an assessment of what we think some of the drivers are of the program's growth? Or do they not really -- or do we not want to do that, I guess is the issue.

MR. HACKBARTH: I'll actually let Mark try to answer that.

DR. MILLER: Thanks a lot.

MR. HACKBARTH: He's really good at that.

DR. MILLER: I really appreciate that. I'm not sure what you mean.

MS. BUTO: Well, there's been a big growth in the program since the ACA, and the question -- I don't know whether that spurred their interest in wanting to know more about it and want to hear from MedPAC what we think is driving that growth, or not? I just don't know. Or maybe

we don't think we're qualified to speak to it because we really have just done an overview of the program as opposed to really delved down into --

DR. MILLER: I'll proceed or if you wanted to cut in. I mean, I think some of this -- and maybe this needs to be teased out more in the report if you don't feel like it's -- we did try and speak to the fact that the criteria were opened in 2010 and all of that, and that decidedly had a burst on it, and maybe that doesn't punch through in the chapter.

The reason I genuinely was asking about the drivers, I was thinking you were going to below that and asking what's driving it, and I wasn't sure we would be able to comment on that. But if it's about the expansions in law, we can make sure that that comes out a lot more clearly than it does, if it didn't punch through to you.

MS. BUTO: Right. I was also -- and I know we're not going to talk about it here, but just talking about the whole system of payment to these entities and looking at that as part of a much larger --

DR. MILLER: So you mean more --

MS. BUTO: -- set of issues.

DR. MILLER: -- the Medicare 340B --

MS. BUTO: Interaction.

DR. MILLER: Absolutely, and I think Ariel said this very clearly in his setup comments. If you guys want to talk about that in the future, we have no problem looking at that. And, also, tomorrow when we talk about -- we're kind of returning to the Part B drug conversation. It's the second session tomorrow, if I have that right. And we'll be talking a bit about ASP there, and if you guys want to build around that, no problem.

MR. HACKBARTH: Okay. Thank you very much, Ariel. Good job.

Okay. We are now to our public comment period. If you wish to make a comment, would you please go to the microphone so I can see who and how many? And hold on for just one minute please. Anybody else planning to make a comment?

Okay. It looks like we have just one. Let me quickly repeat the ground rules. So please begin by telling us who you are and what organization you represent. You have two minutes. When the red light comes back on, that signifies the end of the two minutes.

As always, I remind people this isn't your best or only opportunity to contribute to our work. The best opportunity is by talking directly to our staff. You can also write letters to the Commissioners or lodge comments on our website.

MS. WILES: Great, thank you. My name is Jocelyn Wiles. I am representing America's Essential Hospitals.

America's Essential Hospitals, formerly the National Association of Public Hospitals and Health Systems, is the only national association and champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Three-quarters of the patients we serve rely on Medicaid, Medicare, or are uninsured.

The 340B drug discount program is a 20-year-old program that expands access to medical care for many of our most vulnerable patients and helps to reduce pharmaceutical cost for hundreds of hospitals that serve many low-income residents in the communities our hospitals serve.

As the staff mentioned, the outlined statutory intent of the 340B program is to stretch scarce federal resources as far as possible, reaching more eligible

patients and providing more comprehensive services.

Essential hospitals operate as a negative .4 percent margin. Thanks to the 340B program, essential hospitals nationwide are able to expand services, increase the number of patients they serve, and offset losses from uncompensated care.

As supporters of 340B, America's Essential Hospitals encourages MedPAC to support the program. This program is not only good for the patients and covered entities; it also saves money for both the federal government and state governments.

We hope to see the program to continue to reflect its statutory intent.

Thank you.

MS. TODD: Hi. I'm Laurel Todd from BIO. I just wanted to follow up on some of the Commissioners' discussions before.

I think what's important to keep in mind about the 340B program is less about the -- of drivers of 340B, but considering 340B as a driver of other trends that you see within the Medicare program. So one thing that was not discussed here was looking at hospital acquisitions and

physician practices and what -- that happens in 340B and non-340B, but how does that play out throughout the rest of the system and looking at the system as a whole.

To the discussion earlier about the DSH metric, it's important for the Commission to remember that DSH is a member of inpatient Medicaid days, and 340B is an outpatient program. To that point of acquisitions, when a DSH hospital or other facility makes acquisitions, those acquisitions don't reflect back on the DHS eligibility.

So, in that discussion of hospital systems versus hospitals with lots of sites, in the situation where you have a hospital that qualifies as 340B through its DSH, but it has lots of qualifying -- or has lots of outpatient sites that it's acquired for whatever reason, those sites don't reflect backup into the eligibility for the whole hospital, and I think that's something that the Commission should keep in mind, as they're exploring 340B, less in the program itself. Because it's a HRSA program, it's difficult for you guys to do that, but to think of 340B as a driver of other trends that you're seeing within the Medicare program.

Thank you.

MR. HACKBARTH: Okay. We will reconvene tomorrow

at 8:30.

[Whereupon, at 4:58 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Friday, November 7, 2014.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, November 7, 2014
8:30 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, JD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
SCOTT ARMSTRONG, MBA, FACHE
KATHERINE BAICKER, PhD
KATHY BUTO, MPA
ALICE COOMBS, MD
FRANCIS “JAY” CROSSON, MD
WILLIS D. GRADISON, MBA
JACK HOADLEY, PhD
MARY NAYLOR, PhD, RN, FAAN
DAVID NERENZ, PhD
RITA REDBERG, MD, MSc, FACC
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
CORI UCCELLO, FSA, MAAA, MPP

AGENDA PAGE

P R O C E E D I N G S [8:30 a.m.]

MR. HACKBARTH: Okay, good morning. So we begin this morning with site-neutral payments for inpatient rehab and SNFs. Carol?

DR. CARTER: Okay, good morning. This session continues the Commission's conversation about site-neutral payments. The Commission began its work looking at ambulatory services. In 2012, you recommended that payments should be the same for office visits furnished in physicians' offices and hospital outpatient departments. In 2014, you examined 66 ambulatory services and again made recommendations to eliminate or narrow price differences between the two settings. The Commission also applied to concept to acute-care services and recommended that payments to acute-care hospitals and long-term-care hospitals be the same for non-chronically critically ill patients.

In June, we turned our attention to post-acute care and began a discussion of site-neutral payments between inpatient rehab facilities and skilled nursing facilities. Both settings furnish rehabilitation care to patients recovering from a hospital stay. While there is overlap in the types of patients they treat, program payments differ

considerably by site, with SNFs generally being the lower-priced option.

Today we'll begin with a review of the findings we reported in June and SNF patients recovering from three conditions: joint replacement, hip and femur procedures, and stroke. Then we'll present follow-up analyses we conducted on stroke. Next, we'll describe our analysis of new conditions that could be considered in a site-neutral policy. We are looking for guidance on the design of a site-neutral policy, specifically the conditions to include and how to consider stroke.

As background, the services typically offered in IRFs and SNFs differ in important ways. IRFs are licensed as hospitals and have more physician oversight and nursing resources compared with most SNFs. IRF patients must be able to tolerate and benefit from intensive therapy, often interpreted as three hours a day. In SNFs, the amount of therapy can vary, though the majority of days have at least 2.4 hours a day.

We recognize that the services in the two settings differ. The question is whether the program should pay for those differences when the patients admitted and the

outcomes they achieve are similar.

Aside from program requirements, each setting has its own prospective payment system. The SNF PPS is day based, and there are no additional payments. The IRF PPS is discharge based, and Medicare makes additional payments for teaching, share of low-income patients, and outliers. IRFs also have a threshold compliance that requires that 60 percent of all of their cases have specific diagnoses.

To ensure, to the extent that we can, that we identify services and conditions most appropriate for site-neutral policies, the Commission has taken a deliberative approach. It has consistently used a set of criteria to evaluate candidate conditions and services. For the IRF-SNF work, we have examined: whether the condition is frequently treated in the lower-cost setting, as a way to ensure that the setting safe; that the patients have similar risk profiles;

that and their outcomes are similar.

Ideally we would compare risk-adjusted outcomes but this information is often lacking. And even when it is available, we cannot fully control for selection.

For IRF-SNF site-neutral policy, let me outline

what we have assumed. For selected conditions, IRFs would be paid the average SNF payment per discharge as the IRF base rate. The add-on payments would remain the same. And for qualifying conditions, IRFs would get relief from certain regulations regarding how care is furnished, such as the "intensive therapy" requirement and the frequency of face-to-face physician visits.

Now let me go through our previous findings that were reported in June. On orthopedic conditions, we found that the majority of cases are treated in SNFs and the patients' risk profiles were similar.

The risk-adjusted outcomes were mixed. Readmission rates and changes in mobility -- both of those were risk adjusted -- were similar for both settings, while IRF patients had larger improvements in self-care.

Unadjusted mortality rates were higher in SNFs, though risk adjustment would narrow the differences. We compared the spending in the 30 days after discharge from each setting. Though IRFs had lower readmission costs, they had higher additional PAC spending, and so that, on net, IRF spending was higher. We concluded that orthopedic conditions could be a promising starting point for a site-

neutral policy.

On the stroke condition, we found that the majority of these cases are treated in IRFs, not the lower-cost setting. There was greater variation in the stroke patients. SNF patients were older and sicker compared with IRF patients.

The risk-adjusted outcomes were mixed and consistent with what I just went through for the orthopedic conditions and listed on the slide. Given the variability in stroke patients, you asked that more work be done to see if there was a subset of stroke patients who might be appropriate for a site-neutral policy.

Our follow-up work on stroke had two parts. First, we interviewed 12 practitioners who treat or place stroke patients. They included a director of a stroke service at a major teaching hospital, an internist who conducts health service research on stroke outcomes, geriatricians who direct elderly units at acute hospitals, medical directors at nursing homes, and hospital managers who guide placement decisions. All practiced in markets where there were IRFs. We asked them which stroke patients go to SNFs versus IRFs. We also reached out to a medical

society for physical and rehabilitation medicine to get their thoughts on the appropriate use of each setting.

The themes we heard prompted additional data analysis on three topics: the severity of illness of stroke patients, the severity of the stroke, and whether stroke use was related to IRF bed availability.

We asked interviewees where stroke patients were referred. Each interviewee had clear "rules" about IRF and SNF use. The problem was there was little agreement about those rules, except that IRF patients needed to be able to tolerate and benefit from intensive therapy and would be likely to go home in the time frame of a typical IRF stay, about two weeks.

Some practitioners told us the sickest patients go to SNFs because they cannot tolerate intensive therapy; others told us they go to IRFs because nursing and physician coverage is higher. No comorbidities or the need for special services seemed to dictate the choice of setting. We heard that patients recovering from mild strokes may be discharged home and don't require either setting. Given the wide range in what we heard, we concluded that placement was likely to vary by the capabilities of the SNFs in their

markets.

The medical society gave us a list of comorbidities and medical complexities that were more appropriate for IRFs. We also heard that IRF and SNF use depended on the severity of the stroke, since IRF users must be able to follow instructions. And, last, we heard that IRF use depended on the IRF bed availability.

So looking a patient severity, we looked at Medicare hospital claims data and found that some of the comorbidities mentioned are infrequently treated in either setting; others were more likely to be treated in SNFs, though some of those differences were small.

We also looked at the severity of the prior hospital stay and found that SNFs treat the majority of the most severely ill, while IRFs treat the majority of the least severely ill.

Another theme we heard was about the severity of the stroke, and here I'm making a distinction between severity of illness and the actual severity of the stroke. Medicare doesn't collect data on stroke severity, so we looked at two proxies. First, using claims data, we examined diagnoses codes for paralysis and found that IRFs

are more likely to treat patients with paralysis. However, among patients with paralysis, those with dominant-side paralysis (and likely have more difficult recovery) were less likely to go to IRFs compared with patients with non-dominant-side paralysis.

Another way to get at the severity of stroke patients was to compare the functional status of SNFs in markets with and without IRFs. We looked at 15 measures of function and impairment collected by the SNF assessment tool and found that patients treated in SNFs in markets with IRFs had lower functioning and more impairments than SNF users in markets without IRFs, though some of the differences were small. We infer that IRFs admit the higher-functioning or similar patients.

The last theme we heard was that IRF use depends on IRF bed availability. In markets where IRF beds are tight, we heard that beds may be "reserved" for orthopedic and brain injury patients, while in markets with more availability, stroke patients are referred to IRFs.

We compared markets with high and low IRF occupancy and looked at how frequently stroke patients were sent to SNFs. We found that in markets with high IRF

occupancy, SNFs are used less. But we also found that in markets with low IRF occupancy, SNFs were used more.

This lack of consistency in findings reinforces that there are not strong patterns of IRF and SNF use for stroke patients. IRF use is likely to differ by the prevailing practice patterns and dynamics of individual markets.

Our previous analyses combined with our new analysis leads up to conclude that a site-neutral policy could include a subset of stroke patients: the most severely ill, who generally cannot tolerate intensive therapy, and those patients meet our criteria; and the least severely ill, who do not need the intensity of an IRF.

We also conclude that CMS needs to narrow the definition of stroke cases counting towards IRF compliance. And if it does, the threshold itself may need to be modified. The paper discusses the relationship between narrower definitions and the level of the threshold, and we'd be glad to answer any questions about this.

Now we shift gears, and we want to talk about additional conditions. In June, the Commission noted that it would explore whether other conditions lend themselves to

a site-neutral policy. We started with conditions with high volume and spending in IRFs, and when we looked at the conditions that met our criteria, we were left with -- we looked at 17. All of these met our criteria and were a mix of orthopedic, pulmonary, cardiac, and infections, and they make up about 10 percent of IRF cases and spending.

For these 17, total IRF payments, including their add-ons, are on average 64 percent higher than SNF rates. And just looking at the base rates and comparing that to SNF payments, IRF base rates were 49 percent higher than SNF payments.

We looked at the risk profiles using HCC, the Medicare risk profiles for each beneficiary, and hospital claim information for the 17 conditions. We found that the risk scores were similar -- SNF patients had slight higher scores -- and on average, SNF patients were older.

Most comorbidities were more common in SNF users or were comparable between the two settings, and this is a refinement from what was in the paper. Eight comorbidities were more common in SNFs, seven were comparable, and the exceptions were obesity and polyneuropathy, which were more frequent in IRFs.

From the CMS PAC demonstration, we know that there is considerable overlap in the functional status at admission between patients admitted to both settings. That's looking across all types of patients and not just the 17 conditions we're focused on here.

Turning to outcomes, the results were mixed, in part because not all the measures are risk adjusted. We found that observed mortality rates were higher in SNFs in part because their patients are older and sicker. Differences between the two settings would narrow with risk-adjustment.

We also looked at program spending in the 30 days after leaving the IRF or the SNF. Although payments for IRF stays are generally higher, we wondered if their spending in the 30 days after would be lower. We found that IRF stays continued to have higher spending in the 30 days after discharge compared with SNF stays, 7 percent higher. Although IRF stays had much lower spending on readmissions, their spending on additional post-acute care was considerably higher.

Again, we report CMS' demonstration finding that across all patients, risk-adjusted readmission rates and

changes in mobility were similar between IRF and SNF patients, while changes in self care were higher for patients treated in IRFs.

Now Dana will go over the impacts of such a policy.

MS. KELLEY: To assess the financial impact of paying IRFs the same rate that SNFs would be paid, we first converted SNF daily payments to per discharge rates by summing the 2012 daily payments for each of the selected conditions.

We then estimated aggregate Medicare payments to IRFs using SNF payments per discharge as the base payments for the selected conditions. This approach bases the IRF payment on the average SNF length of stay.

As Carol mentioned, our site-neutral policy would not affect IRFs' add-on payments, so we assumed that IRF add-on payments for teaching programs, treating low-income patients, and having high-cost outliers would remain at current levels.

Here you can our estimated impacts of applying a site-neutral policy to IRFs. In the first line, you can see that replacing the IRF base payment with SNF payment would

result in a substantial decrease in Medicare's payments for the 17 new conditions we've been discussing. Aggregate payments for these conditions would fall by $309 million.

Applying site-neutral payment to our previously considered orthopedic conditions -- the joint replacement, and hip and femur procedures we discussed last spring -- would reduce Medicare spending by $188 million.

Combined, Medicare's spending for IRF services would fall by almost $500 million, or 7 percent of IRF spending.

It is not included in the total here, but applying a site-neutral policy to strokes would reduce Medicare spending by an additional $256 million.

Note that our impact analysis assumes no change in IRF behavior. However, we do expect significant changes in provider behavior. I'll talk about why in a minute, but first I'll just remind you about how a site-neutral policy would be implemented.

Under a site-neutral policy, many cases will still be paid IRF-level rates under the IRF PPS, but CMS would need to make some changes to how it calculates payments for conditions not affected by the site-neutral policy. The IRF

case mix groups will need to be refined, and the weights recalibrated to maintain budget neutrality for non-site-neutral cases.

For IRF cases paid site-neutral rates, CMS will need to help level the playing field between IRFs and SNFs by waiving certain IRF conditions of coverage for site-neutral cases. As Carol mentioned, CMS should waive the requirement that patients with site-neutral conditions receive daily intensive therapy and face-to-face physician visits at least three days a week.

Of course, it will be important to monitor outcomes to ensure that changes in the provision of services do not compromise quality of care.

CMS will also need to make changes to the 60 percent rule, and as Carol mentioned, we've reviewed this issue in the paper, and we can discuss this further on question if you'd like.

Once site-neutral payment has been implemented and certain regulatory requirements have been waived, we can expect to see those behavioral changes. You'll recall that we have seen such changes among IRFs before in response to other significant policy changes. For example, in 2004,

when CMS restricted the conditions that count towards the 60 percent rule and began to strictly enforce the 60 percent rule, IRFs shifted their mix of patients toward conditions that counted towards the 60 percent rule, and aggregate IRF patient volume declined dramatically.

Under site-neutral payment, IRFs may change their costs by reducing the intensity of services furnished to site-neutral cases. The extent to which they make those changes will depend on their current cost structure as well as their ability to modify their variable costs. Even with lower payments, IRFs may elect to continue to treat the cases subject to the site-neutral policy. The cases may still be profitable for some SNFs. Where cases are not profitable, the payments may still cover a facility's patient care costs and contribute towards covering a facility's fixed costs and be preferable to an empty bed.

Under site-neutral payment, IRFs may opt to change their mix of cases to reduce the admission of patients with site-neutral conditions, as they did when the 60 percent rule was more strictly enforced. An IRF's ability to adjust its patient mix will depend in part on characteristics of its market. For example, IRFs located in markets with few

or no other IRFs may have an easier time focusing on cases that the average SNF is not staffed or equipped to manage in the market. On the other hand, IRFs that compete with a number of other IRFs or with specialized "super" SNFs might find it more difficult to increase the number of non-site-neutral cases.

So this concludes our presentation, and we will now turn over the discussion to you. We are particularly interested in hearing your thoughts on the new conditions we've described as candidates for site-neutral policy, and we'd also like your input on how to proceed with strokes.

MR. HACKBARTH: Okay. Thank you, Carol and Dana. Excellent job.

So Round 1 clarifying questions. We'll go down this way, beginning with Kathy.

MS. BUTO: I wondered if you could, when you did the numbers -- and I think that was Slide 18 -- whether you took into account the additional costs of hospital readmission and then offset against that, I guess, the additional cost for IRFs of post-acute care that was provided. In other words, where does that come out? Is that a lot of money? Is that very little money? I don't

have a feel for that.

MS. KELLEY: We did not take that into consideration.

MS. BUTO: I think if we are going to put numbers up there, we need to at least take into account potential costs that you've pointed out in the analysis, and that would be helpful. Thank you.

MS. KELLEY: Okay. We can get back to you on that.

DR. CROSSON: Yeah. We can leave Slide 18 on.

I apologize. This is a little bit off topic, but, Carol or Dana, across all the IRF-eligible conditions, if the patients were treated in acute care hospitals as opposed to in IRFs, would Medicare save money or lose money, and do you have any idea about the magnitude of that?

DR. CARTER: Do you mean instead of an acute care admission or just extending the acute care admission or just extending the acute admission?

DR. CROSSON: Well --

DR. CARTER: Because most of these patients were previously hospitalized.

DR. CROSSON: Right. In other words, that period

of time, if they stayed in the acute care hospital versus being transferred to an IRF, what would the impact on Medicare cost be?

DR. CARTER: We haven't done that analysis. I think what would happen is most of these DRGs would cost -- the payments, I think would be lower in acute care, but these cases would -- given the lengths of stay, if the lengths of stay approximated what you are seeing in post-acute care, these cases would hit outlier payments, and so that would involve that. And we haven't done that analysis.

DR. CROSSON: So, as I remember, the average stay was about two weeks; is that right?

DR. CARTER: In IRFs, it is two weeks, but in SNFs, it is considerably longer.

DR. CROSSON: Right, okay.

So is that a calculation that's possible to do?

DR. CARTER: I would think --

MR. HACKBARTH: It sort of seems analogous to how we thought about LTCHs, and one option was for the patients to stay longer in the acute care hospital and increase funding for the acute care hospital outliers as opposed to pay more at LTCHs, and I think that is sort of the point

that --

DR. MILLER: And I think probably the arithmetic could be done, but I just want to say this out loud. We could do things like, say, all right -- and this is all very simple, but assuming there is a 14-day stay for this IRF patient, we could say, all right, we are going to take the diagnosis they were in, in the hospital, assume they now have a 14-day stay, run it into the outlier payments, and figure out how much would spend out there.

Even with the LTCH example, I am a little bit unclear what we would be saying here, because somebody has a hip replacement in the hospital -- and I am about to venture into territory I know nothing about, and I am talking to physicians, so this is going to go pretty rough from here on out.

DR. CROSSON: Well, if you ever want your hip replaced by a pediatrician, give me a call.

DR. MILLER: Right.

[Laughter.]

DR. MILLER: And I have assumed at this point, in this country, I probably can't get a hip replacement.

If the surgery occurs in the hospital and then

they go out into, let's just say, 14 days of therapy, would you be thinking that then the hospital would reconfigure itself to deliver that therapy, or the hospital would just say I'm now responsible for this, and I might send them to an IRF or I might send them home?

DR. CROSSON: I guess I was assuming that the hospital would reconfigure its set of capabilities to take care of these patients. Since it is only three hours a day, it looks like it is directed in the IRFs, not at the patients who are the most severely ill but moderately ill. So I would imagine that it would be within the capability of an acute care hospital to do this.

In addition, as I think was pointed out in the paper, many of the IRFs are actually sections of acute care hospitals, right?

MR. HACKBARTH: This line of discussion is focusing on substituting extended acute care hospital for IRFs, but the whole gist of this analysis is that the SNFs are lower cost providers of these services, and so the question would be can extended care and acute care hospitals be lower cost than SNF.

DR. CROSSON: Exactly. So if you look at the 500

million, that is not chump change, but my question -- and I am sorry to divert this. I will shut up in a minute. But the question was if we had a different look at this and said why can't this be done in acute care hospitals, would that number be substantially different?

DR. MILLER: So, again -- and, actually, just one minor point. The three-hour rule, if I understand this, is the patient has to be able to sustain three hours of therapy. It is not that they only get three hours of therapy. Is that right? But I don't know how many hours of therapy they get.

MS. KELLEY: That's right. The three hours is sort of a benchmark for judging intensity of therapy, and they need to be able to sustain that.

DR. MILLER: Right. I don't know exactly -- I wouldn't assume that they are just getting three hours of therapy.

Again, I think we can go through the mathematical exercise. Actually, I was going to speculate on which direction the number would go, but I am not going to.

MS. BUTO: Mark, wouldn't you have to include some of the practitioner therapy costs in that cost analysis?

Because I don't know how many of those are already sort of bundled into the payments that SNFs or IRFs get and which ones -- if it were a hospital, for example, which ones would be billed separately.

DR. MILLER: I can look at that, but here is the way I would -- I'd have to think about this. Yeah.

DR. CROSSON: [Off microphone.]

MR. HACKBARTH: Now that we have clarified that question --

[Laughter.]

MR. HACKBARTH: I think you have violated Round 1 rules, Dr. Crosson.

DR. CROSSON: Not quite clarifying.

MR. HACKBARTH: Right.

So other clarifying questions? Alice and then Craig.

DR. COOMBS: On Table 8, page 18 in the handout, it actually does a great job of comparing the readmission cost. I just wanted to bring that up, because it's actually already there, looking at the end result, and even with the readmission cost, it looks like it is a ratio of spending IRFs to SNFs of 1.42.

[Pause.]

DR. CARTER: Was there --

DR. SAMITT: On Slide 19, can you clarify your comments about refining the CMGs in weights, so that there is budget neutrality? I didn't understand whether you implied that that would erode some of the savings that are referenced on Slide 18 --

MS. KELLEY: No.

DR. SAMITT: -- or what you meant from a budget neutrality perspective.

MS. KELLEY: So we would maintain budget neutrality for non-site neutral cases. So we would want to be careful in continuing the IRF PPS for the non-site neutral cases. We want to have case mix groups and weights that accurately reflect the non-site neutral cases as opposed to all the cases, as they currently do. So once we remove certain cases from coverage under the IRF PPS, there may be a need to regroup some of the cases, some of the case mix groups, regroup some of the cases into new or different case mix groups and then to recalculate new weights for those groups in order to accurately reflect the average cost for those cases.

DR. SAMITT: So is there any kind of subsidization at this point that once you regroup those non-site neutral cases, that the cost overall for that group goes up?

MS. KELLEY: We have not done that analysis.

DR. SAMITT: Okay. Then my other question is on Slide 3. Just to help me reconcile the fact that you talked about the most severe cases are going to SNFs, not IRFs, and yet the Medicare requirements have greater intensity for MD and RN oversight in IRFs, not SNFs. So does this reflect the complexity of the other 90 percent of cases that are typically seen in IRFs, that they have a higher level of medical intensity, or how do we reconcile the fact that the more sick and old patients are in SNFs and yet the clinical need requirements are higher in IRFs?

MS. KELLEY: Well, I think there's a couple of things going on here. The first is that an IRF has to be licensed as an acute care hospital, so there are requirements that go along with that, that set these parameters. Then they have additional requirements.

Remember, the IRF status was created in a way when the inpatient acute care hospital PPS was put into place in '83. So some of these requirements were intended to

differentiate a rehab facility from an acute care hospital, so there's sort of that overlay.

The cases that we looked at here were just 10 percent of the IRF cases, as you noted, but the work that Carol and Sara did in the spring was a bigger chunk of cases, and I think you had similar findings about intensity then.

DR. CARTER: Yeah. Well, those were other orthopedic conditions and stroke, so we did find the same thing.

MR. HACKBARTH: So what I hear you saying, Dana, is that the IRF requirements are historical artifacts; they are not analytically based, based on the needs of patients.

MS. KELLEY: Yes. They are longstanding requirements that may or may not reflect the current needs of patients.

MR. HACKBARTH: Okay. Clarifying questions. Any more over here? Jack and then Jon.

DR. HOADLEY: On Slide 18, when you're looking at the total, here you are focusing on the change in spending, but what is the total amount of both spending and cases that are now represented by the 17 new conditions and the

orthopedic conditions combined? Do you have those?

DR. CARTER: I think it is about 20.

DR. HOADLEY: And the same dollars in patients, about the same?

DR. CARTER: Yeah, yeah, the dollars and case accounts go about together.

DR. HOADLEY: Thank you.

DR. CHRISTIANSON: Carol, could you clarify for me the last couple lines in Slide 11?

DR. CARTER: This was our attempt to see whether IRFs are taking easier or harder cases in markets where there are both types of facilities, but because we didn't have comparable, functional assessment data, what we did was we looked at the function of patients in SNFs in both of those markets, and we thought, well, if IRFs take more complicated cases, we're going to see that in the SNF data, and if they take less complicated cases, we will see that in the SNF data. And that's what this analysis was trying to get at.

It's a proxy for trying to measure the function of patients in SNFs, and what we looked at were 15 different MDS measures of both function, self-care, and impairments,

and we found that, typically, SNF patients have either lower functional status or comparable status when there is an IRF in the market. And that led us to think that maybe the IRFs were taking higher functioning patients, leaving the lower functioning patients for SNFs.

DR. CHRISTIANSON: I am a little confused. Should the last two words be "without" then, should be without IRFs then?

DR. CARTER: Oh, it should be, yeah. Sorry.

DR. CHRISTIANSON: Okay.

DR. CARTER: Right. I'm sorry. No wonder you're confused. Yes.

DR. CHRISTIANSON: I'm always confused.

[Laughter.]

MR. HACKBARTH: Okay. Any other clarifying questions?

[No response.]

MR. HACKBARTH: Okay. Let's move to Round 2 then, and what I would like to do is first invite comments or questions related to whether stroke patients should be included within the site-neutral policy. Who would like to address that? Mary and then Alice.

DR. NAYLOR: First of all, thank you. The additional analyses related to stroke were very, very helpful.

I know a really important goal of this Commission is to try to figure out a way. Payment enables clinicians to make the best judgments on behalf of patients and their families. In some ways, some of the data that you uncovered suggests that that might be happening.

On page 12, you talk about patients with paralysis are more likely to be seen in IRFs, unless the paralysis is on a dominant side or is not likely to result in recovery. So, to some extent, there is some indication that the current system is getting people at least into IRFs who are distinguished from SNFs because we can see a path to recovery.

I think the biggest challenge with stroke, generally, is that unlike hips, patients with hips and patients with femurs, there is this known trajectory of recovery, and stroke is much less predictable.

The other is that as we look at the outcomes we have available to us, 30-day and mortality -- that self-care, of course, is a different, positive outcome -- that we

don't often have the measures that are most meaningful, which is long-term recovery, return to job, productivity, et cetera. And that is just because the evidence is not there.

So I guess I am saying I think stroke presents a challenge because of the lack of predictable nature, and then I wonder about the administrative cost of trying to create all of these changes at the same time we're trying to promote clinician's appropriate judgment.

That all being said, I support site-neutral policy, wherever it is, really a trajectory we understand and where two site settings can produce the same.

So, while conceptually I support it, with stroke I am a little bit concerned because our goals here are long term. They're not just about 30 days or post-acute and so on.

DR. COOMBS: For stroke, speaking specifically about strokes, stroke represent a syndrome of a whole constellation of clinical presentations, so strokes are very different in the sense that you can have a stroke, a small or clinical stroke patient goes home, doesn't need to go to a SNF or IRF, and you could have a devastating stroke.

I kind of understand the data, and the reason I

understand it is because, if I have a patient who has a chance of a great recovery, I may steer them toward an IRF, but if I have a patient with a lot of comorbid conditions and then explain the sickest sick are sick over in the SNFs -- because they're way over here, it is almost like a bimodal distribution of who goes where, but I would understand that. Because of the complicating illnesses, I am going to say, "Well, this patient has the greatest likelihood of meaningful recovery. So, therefore" -- I think the market is doing this a little bit on its own right now. I'm going to direct that patient to an IRF. I'm going to direct this person to a SNF.

Where it doesn't happen, I think involves when there are certain clinical things, such as cognition and mental health. When they are layered on top of stroke, I looked at the charts. It is clear whenever you see cognition issues or any kind of cognitive deficit, I don't care if they don't have diabetes or any of the other major comorbid conditions. If they just have that one by itself, it seems to be a predictor of recovery and decision-making, so that those decisions would steer toward the SNF versus the decisions to go toward the IRF.

It may be that there's some inherent problems with just this whole notion of looking at cognition and mental health, but I will bet you it is probably the rate-limiting step for how decisions are made right now.

Because strokes are so heterogeneous and because the presentation can vary, I think that to put it in the site-neutral category can actually result in some other behaviors, such that people will say, "Oh. Well, we'll send you to a SNF because we know you had a stroke, and it qualifies you," when, in essence, the patient could go home or a home with a home health support. So it may actually shift some decision-making into a more costly initiative where you could have gone home, and so that would be one of the things that I'd be afraid of is that people are making decisions -- clinicians are making decisions right now to send people home when it's appropriate, and they don't need SNFs, they don't need IRFs, and I think that's a concern that I would have with site-neutral on stroke.

It's just the heterogeneity of the presentation and understanding that the market is doing some things on its own right now, and I think in talking to some of the neurologists, they are very clear. It is hard with strokes

in the sense that you could have a hemorrhagic stroke -- or not a hemorrhagic stroke -- you have a stroke that presents and it seems like it's straightforward, and all of a sudden, you give them TPA or heparin and they deteriorate significantly.

I think I talked about giving maybe site neutral for TPAs, strokes that are uncomplicated, but then they are not uncomplicated, and then they have a series of issues.

So I'm not quite sure that strokes fits into this category.

DR. BAICKER: So my reaction to stroke is sort of my reaction to the whole thing, which is that site-neutral payment makes a lot of sense, and in principle -- you write down the principle. The principle is straightforward. And then we start unpacking for, I would suspect, almost any given condition. There's a lot of heterogeneity -- conditions even when we focus on ones that are treated in two different settings commonly, of course, there are differences.

And so the question is: Does that undermine the idea of site-neutral payment overall? And my reaction is no. The problem would be if systematically people know

which patients are going to be attracted or to be avoided and steer them that way accordingly because of financial incentives rather than what's best for the patient. If you're underpaying in one setting, that's as bad as overpaying in another setting.

So is this a case where systematically it's going to be wrong for a big enough group of people that you're going to end up with patients not at the site of care that is most effective for them? Or is it going to be sometimes wrong, not wrong by so much in a really predictable way -- it's the predictable way that creates the incentives. The unpredictable, you thought somebody was stable, and then they need more care. That's going to happen both ways, and that's not a problem as long as there are enough resources in the system that sometimes it's a little high and sometimes it's a little low.

So for me, the key question is the magnitude and predictability of how wrong you are, and I'm not -- I leave it to the clinicians to say whether stroke is on the bad end of that spectrum or the less bad end of that spectrum. The fact that we see these patterns of overlapping care and that there do seem to be some predictors, whether it's paralysis

or cognitive functioning or something that could be coded ahead of time into its own group predictively, suggests that it's still a decent possibility as a test case for this. But going down the road, for each of these things, there are going to have to be some nitty-gritty decisions about who's in which bucket, and then they're just not going to be right all the time. And I think that we can live with that as long as it's not a systematic problem.

MR. HACKBARTH: So your bottom line on stroke is?

DR. BAICKER: It seems to me to still have good potential, but I really would defer to the clinicians.

MR. HACKBARTH: Okay. So other comments on stroke?

MS. BUTO: I would say on stroke, no, and the reason would be it seems like we have so much variability that we could be making a huge mistake. And it's one of those irreversible conditions that it's not like you can go back and fix it later. So I'd say no on stroke. I mean, why not go into something like this -- and the principle is a good one, site-neutral policy -- with the most confidence that, in fact, what's going on in both settings is essentially treating the same kind of patient, as Kate said,

and in a similar way. Then we'd feel confident that what we're doing is a good thing.

So my question really follows up on Kate's, which is for the other 17, how much homogeneity is there that we feel confident?

MR. HACKBARTH: Let me come back to that.

MS. BUTO: All right.

MR. HACKBARTH: I wanted to do stroke first, and then we'll go back to the other 17 in a second round. So, Jack, on stroke?

DR. HOADLEY: So if I had to come to that decision without any more discussion, I'd probably say no as well, and I would base it on two things. One is we've got 20 percent of all of the IRF volume represented by the other -- if we end up at the 17 plus the ones we previously discussed, so we've got a pretty good test of this approach that's already going to hit a pretty good volume.

The other thing that struck me is this notion that the subset of stroke patients -- this was on Slide 13 -- is a combination of the most severely ill and the least severely ill. And that kind of almost captures that notion that, okay, so we're taking the two ends, leaving out the

middle, which really makes the notion of boundaries and -- I mean, that just intuitively as a non-clinician seems peculiar, even though there's a logic and it makes sense and there's all the data that point in that direction. But it feels like it sort of captures that kind of uncertainty and that I would on that basis say let's -- we've got a good volume of cases if we like the 17, in addition to the original, that's a good test case, let's proceed that way.

DR. REDBERG: I would support site-neutral payments and for stroke because I think, again, you know, the data certainly shows that there's so much variability. I was very struck by -- and, you know, I think it's great that you did so much intensive interviewing with doctors and people, clinicians, that are involved in the care of stroke patients. But the fact that there was no consistency in the markets between -- you know, it really depended on where you were, whether you went to an IRF a SNF, kind of tells you that there's nothing special about what IRFs or SNFs are doing and that it really depends on a lot of local factors, and that, again, any outcomes aren't very different in the patient. And as Alice mentioned, I mean, there are other choices, too, for stroke patients like going home with

physical therapy. And I think actually some patients -- most patients prefer to go home, and if we offered more intensive home health physical therapy services, that more patients would, I suspect, choose that option.

But, again, the whole principle of if you're looking at what's best for the patient, you know, it's hard to say that this separation, which is very artificial now between IRFs and SNFs, is what's best for the patient. We're spending a lot of money and these requirements, which really is kind of, I think, forcing doctors to make choices where to send stroke patients that they wouldn't make based on what's best for the patient, and that having sort of a range of services that can be individualized to the patient and think about that would be the better focus, when now, you know, I think everyone's trying to look at these lists and sort of do what's according to the list, which is not necessarily what's best for the patient. And the fact that there's big differences in payments and not very big differences in outcomes tells you that this is probably not the best way to do it. Therefore, I think site-neutral payments would be a better approach.

MR. THOMAS: Hearing Rita's point, I see that

there is definitely some rationale behind a site-neutral payment here. The concern I have is that, at least in our experience in our organization, we see that there is a difference between the type of patient that would go to a rehab versus the type of patient that would go to a SNF. The type of patient that would go to a SNF would have more medical conditions and usually more medication issues that they need to have managed versus someone that would go to a rehab would have more physical therapy needs than they would necessarily see. And, frankly, SNFs for the most part are not well positioned or well equipped to be able to deal with those needs, and that would be my concern.

I'm not certain that if we went to a site-neutral payment that it would just mean that it should be at the SNF rate, quite frankly, because once again I think if you look at the amount of SNF beds in the country, they continue to decline, because I think that's a concern about whether they're reimbursed appropriately for the type of severity patient that they handle. People use SNF beds because they want to have them out of the acute-care environment, the patient out of the acute-care environment, which is more expensive. But it is certainly a challenge.

So I think there are -- there is definitely some rationale based on your data. I think it would be interesting -- and I don't know if you've done this -- to actually look at facilities and the types of capabilities they have, because I think you're going to find they are different. They are different in the types of capabilities they have for patients in a rehab versus a skilled nursing. I think Alice was saying it a little bit, if I understood specifically, that you really kind of bifurcate and you send patients to different areas depending upon the type of situation that they have. And I think that's my concern in just having one payment, although looking at your data and hearing that there's not a lot of consistency and hearing Rita's point, I mean, you can see that, you know, perhaps that would make sense.

I'm not certain, based upon what you've indicated here, that the SNF rate is the right proxy for that payment.

MR. HACKBARTH: Warner, you said that the number of SNF beds is declining, which you see as evidence that maybe the SNF rate is not -- you're referring to hospital-based SNFs?

MR. THOMAS: Certainly in our region that's what

we see. You know, that's what we see, and I don't know what that is nationally, but that's what we see in our region.

MR. HACKBARTH: Nationally, I think the number of SNF beds is pretty stable.

DR. CARTER: Pretty stable, yeah.

MR. THOMAS: And I don't know if those are hospital based or --

MR. HACKBARTH: Hospital --

DR. CARTER: Well, there was a decline in hospital based, but I think that's been pretty stable now for four or five years. But there was a large -- they used to make up maybe 9 percent of the industry, and now they're about 5 percent.

And just getting back to your point, we heard that version of what you say. We also heard exactly the opposite version.

MR. THOMAS: Okay.

DR. CARTER: Where if patients needed a lot of medication management, they wanted the around-the-clock nursing coverage in SNF and physician coverage of IRFs. So we heard completely different --

MR. THOMAS: And perhaps it is -- you know, it's

contingent upon the staffing and each individual facility. I mean, perhaps that is what happens in these in a broader fashion.

DR. CARTER: And I did want to remind everybody that we have about 30 percent of beneficiaries living in markets without IRFs.

MR. HACKBARTH: So if I could, let me just try to characterize what I think I heard about the evidence. So within a given provider, like Warner's organization, there may be consistent patterns of this type of patient goes to SNF and this type of patient goes to IRF. But I think what I heard is that that may not be consistent across providers within a market and certainly not consistent across markets. Is that a fair --

DR. CARTER: That's right. People were very clear in their rules, and there was no consistency in their rules.

MR. HACKBARTH: Right, okay.

DR. MILLER: And also -- and I think this is implicit in the comments, but I think your experience is very peculiar to your market. So if you don't have any IRFs in your market, your SNFs behave one way; and then if you have IRFs in the market, the SNFs kind of staff and behave

differently. And so I think that's also part of what you could be experiencing in your market.

MR. HACKBARTH: Before I go to you, Kathy, did I see another hand for a Round 2 comment on the inclusion of strokes in site neutral? Let me get the people who haven't been in yet.

DR. NERENZ: I'm not sure there's a lot to add, but just following up particularly on Warner's comment, and I'm struggling through this and thinking about a yes-no answer to stroke. I'm trying to sort out what's the difference between the rehab needs and the ongoing medical care needs. And it seems confusing in the sense we just talked about, that part of what you pay extra for in an IRF now is the 24-hour RN coverage, which seems to be related to medical issues, not to much rehab issues per se. And you have the more frequent MD coverage. And I haven't quite figured out in the comments yet in these patients with stroke, is there a set of ongoing medical needs or some medical instability that would justify the IRF?

And I think, Warner, what you just said sounded to me sort of the opposite, that if those needs are present, then you send people to the SNF.

So I think what I'm hearing is that any higher level of medical instability in stroke patients does not automatically say IRF and, yes, let's pay more for IRF. But am I tracking this all correctly so far?

MS. KELLEY: So I think this goes back to what Glenn was just saying, that what you just said I think perfectly captures what we heard among some practitioners we talked to, that when there are higher medical needs, patients automatically go to SNFs. But we also heard exactly the opposite, that higher medical needs require greater nursing care, more medical attention from physicians, and so that an IRF was a more appropriate place for patients with greater severity of illness as opposed to severity of stroke. So we heard both.

DR. SAMITT: What I've heard thus far in the comments -- and I'm still trying to reconcile how I feel about it -- is the presumption that if we create site-neutral payments for stroke, that a majority of the cases would shift to SNF from IRF. Well, what I read in the paper would suggest that, while coupled with a site-neutral payment, we also could make the recommendation of liberalizing some of the requirements for IRFs for this

population, which means that some of the intense nursing or medical care could actually be reduced, allowing IRFs to reduce their costs.

So I'm not sure I agree that we're going to see a full-scale shift. There may still very well be the case where certain cases are still referred to IRFs and IRFs are able to manage under a lower reimbursement level those admissions, because the intensity of the cost to manage those patients goes down.

The other comment that I would make is we talk about sort of site-neutral equivalency, but maybe we don't even have to go as far as that, to Warner's point. Maybe we say, all right, we reduce the payments for stroke to IRFs, but we don't bring it all the way to a SNF level. And I know the proposal also was a three-year window to blend the rates. And so maybe that's a perfect opportunity to see how do IRFs do under a more blended rate model for three years with relaxed requirements to see how this plays out over the next few years, and we can always go back if it doesn't work well.

MR. HACKBARTH: And that approach is, in fact, what we used with LTCHs, where we, A, reduced the regulatory

requirements and, B, phase in the change. It does give you an opportunity to sort of monitor what's going on.

MR. ARMSTRONG: I'm not sure that I have a lot to offer, but not being burdened by knowing the specifics about stroke patients, I just would say given the criteria we've described and the position we've taken on this policy for a whole host of other populations of patients, it seems to me that there's a very logical and supportable extension of this site-neutral payment policy to stroke patients, and that it's not necessarily to steer volumes, but in a system where referral patterns don't have, you know, consistency across markets or even within markets across medical groups, that's exactly the kind of situation that a site-neutral payment policy is relevant and a way of better using the Medicare program's limited resources.

MR. HACKBARTH: Okay. So have I missed anybody who hasn't spoken yet who wants to address the issue of including strokes in site-neutral policy?

MS. BUTO: It occurs to me that this falls in the category of a group of patients who are being served by multiple different approaches, including home health and rehab and so on, that beyond this issue of site neutral, we

probably should look at are there clear protocols for different levels of stroke patients and potentially a post-acute care bundle that could advance more than just a site-neutral policy between IRFs and SNFs, but really advance better care with outcomes measures in the least, you know, burdensome, most beneficial way.

So I see this as a perfect -- especially if it's, what, $200 million just on these two providers that could be saved in a site-neutral policy. This has got to be a growing issue in Medicare where the patient group itself is so large but variable that there ought to be more than site neutral that we can look at as a way to address the issue.

MR. HACKBARTH: Yes, and I agree, Kathy, and thanks for highlighting that. This, pursuing site-neutral policy for IRF and SNFs, is not instead of pursuing potential options that would involve bundling, including post-acute care. It's not an either/or. Getting to a post-acute care bundle is something that we've talked about multiple times, and, you know, there are some demonstrations now being organized about bundling post-acute with hospital acute care.

So the way I think of this is what do we do while

the bundling approach is developed, tested, et cetera. But it's not an either/or.

MS. BUTO: I just think that at some point -- I don't know if we're keeping a list, but this is a huge group that both from a clinical standpoint and a cost standpoint could be a good target for that kind of work, whether CMS does a demonstration or not. And, you know, we ought to be able to identify those subcategories where there could be real benefit to...

MR. HACKBARTH: For the appeal of bundling is that then you have decisions made by clinicians who are really well informed about the capabilities of the local SNFs and IRFs, and all of the -- home health and all of the alternatives. And I think ultimately that's better for patients. But the nature of these things is we're not going to get there quickly, and so we need to do some things in the old structure to try to improve it in the meantime.

I want to get to the other 17 conditions. Alice, on stroke?

DR. COOMBS: It's on this [off microphone].

MR. HACKBARTH: Yes.

DR. COOMBS: I think one thing that I thought

about -- and it's in the back of my head, and I might as well put it out there -- is some decisionmaking is based on resuscitation status, DNR, and I didn't say it earlier, but that may be that push toward the real complex, you know, less likelihood of recovery from all the conditions that are co-existing with a stroke. So I wonder if we could look at that. I bet you it's going to reveal something very interesting.

MR. HACKBARTH: Okay. So we will do Round 2A now, and here, I would like people to address the other 17 conditions that have been proposed for inclusion. Of course, a central issue here is the criteria by which those were chosen.

The reason I am trying to be a little bit more directive today in Round 2 is that we are getting close, I hope, to the point where we are going to formulate a draft recommendation, so I need some information to do that.

On the other 17 conditions and the criteria used to develop them, what do people think?

[No response.]

MR. HACKBARTH: Let's see. Silence could be "I don't understand the question." I could be assent; it could

be dissent. I need a little bit more.

[Laughter.]

MR. HACKBARTH: Dave.

DR. NERENZ: Well, this just echoes what I asked earlier about stroke, but I'm trying to understand here, as well.

Among the features in these 17 conditions that are used in the analysis was comorbidity, and perhaps for the clinicians or others, as that plays out in this period of time when people are in one setting or another, is the comorbidity something that involves active medical management that might conceivably be different in the two places, or is it something that relates to the ability to do the rehab part, more or less? And I understand it could be both.

DR. CARTER: So we measured it in two different ways. One would be the comorbidities the patient had and was being managed while they were in the hospital, and that was looking at secondary diagnosis on the hospital claim.

But we also looked at the HCC scores, and I will remind you that that is looking at the diagnosis over the past year that the patient had, so it is sort of a better

measure maybe of chronicity, and so we tried to get at both of those by looking at two different ways.

DR. NERENZ: Okay. But in either of those, we don't know precisely whether these things are under some kind of active, almost daily medical management.

DR. CARTER: Oh, I think they would be. That would be my guess. I'm not a clinician, but many of the chronic conditions would require active management in the hospital, I would think.

DR. NERENZ: Like by a nurse or doctor to --

DR. CARTER: Yeah.

DR. NERENZ: That last thing surprised me a little bit because it would seem that in some these settings, a lot of these comorbidities are stable, and you need to sort of be aware of them. But I guess that is the essence of the question, because some of the other things you have said about outcomes and this idea of sending the sickest patients to the SNFs, again, suggests that whatever additional capability the IRFs have as an acute care hospital is not actually being linked reliably, regularly to medical management.

Now I am applying that set of questions to the 17.

DR. CARTER: Well, I guess I was thinking of medication management, which could happen both in a SNF and an IRF.

DR. NERENZ: [Off microphone.]

DR. CARTER: Right, yeah. And we heard completely different stories about that. Yeah.

DR. MILLER: The only thing I wanted to add to that is, so the profile is that you end up with the more complex patients in SNF, generally, as a general statement, and for the set of conditions that we are talking about now, the majority of the time, the patient is dealt with in the SNF.

So I can't answer your question, like what actively is going on at any point in time, but the majority of the time, whatever is going on is going on in the SNF, and the most complex patients end up there. That was all factually --

DR. CARTER: It was all factually correct, yes.

MR. HACKBARTH: Okay. I had Warner and Mary.

MR. THOMAS: This may be more of a clarifying question, so I apologize.

For the IRF cases where you have cardiac and

infections, what types of cases were those? It just seems interesting they would be going to a rehab for treatment. Was there anything that you learned as you were digging into this?

DR. CARTER: No. We didn't look at that specifically.

If you look at the case mix groups of IRFs, they are not all orthopedic. They include many different types of major reasons for rehab, and they include cardiac, they include infection, and they include pulmonary, so --

MS. KELLEY: And a category of condition is debility. So, if someone has been in the acute care hospital for a long period of time and has lost a lot of their strength --

MR. THOMAS: I got it. These are probably long length of stay in acute care, so they are being sent to rehab because of the mobility issues. I got it.

Okay, thank you.

DR. NAYLOR: So, unlike stroke, I actually believe the bigger concern here is the least severely ill who generally do not need either SNF or IRF and who could be cared for elsewhere, in their homes. I am very concerned,

so, again, supporting site-neutral policy but also recognizing here is not where we want to motivate nursing home residents to be moved to SNFs for septicemia, urinary tract infections, other problems, conditions that could be very well earlier identified in the nursing home, the long-term care part, and not be a basis for movement.

So I really think that as we move in this general direction, we pay very close attention to where other sites might be much more appropriate, including people's homes or the nursing home where they live.

MR. HACKBARTH: We still would have the three-day rule for SNFs, which his sort of the wall between taking nursing home residents and moving into SNF care.

DR. NAYLOR: Yes.

MR. HACKBARTH: Let's see. Craig? Anybody else want to get in on this? Alice.

DR. SAMITT: For all the reasons that have been discussed previously in the rationale for site-neutral payments, I would support the methodology and the conditions described.

I think that if there isn't sufficient appetite for the full list of 17, one compromise could be we set a

higher threshold for the percentage of cases that are seen in SNF versus IRF, so we set a bar at 75 percent instead of 50 percent, and the large majority of these 17 are still more than 75 percent managed today in SNF. Maybe we start there with those 12 or some odd cases, and we can always extend to the broader 17 as needed.

MR. HACKBARTH: As you noted earlier, Craig, another feature of this is the transition, and so those are sort of two ways to accomplish a similar goal, focus the list of conditions or transition.

DR. SAMITT: Absolutely. The same would apply. If we have a blended rate for these 17, as well, it would give the IRFs the opportunity to either reduce the cost --

MR. HACKBARTH: Yes.

DR. SAMITT: -- and see if this is a problem over a three-year period.

MR. HACKBARTH: The question I am trying to get at, would you rather go with a shorter list and a higher threshold and no transition or a longer list, lower threshold, and transition? Let me ask it that way.

DR. SAMITT: I prefer consistency, so I would say the longer list over the current three-year proposed blended

rate.

MR. HACKBARTH: Make it consistent with our LTCH approach.

Let's see. I have Alice and then Kathy.

DR. COMBS: First of all, thank you, Carol and Dana. This is excellent.

I, too, agree with Mary. Unlike stroke, these conditions are relatively predictable. They are well described in terms of how they present clinically. I agree with the conditions on this list.

Of interest is the ratio, IRF-to-SNF payment, and that is very revealing, I think, looking at the conditions and the gradient that exists between the two sites.

MS. BUTO: Yeah. I think this is also a clarifying question, but it occurred to me that beneficiary liability or copayments would be different in these two settings, and I wonder if you had done that analysis and also looked at the length of stay differences for these different conditions. Let' assume that we are essentially incenting the use of SNFs rather than IRFs by moving to the policy, which seems like definitely what we're doing here. If SNFs tend to have longer lengths of stay and that has

implications for beneficiary co-insurance, I would be interested to know what that is.

So I think there is something we are not seeing here, which is what is happening to the bene, are they going to be saying longer than they might in an IRF, that kind of thing. I'd just be curious. I know it doesn't change the payment ratio, but --

DR. CARTER: Right. So I do know what the lengths of stay are by condition. It was just a lot of information I didn't include. So I can definitely get that to you. They are much longer in SNFs.

Particularly for these 17, the majority are being seen in SNFs, and so they have longer lengths of stay. That's the practice pattern now.

If you move these IRF cases to SNFs, their occupancy rate would go up very modestly. For IRFs, this is a big chunk of -- this 10 percent or something is a large share of their business. For SNFs, it's very -- it's a small increase in the in volume. So I am not sure that it would affect SNFs in that way.

You are right that the bene copays would kick in on day 21 for patients that had -- for patients who might

have been going to an IRF but now are going to go to a SNF, they will incur copays starting on day 21. We can think about how that would affect on average, what that would mean.

MS. BUTO: I just think it is something we should be aware of if we are promoting the policy.

DR. CARTER: Yeah. Right.

DR. MILLER: But I also wouldn't assume that there is a wholesale shift here. If you relieve the regulatory requirements, IRFs may want to stay with this group of patients. Assuming they are paid at the SNF rate, I don't know the profitability of these specific cases, but SNFs have relatively high -- very high profit margins in Medicare, generally, and the IRF, relieved of the regulatory requirements, may still want to see this patient.

I don't think everybody should walk around assuming all these patients --

DR. CARTER: Wholesale move, right.

DR. MILLER: Move, because I don't --

DR. CARTER: Also, I was curious to hear Jeff's findings yesterday about how much of a facility's cost are variable. So I would assume that IRFs are going to have --

if they don't have to meet all of the regulatory requirements, they are going to have the flexibility and can lower their costs if IRF cost structures act in the same way that the acute care hospital structures do.

MR. HACKBARTH: Okay. Jack and then Rita and Scott, and we're getting -- actually, we have 15 minutes left. Jack, Rita, Scott.

DR. HOADLEY: So just following on Kathy's point, is there a cost sharing in the IRF?

DR. CARTER: There is, but most of them meet it with the first acute hospital stay.

DR. HOADLEY: So there is no additional cost if they have been --

DR. CARTER: There is no additional cost.

DR. HOADLEY: Okay.

DR. CARTER: I mean, some, 10 percent of IRF patients are direct --

DR. HOADLEY: Are direct, okay.

DR. CARTER: But most of them --

DR. HOADLEY: So my overall view on this is I haven't heard any reason not to go forward with this. I'll say that, oddly negatively. It is a good principle, and

there don't seem to be any issues that are complicating this, the way there were some issues around the stroke.

DR. REDBERG: And I will say I think there are reasons to go forward with it because it seems to make more sense in terms of Medicare spending and patient outcomes to have a longer list for site-neutral payments and relax regulatory requirements for IRF, so that we are better able to spend money on things that beneficiaries need and not on things that they don't need because of regulatory requirements.

Again, I will just say I think for a lot of these, if we increased what was available, discharge at home, that a lot of beneficiaries would prefer to go home, with therapy at home. That may be a better outcome.

MR. HACKBARTH: Scott.

MR. ARMSTRONG: Yeah. Just briefly, a comment and then a question.

To affirm, I believe we should be moving with site-neutral payments for the full spectrum, 17 conditions, including stroke. I think we have talked about this for many, many months. We had asked a lot of very good questions, and Staff now have come back with extensive

answers to all of our questions.

It is a policy we have applied in a lot of other areas with very similar issues, and I think it is a responsible way of making sure we are spending the Medicare program resources as we should be.

The question I have is, one more time, it does feel as if we are trying to work within a fee-for-service payment structure that in and of itself has issues. Glenn, you referred to the status of post-acute bundled payments. I was hoping we could just remind ourselves of what really is the status of that, based on my belief that that actually offers a much better solution to a lot of the issues we are talking about.

DR. CARTER: So on the bundling initiative, there's been a second round of applicants that are now participating in the program. Lots of participants and conveners got data and are in sort of Phase 1, which is deciding really if they want to move to the second phase, which is being at risk.

Different participants signed up for a lot of case types and not many cases types, and they have until April to decide whether they are going to move forward to be at risk.

So it is moving along. There's lots of interest. That's the good news, but most entities still haven't moved to the at-risk phase, so it is going to be a while.

DR. CHRISTIANSON: Carol, remind me. The dollar value of the bundle is constructed based on the fee-for-service system, right?

DR. CARTER: You mean in the Medicare demonstration?

DR. CHRISTIANSON: Yeah.

DR. CARTER: Yeah.

DR. CHRISTIANSON: So what we do here, assuming the recommendation was accepted, will feed into the dollar value of the bundle. So they aren't totally disconnected?

DR. CARTER: Right, in the same way that it kind of feeds into --

DR. CHRISTIANSON: Exactly.

DR. CARTER: -- the framework of ACOs. That's right.

MR. HACKBARTH: Let's assume. We turned the clock forward, and it's however many years from now, and the demos have worked, however that is measured. Then sort of a next level of question, is this implemented everywhere, all

providers required to participate in a new bundled system, or is it an option that people have to assume responsibility for post-acute care under a bundle? If it is the latter, which is sometimes the easier course politically, then you still have the old siloed system running alongside, and we got to make sure that it works as best as we can make it work.

I am a fan of bundling, as everybody well knows, but we just won't get there overnight.

Cori, we haven't heard from you.

MS. UCCELLO: Yeah. I have nothing really new to add, but I felt like I should get myself on the record.

Like Scott said, and many others, I, too, am fully supportive of this site-neutral approach, and I think it makes a lot of sense for these 17 new conditions that we have identified.

Like many of the others, I am less comfortable with the stroke, but in general, I think this is something that we should pursue and hoping that we eventually get back to some of the more bundling types of approaches.

MR. HACKBARTH: Anybody else want to address the 17 conditions and the criteria?

[No response.]

MR. HACKBARTH: This is how I interpret that. I think we have got a pretty strong consensus in favor of the 17 and the criteria used to select them and the idea of relieving regulatory requirements on the IRFs and doing a transition, as we had recommended with LTCH in a toughly analogous situation.

Opinion is more split on the issue of whether to include strokes.

Consistent with how I usually handle these things and try to move based on consensus, I don't hear a consensus on the stroke side, and so I am inclined to set that aside for now, and we will bring back a draft recommendation focused on the 17 and do that for the next meeting.

MS. BUTO: We mentioned the bundled issue, post-acute bundled issue was part of --

MR. HACKBARTH: Sure.

MS. BUTO: -- the next round of this paper as a longer term objective.

MR. HACKBARTH: Yeah, sure. Sure, we can do that.

DR. MILLER: Jim, did you have question?

MR. HACKBARTH: About the timing, is that okay,

Jim?

DR. MATHEWS: Yeah, that's fine. My hesitation was just the recommendation would be for the 17 new conditions and the orthopedic conditions we discussed previously, correct?

MR. HACKBARTH: Yes. Right, correct.

DR. CARTER: Yeah.

MR. HACKBARTH: Thanks, Jim, for that addition.

Jack.

DR. HOADLEY: That was actually my question, too, is whether we had gotten as far in the recommendation on orthopedics. I didn't think we had.

MR. HACKBARTH: Yeah. I'm sorry for that oversight. Thanks for the reminder.

Okay. Any other comments before we close those?

[No response.]

MR. HACKBARTH: Okay. Thank you, Dana and Carol. Great work.

[Pause.]

MR. HACKBARTH: So Nancy and Katelyn have the easiest topic, which we reserved for last -- developing payment policy to promote use of services based on clinical

evidence.

MS. RAY: Thank you for that intro.

[Laughter.]

MS. RAY: Good morning.

At the March and September 2014 meetings, we discussed linking Part B drug payment to clinical comparative effectiveness evidence in fee-for-service Medicare. Medicare's fee-for-service payment policies generally reflect the cost of a service, not its clinical effectiveness relative to its alternatives.

We specifically discussed Medicare's application of least costly alternative policies between 1995 and 2010. For two or more drugs that clinicians prescribe for the same condition and produce a similar health effect, the policy bases the payment rate on the least costly product.

The Commission discussed restoring the Secretary's authority to apply least costly alternative policies to Part B drug payment. The intent of LCA policies are to obtain the best price for beneficiaries.

We discussed these three case studies during the September meeting. Both CBO and the OIG have shown that basing Part B drug payment on the last costly product would

help beneficiaries obtain a better price. In addition, the OIG, in the 2012 report, recommended that CMS consider seeking legislative authority to implement LCA policies for Part B drug classes under appropriate circumstances.

At the September meeting, you asked us to look at two additional approaches that link clinical evidence to Part B drug payment.

The first approach we call consolidated payment codes, which combines drugs with similar health effects used to treat a given condition into a single payment code.

The second approach is bundling under which Medicare would establish one payment for services, including Part B drugs and other medical services, furnished across one or more settings and by one or more providers during a defined period of time for a given condition.

Before we start discussing these new approaches, a quick review about how Medicare pays for Part B drugs, which we also discussed in September.

Most Part B drugs are injectable drugs administered by physicians in their offices or hospital outpatient departments. These drugs include chemotherapy products and products that treat retinal eye disorders.

Medicare pays providers 106 percent of a drug's average sales price, ASP. ASP is a market-driven price. It is the manufacturer's average transaction price for sales to all purchasers net of rebates, discounts and price concessions.

ASP gives providers the incentive to seek the lowest price to purchase the product since they are paid 106 percent of ASP regardless of their acquisition cost.

Under the MMA, most brand name drugs and biologics are paid based on their own ASP base payment rate and are, thus, assigned to separate payment codes.

Separate payment codes could motivate some providers to select the higher-cost drug among a group of drugs with similar health effects used to treat a given condition because the higher-cost drug yields a greater 6 percent add-on than the lower-cost drug.

The intent of consolidated payment codes is to reduce providers' motivation to use the more costly product among drugs that treat a given condition and result in a similar health effect.

Under consolidated payment codes, two or more drugs with similar health effects would be combined into a

single code. Medicare's payment would be based on the volume-weighted average of the program's payment for these products. This policy approach is intended to help beneficiaries obtain a better price by reducing the revenue-based add-on incentive.

So here is an illustrative example for you to consider. We have two drugs that result in a similar health effect that is being used to treat a specific condition. Providers can purchase each drug at ASP; that is, ASP is equal to providers' acquisition cost.

Drug 1's ASP is $100. Medicare's payment rate of ASP plus 6 percent is $106. So the difference between Medicare's payment rate and providers' acquisition cost is $6.

For Drug 2, its ASP is $200. Medicare's payment rate is ASP plus 6 percent, or $212. And the difference between Medicare's payment rate and providers' acquisition cost for Drug 2 is $12.

Under separate payment codes, drugs compete based on the higher add-on. Some providers may be motivated to select the drug with the greater add-on, and that would be Drug 2.

Under the consolidated payment code approach, the Medicare payment would be $159 with each drug at 50 percent of the volume. Compared to separate billing codes, the consolidated payment code is intended to remove or minimize the revenue-based incentive to select the more costly product.

In this example, it would motivate providers to select Drug 1 where the difference between providers' acquisition cost and Medicare's payment rate is $59.

Over time, if volume shifts to the lower-cost product, the Medicare payment rate would decline, and price competition between the products might increase.

Your briefing paper discusses some of the implementation issues associated with consolidated payment codes. These issues are similar to the issues associated with implementing least costly alternative policies that we discussed in September.

These issues include implementing a process that is transparent and predictable. It would also -- other implementations include implementing -- establishing a process that would consider available comparative clinical effectiveness evidence on drugs. It could make use of the

MEDCAC. And it could also obtain objective assessments of the literature from the academic evidence-based practice centers. It could also include a process for making medically necessary exceptions.

At the September meeting, commissioners asked us the frequency of medically necessary exceptions when Medicare applied the least costly alternative policy for prostate cancer drugs.

We tried to infer this from the Medicare claims data by looking at the two higher-cost products in 2009, when Medicare implemented an LCA policy for these products in nearly all states.

Our preliminary analysis of the 2009 claims data found that, looking at the 2 higher-cost products, 4 percent of their claims were paid at their own payment rate; that is, it was not paid at the rate of the least costly product.

Now Katie will discuss the notion of bundling.

MS. SMALLEY: As the Commission has discussed previously, bundled or episode payment is a fixed amount paid to a provider for a combination of drugs and services that are required to treat a certain condition.

One area in which bundles have been explored is

oncology care. Bundles could be structured in different ways. For example, an oncologist could be paid prospectively for all chemotherapy drugs administered to a patient during the episode period or for all care provided in the hospital or for all cancer-related utilization in a defined time period.

The logic is that by grouping drugs and services together, and counterbalancing that with quality indicators, bundling may incent a more efficient use of resources.

Bundles may be one way to encourage practice based on clinical evidence, but some questions must be answered in developing the design of the bundle or episode.

For instance, which conditions could be paid for under a bundle?

What would trigger an episode, and which products and services would be included?

How would providers be paid, especially when the episode requires collaboration among multiple providers, and how would the payment amount be established?

In this presentation, we will go into detail on two examples. First, we will discuss Peter Bach and colleagues' bundling proposal for cancer care in Medicare,

and second, we will outline UnitedHealthcare's episode payments for oncology, which they have been piloting since 2009.

In a 2011 Health Affairs article, Peter Bach and colleagues outlined a bundling proposal for cancer care in Medicare. The bundle would be relatively narrowly defined. They discussed covering the cost of chemotherapy drugs and their administration during an oncology episode but mentioned that more services could be incorporated into the bundle over time. The design of the bundle would be informed by evidence-based guidelines for cancer care, and payments would be periodically readjusted to account for the cost reductions associated with bundling.

In a bundle like this one, that covers primarily drugs, the incentive is to use low-cost, but effective, therapies. Bach noted that financial structures like risk corridors or shared savings could also be built into the model to strengthen the incentives.

Another advantage to this approach is that because the scope of the bundle is limited the oncologist is in control of the treatment regimen and few others would be involved. This situation would make the bundle more

straightforward to implement.

While they were not detailed in the paper, Bach also acknowledged the importance of addressing issues such as cost-shifting, upcoding and stinting in designing a successful bundle.

UnitedHealthcare's insight is that paying for oncology drugs via ASP plus some add-on provides a revenue incentive to prescribe a particular, often more expensive drug without much regard to quality. They wanted to remove that incentive and to strengthen the incentive to evaluate drugs based on their effectiveness and prescribe on that basis alone.

To do this, they took the funds that they would have paid out in drug add-ons and, instead, paid them out in a flat fee to oncologists for each cancer episode.

This is not a bundle in the same way that the Commission tends to think of, in that most payments were still made fee-for-service.

This separated the drug add-on from the drug and repurposed it as a fee that could be used to provide services like in-hospital care or hospice management if the patient and oncologist decide to discontinue treatment.

Provided that the survival rate improved over the cycle, the oncologists were also eligible for shared savings.

From 2009 to 2012, spending was reduced overall by about $33 million, $11 million of which went back to the practices. Interestingly, however, drug spending during that time increased. It seems that total spending went down because of decreases in hospitalizations and radiology; on the other hand, drug utilization rather than prices probably drove the increase in drug spending.

It is also worth noting that the five practices that participated were all large groups, and this may have been integral to their success. If smaller practices were to participate in such a model, they would probably have to be aggregated into coalitions of some type.

Now I'll turn it back over to Nancy, who will wrap up and lead you into discussion.

MS. RAY: Thanks, Katie.

Before closing, I want to remind commissioners that at the September meeting you discussed the notion of implementing least costly alternative policies in Medicare Advantage plans and accountable care organizations as an

alternative to fee-for-service.

Katie and I could assess the flexibility of MA plans and ACOs to implement these approaches, and we could come back with this material potentially in the spring.

However, leaving fee-for-service policies untouched results in fee-for-service beneficiaries not obtaining the best value.

We have discussed four approaches to using fee-for-service Medicare that would help beneficiaries get a better price. We would like commissioner feedback about the four approaches that we have discussed -- least costly alternative policies, consolidated payment policies, Bach's bundling approach and the United episode approach -- as well as any other additional directions for future work.

MR. HACKBARTH: Okay. Thank you.

I have a question about ASP plus 6. This, to me, has always been maybe the most troubling payment mechanism used in the Medicare program.

With the current system, while we don't have consolidated codes and each drug has its own code, it almost seems to me like the way a manufacturer can market its drug is by increasing the price because that means that the

physician add-on is greater.

Now the beneficiary cost-sharing increases. But looked at from the physician's standpoint, it's a good thing when a new drug comes in or the price goes up. It's more revenue for the practice, in a system where you have a single code for each drug.

Am I missing something?

DR. MILLER: Cash flow. You've got to be able to purchase it.

MR. HACKBARTH: And, Kathy, if you wish to jump in.

DR. MILLER: Yeah, I mean, also, just before you go -- I mean, the practice obviously has to have enough cash flow to purchase the higher-priced drug at that particular moment, but there are people who make this argument.

MS. RAY: Right. I just -- right. And there may be certain instances where that does, in fact, happen.

I just want to point out in the September mailing material we summarized the OIG analysis of the two drugs used for macular degeneration, and there's a large difference in Medicare's payment for those two drugs. And they did find that many practices did choose the lower-cost

product.

So it doesn't happen in all instances.

MR. HACKBARTH: Yeah, and that's really important to note.

And I'm a big believer that, in fact, physicians are motivated by things other than just filling their pockets with money, and there are a lot of physicians who take their professional responsibilities very, very seriously, and they are to be commended for that.

But just in terms of the incentives created by the payment policy, I think we're depending a lot on the professionalism of our physicians. So the incentives justify this --

MS. RAY: Right. And just as an alternative example, though, the OIG also pointed out that when the least costly alternative policy was rescinded for the prostate cancer drugs the year following that you saw an uptake, an increase, in the use of the most costly product.

MR. HACKBARTH: Yeah.

MS. RAY: It went up dramatically.

MR. HACKBARTH: Kathy.

MS. BUTO: Glenn, a couple things.

One is I think, worse than ASP, if you don't like ASP, was the AWP policy.

MR. HACKBARTH: That's true. I agree with that.

MS. BUTO: So I'll go with that.

MR. HACKBARTH: Right.

MS. BUTO: As to the --

MR. HACKBARTH: That was -- for people who haven't been involved, that was the policy that predated ASP.

MS. BUTO: Pre-dated ASP.

And, of course, the average sales price is a combination of market-based prices, not just the Medicare reimbursement price or whatever we want to call it. So there are other market pressures that influence the drug, including whether there are competitors -- okay, so whether there are like drugs.

Avastin and Lucentis would be an example of that.

I think this policy gets a little -- I agree with you; the 6 percent is an issue for physicians who are looking to make money. I totally agree with that.

And we discussed that in relation to the 340B payment under Part B for 340B drugs that are covered by Part B -- the same issue of the hospitals being able to recoup

the differential, whatever it is.

So that's an issue with the methodology, and I'll agree with that.

One thing I wanted to point out just in relation to Lucentis and Avastin-and I think they have corrected this. But at the time physicians were making that choice they're obviously making the choice to be responsive to beneficiary co-insurance. That's among the reasons they did it.

They were often choosing an off-label use for Avastin at the time they were making that decision.

Now I think they've gotten the label indication maybe for macular degeneration now, but it complicates the issue of how you put -- what drugs get to be compared in this ASP fairness issue because some are labeled one way, some are labeled another way.

But that's just a point of clarification.

MR. HACKBARTH: Those are good points, Kathy, but the notion that, you know, this is a market price, I only draw comfort from that if there's a market that's functioning and it has an incentive to be cost conscious. This payment mechanism creates a market where the people

buying the drug don't have an incentive to be cost conscious.

MS. BUTO: Well, the private sector doesn't necessarily follow the same methodology that Medicare does, if that's what you're -- because this reflects private sector discounts, et cetera, the ASP does.

MR. HACKBARTH: I understand that, but for a lot of these drugs, like oncology drugs, Medicare is a very big part of this market.

DR. MILLER: Kim, you were going to say something [off microphone].

MS. NEUMAN: There's one piece of the ASP system that does serve to provide an incentive to not increase prices quickly, and that is the two-quarter lag. So there's a two-quarter lag in the ASP filtering into the payment rate. So drug manufacturers have an incentive to not increase their price quickly because of the ASP system. They can set a very high launch price, but then once it's set, the ASP controls inflation to some extent.

MR. HACKBARTH: Okay. So let's open up Round 1. I don't mean to focus the discussion solely on that.

DR. MILLER: Can I say -- I know you said you

didn't mean to focus on it, but I also think as you go through and talk about this -- and this is more when you get into Round 2 -- at least around the campfire we were thinking it was kind of interesting that what United did is they took, with their first step in redesigning theirs, the profit off of the drug, which we thought was kind of an interesting concept. And I'll be very interested in your reactions to that.

MR. HACKBARTH: Let's do just the Round 1 clarifying questions on any aspect of this.

MR. GRADISON: I'm kind of intrigued with the idea of substituting a fixed payment for the -- as United apparently did -- for the percentage. And so the question I have -- and perhaps you have to come back to us another time with the response -- is if you had a budget-neutral change in that, approximately what would that add on B if it were dollar rather than -- uniform dollar amount rather than related to the price of the drug?

DR. MILLER: We can come back to you on that.

MR. HACKBARTH: So clarifying questions on this side?

DR. CROSSON: So getting back to the issue of the

physician incentives inherent in some of the changes, could we look at Slide 7? Because I want to make sure I understand that.

So in the base case, if the physician decides to use drug number one, there's a $6 add-on; if the physician decides to use drug number two, there's a $12 add-on.

Under the proposal, I guess -- I'm assuming that the average sales price then becomes assumed to be $159. Is that right? So that if the physician chooses drug number one, there's a positive incentive of $59. Whereas, if the physician chooses drug number two, there's a loss of $41 -- or a $100 swing in that decision. Am I reading it incorrectly or is that the case?

MS. RAY: That is the case. And, again, when we say add-on in this slide, it's Medicare's payment rate minus provider's acquisition cost, to be clear.

DR. CROSSON: Right. So I'll make a comment later, but that seems like a pretty Draconian design for changing the incentives.

MR. HACKBARTH: Are you talking about the effect on the physician or the effect on --

DR. CROSSON: On the physician.

MR. HACKBARTH: -- the drug company?

DR. CROSSON: The physician.

DR. MILLER: But the --

DR. CROSSON: I'm missing something.

MR. HACKBARTH: The effect on the physician's income would be the add-on numbers. It would be --

DR. BAICKER: I think they pay [off microphone] -- My impression is the same as yours, that the physician would be paying out of pocket $41 to prescribe Drug 2.

MR. HACKBARTH: Oh, I see. I'm sorry. I got you.

DR. CROSSON: Right [off microphone].

DR. MILLER: Or they move to Drug 1.

DR. CROSSON: Right. But all I'm saying is we would be going from a situation of $6 versus $12 to a situation of $51 positive, $41 negative. Big difference.

DR. MILLER: Well, keep -- no, no. In this example you're right. Keep in mind the actual dollar -- and you keep track of me, Nancy. The actual dollar amount will be a function of the volume-weighted averages, and so if everybody was housed initially in Drug 2, the higher-cost drug, then the volume-weighted average would be higher, the swing wouldn't be as high, and as people moved to the lower-

cost drug, the ASP would drop.

I think what Nancy did, at my request, I think here you just kind of assume it's equal and, you know, on day one this is what would happen. But you do understand the concept.

MR. HACKBARTH: Okay. Clarifying questions?

DR. BAICKER: So following up on that, when we had talked about LCA policies, there had been a little bit of discussion about whether we intended for patients to be able to pay the increment or someone to be able to pay the increment to get the more expensive course of treatment versus saying here's what the reimbursement is, here's what the total payment will be.

For this, my impression is that we're saying if the physician and patient choose Drug 2, they lose, you know, whatever the weighted average amount would be, and presumably that would increase over time as the weight shifts to the cheaper alternative, but that there's no option to say I actually want to just pay more and get the -- can the patient pay more to get Drug 2? Or is that not on the table?

MS. RAY: It could certainly be on the table. As

we discussed with the -- when we discussed in September for the LCA policy, and the patient would just pay the difference. Certainly.

MR. HACKBARTH: Actually, this particular option, I think we were trying to do something that Jack had proposed at the last meeting, so, Jack, do you want to address that?

DR. HOADLEY: Yeah, I mean, my notion on this option was that you're really resetting the price, as it was just described, and the beneficiary can have the more expensive drug provided the -- since these are physician administered, provided the physician is willing to do that. In some of these examples, the physician might not be willing, and the LCA option allows -- is more set up to allow the patient sort of the free choice to say I'll pay extra. But the only way, if they need the higher one for some clinical reason, they'd either have to go through an exceptions process or they would have to pay the extra.

DR. BAICKER: But in this case, are you envisioning the patient being able to pay the extra, or are you envisioning the only circumstance in which Drug 2 is used is if the physician loses money on it?

DR. HOADLEY: Well, we can talk about what it means to say losing money on it, but the straight answer is yes.

DR. BAICKER: The straight answer is --

DR. HOADLEY: I'm sorry. The straight answer is the --

DR. BAICKER: -- the patient's not paying the extra.

DR. HOADLEY: The patient cannot pay the extra to get that option.

MR. HACKBARTH: So that's how Jack conceives of it, but it could be designed --

DR. HOADLEY: You can obviously design other options.

MR. HACKBARTH: Clarifying questions?

DR. HOADLEY: So I did want to get into the percent add-on thing, but we can wait until Round 2 on that.

My clarifying question really is still on kind of the same point. It was mostly made, but the example you used with the 159, as you said, it was 50/50 weighting. And I don't know whether we have -- we could draw some examples from sort of drugs that might naturally fit into this

situation of what sort of the weights are, because if the behavior that we're worried about is true, then a lot of them are going to be heavily weighted towards the more expensive option. To the extent that's counterbalanced by either being professionals or, you know, co-pay-related concerns, the weight might be the other. So it might be just interesting to see where weights typically lie.

The other sort of clarifying thing, we've got to -- I think we should be careful about how we talk about this 106 percent, because it's often talked about as an add-on sort of in a literal sense. But the acquisition prices for the practices are not locked in at the ASP. So partly it's -- a different way to conceive of it is that it's a plus or minus, except that we're only seeing the plus. It's to allow for market variation to say, well, we're not going to lock everybody in at exactly the 100 percent level, we're going to allow market fluctuation, because sometimes it will cost 106 percent. Sometimes it will cost 110.

MR. HACKBARTH: And that's a good point that in my comment I neglected, Jack. So just to carry it to the next step, to the extent that a physician or group can get the drug for less than the average, they have an opportunity to

increase their margin on the drug --

DR. HOADLEY: Yes.

MR. HACKBARTH: -- which in turn creates an incentive to try -- yeah.

DR. HOADLEY: Right. Exactly. And we can get back into some of this relating to the add-on --

MR. HACKBARTH: That's a good correction.

DR. REDBERG: I do have a clarifying question, although I wanted to make a comment just on the earlier discussion, because, I mean, that was a particular case, Avastin, Lucentis, because it was exactly the same medicine. So, you know, there were medical ethicists who said it was unethical for anyone to prescribe the higher-cost one when it was clearly the same medicine at the lower cost.

Having said that, I want to say I absolutely think, you know, doctors often do the right thing not having to do with money, but having said that, I mean, having graduated medical school more than 30 years ago, I have seen big changes in physician behavior, and I think, you know, doctors are human. And when you have a fee-for-service security that rewards high-volume, unneeded, unnecessary, inappropriate care at very rich rates, you know, doctors are

human, and there have been definite changes, and we clearly have a system where we are paying for a lot of things that are not just costly, but they're hurting our beneficiaries and they're hurting our patients, and they're leading to lots of, I would say, unnecessary deaths and lots of adverse events. And that's why I think we need to be looking closely at these alternatives to stop putting a system that is rewarding inappropriate, unnecessary, and harmful care.

But my clarifying question is actually on the mailing materials because I just didn't really follow this -- just the little paragraph on page 4 on follow-on biologics. And what was the basis for those CBO estimates for the 2010 to 2019 period on the difference between the abbreviated follow-on, biologic approval process compared to the same payment code as the reference biologic. Do you know anything about why those came out $3 billion different?

MS. RAY: I presume -- I don't know for sure, but I presume that CBO -- that, again, putting the drugs in the same code would motivate additional competition and, thus, result in greater price competition than in separate codes, and that would be the reason for the difference in the two dollar figures, estimates.

DR. REDBERG: That was a 2008 report. I mean, we've gone now six years. Have they looked at it again? I'm just -- I mean, there's been so much movement in biologics.

MS. RAY: Right, and at this point, under law, follow-on biologics would have to be included in their own payment code. So we provided this just as an example of potential savings, but in law right now, a reference biologic would get its own billing code and the follow-on biologic would get its own billing code.

DR. REDBERG: Which is different than other drugs.

MS. RAY: Well, for drugs, brand-name drugs get their own billing code. When a generic comes out of that brand-name drug, that would go into the brand-name drug's billing code, right.

DR. REDBERG: Because the biologics then would be being treated differently.

MS. RAY: Yes.

DR. REDBERG: So essentially follow-on or generic biologics are --

MS. RAY: Yes.

DR. HOADLEY: Presumably part of the logic is that

your savings would not just be because there would be price competition from the manufacturer side, but it might be easier to -- it might influence prescribing practices if there's the same billing code.

MS. BUTO: Just a clarification point. I'm trying to remember, but I thought that the reimbursement for follow-on biologics is a little weird. It's like they get their own ASP plus 6 percent of the reference biologics. Isn't that right, something like that? So the idea was to level the playing field between --

MS. RAY: Right, follow-on biologics get the add-on of the reference product.

MR. HACKBARTH: Clarifying questions?

DR. NERENZ: Slide 11, please. I'm just wondering if you can tell us a little more about what you want us to think about this United Healthcare example. In all the other slides, we're talking about dynamics within prescription drugs. We're talking about policy change. We're looking for behavior change. And I think eventually the expectation would be savings in that payment domain or in that silo.

Now, here in the first bullet, we talk about, you

know, changing incentives to prescribe one drug over another, but then under the last bullet is interesting. You were kind of polite in your wording here. Actually in the paper it's pointed out that drug spending didn't just go up a little bit. It nearly tripled. So what are we to think about this? What's the lesson here?

DR. MILLER: What I would say is what -- and we would come back to you if you wanted to pursue this. And keep in mind what we're trying to do is follow up on statements that were made, like tell us more about bundling, tell us more about consolidated billing, Jack. And they are two different things. And certainly the Bach discussion and the United discussion really turns the conversation into a discussion of oncology, which is a lot of the Part B stuff which is the space we're in, but decidedly it's a different direction.

And here's what I would say that I think I found interesting about the United stuff. Regardless of the specifics of the United, just set that aside. It took the profit off the drug. They gave a case management fee. They drew kind of a dotted line around the episode and put more than the oncology in -- hospitalization, ED use, that type

of thing. And then said if you lower the total spend and survival rates, you know, maintain, you can share in the savings.

So I know we were supposed to be in clarifying questions. What I'd look for in the second round would be for you guys to say things like, "Interesting concept, how would that work in Medicare?" -- if you thought it was an interesting concept.

DR. NERENZ: And that's why my -- it really was a clarifying question. I just want to make sure I understand what's your message to us about this experience.

MR. HACKBARTH: Well -- go ahead, Nancy.

MS. RAY: I just want to point out that -- so the five centers that were included in the United episode, what I'll call the cases, I mean, many of them provided, you know, like 24/7 access, nurse coordinator, those kinds of services that might have led to the decreased admissions, decreased ED visits, et cetera. And so that could have had an influence on, you know, what we see here with the decreased admissions.

MR. HACKBARTH: My recollection -- and please correct me if I'm wrong -- I think I read at the time this

was published that the people at United weren't exactly sure what to make of this pattern. It was not what they anticipated would happen. Is that --

MS. SMALLEY: Right, they anticipated decreases in drug spending, but that's not what happened. So it's just kind of interesting that that's -- you know, the incentive was to reduce drug spending, but they decided -- the practices ended up reducing spending in other areas.

DR. NERENZ: Just one thing and I'll leave this alone. Was there any hint in any of this that there was any sort of causal connection between the increased drug spending and then the lower overall episode spending? Did the one somehow lead to the other, means to end?

DR. MILLER: There was nothing that I saw that said there was a causal link.

DR. REDBERG: [off microphone] a lot of things, and I don't think they could say what.

DR. SAMITT: My question is about ACOs. Can you clarify whether Part B drug costs are included in the benchmarking, gain-sharing formula for ACOs?

MR. HACKBARTH: Part B drugs, yes.

MS. RAY: Yes, I'm looking at --

DR. SAMITT: Part D is not, as we've discussed in prior --

MR. HACKBARTH: Yeah, Part B is.

DR. SAMITT: Part B drugs.

MS. RAY: Part B, I'm looking at the ACO experts. Yes, it's included.

MR. HACKBARTH: Clarifying questions?

MS. BUTO: I'm just trying to find the reference in the paper, but you talked about repurposing funds. So I know it was ASP plus zero. Then there was some kind of episode management fee that was added. What was repurposed exactly? I saw that they also subtracted the ASP from the actual acquisition cost. Did they repurpose those funds? Which funds were repurposed? And how were they repurposed? By United or by the group that was managing the episode?

MS. SMALLEY: So what United did is before they implemented this pilot, they would pay for drugs, an ASP plus some contracted percentage. And so for each of the practices, for each of the cancer episodes, they estimated how much each practice would get per episode in drug add-ons. And then instead of paying those out with the drugs, they repurposed that money, that add-on money as an episode

fee, as a case management fee.

MS. BUTO: Okay, so more like a case -- so it wasn't added to the drug.

MS. SMALLEY: Right.

MS. BUTO: And wasn't it a flat fee, not a percentage of the drug that was paid? Isn't that what you said in the paper? I thought it was a flat fee.

MS. SMALLEY: Yeah. I'm sorry. I misspoke.

MS. BUTO: All right.

MR. HACKBARTH: They took the pool of dollars --

MS. BUTO: And they gave it as a case --

MR. HACKBARTH: -- and converted it into a flat --

MS. BUTO: -- management fee.

MS. RAY: Right. And just to be clear, there are 19 different episode types, and they assumed that providers' acquisition cost for the drug was ASP.

MS. BUTO: Okay.

MR. HACKBARTH: Any other clarifying -- Warner?

MR. THOMAS: And I might have missed this in the chapter, but there was examples of the financial benefit for implementing this policy for specific areas or specific drugs. Is there a calculation of kind of in total what this

would mean if this was really implemented across the spectrum of drugs in the program? I don't know if I missed that specifically.

MS. RAY: I'm sorry. For the bundling or the consolidated --

MR. THOMAS: For the consolidated --

MS. RAY: Oh, I'm sorry.

MR. THOMAS: To go to lower cost, alternative pricing.

MS. RAY: No, we did not estimate what it would -- no, we did not do that.

MR. THOMAS: Okay.

MR. HACKBARTH: I am ready for Round 2 then. Okay. Round 2 comments? Let's come down this way, starting with Jack.

DR. HOADLEY: So a number of things I could talk about, but let me focus first on the one you raised. I was just trying to track some information that I had looked up a while back in something I was working on.

There is a CBO estimate that said, for example, if you change the 106 percent to 103 percent, it would be savings of about $3.2 billion over 10 years, which gives

some sense of the magnitude of dollars that are playing around with these things.

I was going to raise the issue of changing it to a flat add-on as a reasonable sort of addendum or issue, separate from the exact thing that we are looking at here, and I think we've sort of already surfaced most of the logic behind that.

One other overall comment I wanted to make is anticipating the follow-on biologics -- and while there's some -- there are some different rules that are going to apply there, and I am not totally up to speed on all the ins and outs of what was set up on that. There's going to be a lot more volume of potential savings and potential impact once those start to come on board more.

So I think whatever we are doing here, we should also think about with that framework in mind, so it's the set of drugs now. Mostly it's oncology, and there are some others, rheumatoid arthritis and some other injectables and some that are used with DME that are affected by this, but as follow-on biologics come on and as more drugs move into this biologic phase, it's not -- this is not about the oral, some of the oral bio. So something like Sovaldi is not

falling under this because that's on the Part D side.

I was really appreciative of all these new things, and I think to some degree, this is the kind of thing where similar to our last discussion, we might want to look at some of these bundling options in a broader, different kind of context, either in demonstration or something like that, and there is certainly some appeal to oncology, where it seems like -- and I would defer quickly to the clinicians, but it seems like treatment for cancer is often evolving, and you are making different decisions from time to time.

There may be some logic to sort of developing something along the examples of these two. But the same thing, even if we like that approach for something that we ought to pursue, looking at some fixes in this to try to force -- I mean, really the idea is to force more competition around the cases, which there aren't a lot of, but there are going to be more where there are more than one drug alternative to treat the same thing.

For a long time, we were in situations where most of these drugs were one of a kind. There was the one drug. There may be other drugs to treat that particular cancer, but there are different products doing different things.

Well, now we are getting more examples of drugs that are really treating the same thing, and it does raise all those issues about what goes into the bundle.

What I like about the consolidated code approach is you are not sort of putting the burden on the beneficiary to sort of think about when do I need this thing. On the other hand, you are potentially, along the lines that Kate's question suggested -- you know, there is a question of whether you are cutting out access if the price -- what I would hope would happen in a lot of these cases, that we'd see price movement, and certainly, some of the reference pricing examples overseas, what we have seen is price consolidation where the losers, the ones who were priced higher and now have to deal with a lower price, start to lower their prices to come down closer to the average, to the -- in this case, we wouldn't be doing a peer reference price. Under the LCA, it would be more like a reference price. But in either model, you could see price movement potential from the manufacturers to try to get to, and that would be, in many ways, the best outcome.

MR. HACKBARTH: As usual, there are a lot of important things in what Jack said. I want to pick up on

two of them, focusing on the context for this discussion as opposed to the merits of particular options.

Jack, very early on, made the observation that if you are concerned about the incentives in ASP plus 6, an option that could be considered would be a flat management fee as opposed to a percentage add-on.

What that flags for me -- I want to make it clear to everybody here and in the audience -- this array of options that we are talking about is not the universe of options for thinking about how to reform Medicare payment policy for drugs to create different or better incentives.

These options that are here are really trying to respond to questions that Commissioners raised at the last meeting, and we could bring another or broader set of potential options for a discussion.

Second point I'd want to pick up on is that here, too, you could have a two-track approach. Some of these things are a lot easier to do than others. Bundling approaches tend to take more time to develop, test, may not be universally applicable. Whereas, other approaches, Jack's two ideas now of consolidating codes or flat management fees are things that could be done much more

quickly, setting aside the debate over their merits.

We may want to look at a broader array of options, and we want to look at both, some short-term and longer term reforms. That is a message that I heard in Jack's comments. Is that --

DR. HOADLEY: That's fair.

MR. HACKBARTH: Yeah.

Now we're doing Round 2 comments. Let's go around this way. Kate and then Kathy and Jay.

DR. BAICKER: I very much agree that introducing a financial incentive or having a financial incentive to prescribe the most expensive drugs is hugely problematic, and I would think that our goal would be to have patients only use the more expensive drug when the incremental health benefit warrants that. My suspicion is that for most drugs -- for most things, there are very few things that are strictly equivalent for all patients. We know that's just not always the case, and so we don't want to introduce a huge financial disincentive to use the more expensive drug in a way that then patients who might really benefit substantially from it have to ask their physicians to basically pay out of pocket for them to be on the more

expensive drug. It seems like maybe swinging too far the other way.

Something that is more like either a fixed payment -- if it were a fixed management fee, regardless of the drug, then you are not introducing incentives to use the most costly way to achieve the gain. Maybe an approach that maintains access while maintaining incentives for efficient use to me would look something like paying a sort of fixed amount, and then if patients want access to more expensive things, letting them do so, but having some financial risk for doing that, some financial responsibility for doing that.

So for the patients for whom it's really worthwhile, they can get the more expensive drug, but for the patients where it's not producing a sufficient health improvement over the less expensive ones, the incentives are lined up to get the less expensive one. And that, I think would introduce price competition without necessarily restricting access in the cases where we think there is actually an incremental health gain.

MR. HACKBARTH: So let me be the devil's advocate for a second. In a bundling world, which you often say you

prefer, isn't the patient in the position, let's say, asking the physician or the provider, "I want the more expensive thing. You eat the cost"?

DR. BAICKER: I think that that is true and that there is a risk of -- we always worry about the risk of stinting in those circumstances, and that requires layering on measures of quality, measures of satisfaction and the like.

Patients do have an option in most circumstances to go ahead and buy extra stuff, bearing 100 percent of the cost of that. You can get anything you want uninsured for the most part, and that's particularly problematic when we think that it is care that is of high value for patients who are of limited means.

We don't want to have only wealthy people be able to afford those things, so the question is what is the right balance there in terms of the financial risk of the patient for the incremental cost. And it's something between -- obviously something between zero and 100. 100 percent might be too high for the incremental -- for the share of the delta for the patient to expect to be -- to expect the patient to bear, particularly for low-income people.

Obviously, if we were going down that road, we would want to think about specific provisions for low-income beneficiaries and the like.

But I think that there is a middle ground where you do expect somebody to bear the financial risk of incremental care, because we only want the incremental care used when it's producing sufficient value.

MR. HACKBARTH: Let me just ask a question about Medicare Advantage for a second. Let's assume there is a Medicare Advantage plan that has an oncology patient, and the patient has done their Internet research, and they want to use a more expensive drug than the MA plan, including their physician in the MA plan, thinks is appropriate.

Under the existing MA rules, is the beneficiary allowed to make an add-on payment to the plan to help them cover the cost of an additional, higher expense drug? I think the answer is no.

So, in that setting, we do have this situation where patients may want something more, and they have to ask their doctor to eat the cost.

Kathy.

MS. BUTO: So I wanted to mention a couple of, I

think, benefits that we could think about. I realize the episode bundling is more difficult. I think it moves in the direction that we eventually want to move in Medicare, generally, but there are two things I thought of as I was reading the paper that I think might be helpful for us to think about.

One is that, potentially, you could look at, assuming we are trying to figure out which drugs maybe are either being over-utilized or where we want to look at better management, better quality, et cetera, and better price, you could potentially look at a larger range of drugs, I think, than you can with an LCA or consolidated billing. And I would include in that something like a Sovaldi.

So you could also include Part D and Part B drugs in that bundle, so that if there is a tradeoff, as there is for many of the conditions that are prevalent in Medicare, you could include both D drugs and B drugs. I think that's what United did, and it gives you a wider array of tradeoffs.

Obviously, the real challenge is how do you set the bundle, but that's one. So I don't think you need to go

the multiple drug route that you'd need with the other approaches, although I think they are quite appealing in many respects. So that's one thing.

The other is that I think you could, depending on how you set the bundle, provide much more flexibility for the physician and the patient to work things out. It may be that the patient is stuck with whatever the physician decides he/she is most comfortable with, and they can't buy up, if you will, the other drug. So I think you can get at a lot of these issues that we are trying to get at with the other policies.

I am not going to repeat what I said last time, which I think there are implications for beneficiaries and for incremental innovation of an LCA approach or the consolidated billing approach, which I think is just a variation on that.

The other thing that I'd be interested in -- and this is really more of a follow-on -- would be which drugs we think would be good candidates for an LCA and then which drugs would be good candidates for an episode-based payment. I don't think they are the same drugs, but there is definitely overlap.

For LCA, I see real limitations in things like the oncology drugs where doctors tend to use combinations. It might be very difficult to do an LCA with oncology, but I think as United demonstrated, you can do an episode-based payment.

So it would be just interesting to know are we talking about a big range for each, or are we talking about a fairly narrow range of drugs that might fall into one or the other options. So I would be just interested in your thoughts on that.

DR. CROSSON: Yeah, I think my comment is simple. It's what Kate said.

If I had to choose between the consolidated code approach or bundling, my answer would be yes.

[Laughter.]

DR. CROSSON: For the reasons that Kathy said, I think we will probably find in the end that some situations and some drugs, some clinical conditions lend themselves more to one direction or the other.

I favor bundling when it can be done. I think as Kathy said, the broader the bundle, the more things that are contained within it, the more flexibility you give to the

clinicians, and it tends to mute over time, I think, the concern you brought up, Glenn, which is don't we already have, in Medicare Advantage, negative incentives for more expensive services. Yes, we do. But that's balanced, I think, by the range of flexibility that perhaps was demonstrated in the United situation to balance larger costs in one area with lower costs in another area. So, in terms of choosing that type of bundling or the size of bundling or what's included in it, that's an important thing to take into consideration.

In terms of the consolidated code thing, I know we saw one example of a 50-50 situation, but that was a little shocking to me, and I think before I was in favor of something like that, that created such large incentives and counter-incentives for physicians to choose one or the other, I'd have to sort of see what the general situation would be. If the 50-50 situation would be very transitory or unusual, that's one thing.

But in the absence of that, I would be much more interested in Jack's suggestion, which is to have a fixed add-on or fixed code, where I think you maintain incentives, but they are much muted.

DR. BAICKER: And just one additional distinction between this case and the MA case, MA plans are still competing for enrollees based on the quality of care that they are delivering, and they have an incentive, albeit fairly attenuated, to keep enrollees reasonably happy, to keep enrollment up.

It's kind of a weird situation to think of any one doctor facing a big disincentive for a patient who is not locked into the doctor. It is a distinction in terms of metrics of outcomes.

MR. HACKBARTH: You know how much I love global payment and all that, but you could actually flip that around and say, actually, it's not too bad for an MA plan to have oncology patients who want expensive drugs to leave.

DR. BAICKER: That's a fair point.

DR. SAMITT: So just a few things. I agree with your comment, Glenn, that there is likely to be a multitrack approach to this. I'm not sure this is an either/or, and similar to what others have said, I think it's an "and."

I, too, sort of am in favor of Jack's additional recommendation about a flat fee. I think right now, the incentive is a perverse incentive when at least a flat fee

is a neutral incentive, but we could even think about other alternatives to a flat fee concept to say the flat fee is offered in the setting of the prescribing of the lower cost alternative, and there is no add-on if another choice is made. So I think there are other ways to think about other variations on the theme, as you had described.

I also wanted to comment on bundling. I like the United approach. I don't see why that couldn't be piloted. It really isn't a bundling scenario. We shouldn't call it that. It is really a gain-sharing alignment.

I am less comfortable with the notion of a fixed bundle for oncology. I think it is too complicated to develop the price of a bundle, but this is not bundle. This is looking at bonuses associated with total cost of care. It is more of a budgeting exercise than it is a bundling exercise.

MS. BUTO: More like ACOs.

MR. HACKBARTH: Yeah. So you would reserve the term "bundling" for a lump-sum payment, an actual flow of dollars using that method.

DR. SAMITT: Exactly. And I would not be in favor of that. I would be more in favor of sort of this budgeted

ACO model, and that's what I ultimately wanted to add, that if we have faith in the ACO model, that this type of example for oncology falls within the broader rubric of ACO. If you are an ACO, you are likely to refer mostly to oncologists that have the best survival rates for your patients, and that have demonstrated that they can practice efficiently. So there are already built-in incentives within an ACO to be accountable for exactly what United has designed on the oncology basis.

Now, the only distinction is that it is an open referral network. So patients could choose to go to any oncologist that they wish, but there already is an incentive within ACOs, because Part B drug costs are included, to take a look at these factors when they are considering who they should refer to.

MR. HACKBARTH: So let me just think aloud about that. Let me step back for a second. One of the choices that we always face implicitly that we potentially don't focus on enough is should we start the wheels turning here, in Congress, in CMS, on a new payment method, say United, or should we count on existing payment innovations like ACO that make things like this happen and not have a separate

set of initiatives and resources and political conflicts created.

It may be a little different path, it may take a longer time, but it takes resources to create something like the United model within Medicare. And we have to be careful about just saying, "Well, we want to do more of everything," just throw stuff and the wall and hope something sticks.

So what I am picking up here is, you think, well, maybe you get to a United-type model through the ACO door. Am I understanding you correctly?

DR. SAMITT: Yeah, I mean, I think that the pros and cons of weighting with the ACO model is that it will take some time for the ACO model to flourish, and it doesn't apply in all sectors, in all markets in the U.S. And so in some ways, you accelerate the -- at least focus on oncology when you more universally say we're going to provide a shared savings model or an ACO-like budgeting model for oncology only. It starts to create a belt-and-suspenders, more accelerated solution. But obviously there's added cost to it.

So I think there are pros and cons to weighting with the ACO versus adding some supplemental strategies.

MR. HACKBARTH: Okay. So just one last clarification here. I now understand that you're saying it's -- maybe do both, do an ACO-type model for oncology specifically.

You know, one of the questions about whether ACOs would ever produce this is that in the current ACO system, the dollars continue to flow through fee-for-service payment to providers. So the ACO would have to go to the oncologist and say send us a check so we can redistribute money. The dollars don't flow to the ACO to then be redistributed. So it's an inherent limitation in the ability of ACOs to do reforms like this the way they're currently structured.

DR. SAMITT: Well, that is true, although the ACO has a gain-sharing formula that if the total cost of care, including all of the care provided here, is more efficient, then the ACO is going to receive a bonus. So the ACO doesn't need to go and get a check from the specialist because I think they're looking at the gain-sharing opportunity here, unless -- if I'm understanding it correctly.

MR. HACKBARTH: Well, to convert to a management fee [off microphone] and start paying a flat management fee,

where are those dollars going to come from in the ACO model?

DR. SAMITT: Well, I think we're comparing apples to oranges. Again, the management fee -- the add-on, you mean?

DR. SAMITT: Yeah, taking the payments above the acquisition cost, as I understand the United model, and saying we're not going to pay above the acquisition cost, we're going to instead use dollars to pay a management fee, right now under ACOs the payments for oncology go directly to the physician, including the 6 percent add-on, the ACO doesn't have a mechanism to reclaim those dollars for redistribution unless it says, "Send me a check."

DR. SAMITT: And that's a whole other separate issue, and, again, I'm in favor of that because I think that it removes a perverse incentive. This is something very different, which is how do we create an incentive to maximize survival rates for cancer and reduce the total cost of care, including hospitalizations and the choice of drugs when there are bioequivalent drugs. That performance does accrue to the ACO. So aside from the add-on, which would continue to accrue to the oncologists themselves -- that's perfectly fine -- this takes into account all the other

costs associated with cancer care. And I think that they would work side by side. So a fixed add-on, an ACO-like solution in cancer, and an overall ACO solution I think can all co-exist.

MS. BUTO: Yeah, my point is related to that, and I would say that one thing we ought to consider is giving ACOs new authority to establish episode bundling around things like cancer care and then inviting oncologists and others into that payment arrangement that would allow for management fees and other things. Right now they don't have that kind of free authority, and I think it's holding them back that they don't have the ability to do that kind of thing.

DR. NERENZ: I was just going to build on Craig's point. I think it's even better that they can co-exist. I think actually it might be essential, because right now in the ACO models in Medicare, my sense of it is you have very weak incentives for cost saving, but in the fee-for-service platform, you still have very powerful incentives for doing more. If you leave those incentives in there, it's hard for the ACO to make the cost-savings incentives work.

If the fee-for-service part can be tweaked in a

way that the up incentives are removed or go down, then the ACO dynamics work better. It's not just that they co-exist. It may almost be a success requirement because, otherwise, the ACO incentives are running directly against powerful fee-for-service incentives.

DR. SAMITT: So you're saying, though, that ACOs won't lead it, in a way that reform has to happen in fee-for-service for ACOs to then adopt it. There's a question at the end of that.

DR. NERENZ: Yes. I would say yes. I mean, the strong version of my point, and it's going to have to play out in practice, is that for ACOs to succeed, they may need these kind of reductions in the fee-for-service incentives to do more, spend more, take the higher-cost alternative. Otherwise, they're just -- they're running too much against those.

MR. HACKBARTH: Other Round 2 comments?

MR. THOMAS: Just building on the points that have been made, I would agree also that I think a fixed administration fee for physicians makes sense, that the incentive there is certainly not probably the best one we have today.

On the idea of the LCA, to me that -- especially for drugs that are relatively similar, I mean, I think we make these tradeoffs every day in the system today, in hospitals where we're kind of paid on fixed payments around DRGs, we're really trying to make those decisions every day. So I would support, you know, moving to that model.

I agree that oncology could be more complicated because there is, you know, different drugs there and the efficacy can be different. There can be different mixtures of drugs. But I also -- the idea that a patient may not have access to a more expensive drug, we have this, you know, once again today where it might not be -- you know, we might get paid a global fee, and the devices that we implant in patients could be different. And hospitals are making those decisions with the physicians, with the patient, every day today.

So I would really just encourage us to look at the global payments, to look at the LCA model. I think there's a lot of opportunity here -- going back to the point made earlier -- to spend the resources that we have wisely.

DR. REDBERG: I like the LCA model because I think the idea of paying similar prices for treatments that do

similar things makes sense, and the current system we have, where we pay a lot more, again, for treatments that don't lead to better outcomes doesn't make any sense. And not only is that what we do, but there are a lot of incentives to keep doing that in our current system that, you know, are not really a wise use of resources or, I think, good for our Medicare beneficiaries. And so I think sort of doing an evidence assessment is a good idea.

In terms of -- the problem with the payment codes is that it doesn't really allow us to compare non-drug treatments that might be better. So, for example, sometimes you would be better not having anything than having drugs, because we are using drugs in lots of situations where you would be better off without them. And just so that's why sort of a bundling or a bigger approach I think makes more sense, and, you know, I can see doing this, consolidated payment codes initially, and then moving towards a bundled system.

I don't think ACOs are going to, unfortunately, achieve that goal for the reasons we talked about, the fee-for-service chassis that they're built on. And the other thing is that, just to remind us, all of this is predicated

on the fact that we're actually collecting data on outcomes and on how patients are doing. And right now, even if I wanted to refer patients to an oncologist that's getting better outcomes, how could I? Because I have no idea, and we don't collect that data. And we really do, you know, need to have -- you know, we pay for a lot of things, and we don't do very well in tracking them in terms of physician outcomes, treatment outcomes, device outcomes. And that was the last point.

And another advantage of having a bundled payment as opposed to just stopping consolidated payment codes is that there are times, for example, in cardiology where you could have -- for current stable coronary disease -- and now we're not talking so much about Part B drugs, but you could either get medical therapy or a stent, be equally effective, but the reimbursement is much higher for a stent, physician reimbursement is much higher, and guess what? We have a lot of stents being placed in people that would do equally well on medical therapy. That's not going to be affected by having a consolidated payment code. So, again, I think a reason to have a bundle so we can really achieve the best care for our use of Medicare resources.

DR. HOADLEY: I wanted to follow up on several of the points that have been made. The line that Kathy started about sort of how many drugs are involved in some of these different approaches, and it really has been kind of picked up, I mean, it really -- I think that's really important to think about. Under bundling we can go all kinds of places. Some of them may work better than others. Oncology is probably rarely going to show up in these sort of least costly alternative or, you know, consolidated code because they're not the same drugs. They alternative treatments. Some may be more effective, and you kind of have to do it.

So I think at least today there are relatively few drugs that sort of fall in this least costly alternative consolidated code kind of category. There will be more, particularly as follow-on biologics come along. So it's going to become a more important issue over time.

The second point on the flat fee, I think it is important to kind of remember that it's mostly just a separate issue, even from the coding issue. So it applies all across all Part B drugs; whereas, the coding ones were talking about, again, as I just said, are probably relatively few cases.

There are some ways to probably go other than just pure percent, pure flat. I don't know that we'd want to go there. A little bit of what came up in the follow-on biologic where it said, you know, we'll continue to give you the higher percent markup of the higher drug to help create the incentives to use the less expensive product is sort of along that line of thinking, try to get the straight percentage calculation away from being an incentive. There are going to be some issues with flat fees, sort of what do you base it on and so forth as well.

The third point and last point is, as you sort of think about the difference between consolidated coding and least costly alternatives, it actually strikes me that maybe they're on some level the same thing, but with two parameters that you could change, and you could actually get more in between. So one is how you determine the price point. So when we're talking about consolidating, we're saying straight weighted average. When we're talking about least costly alternative, we're saying generally the lower price of the two. You could obviously define other things and kind of make that more of a variable set of policy choices. And then the second thing is sort of the cost of

buying up.

In the simple way we've designed the one, the patient is fully responsible for the cost of buying up under the least costly alternative. And under the consolidated code, we're saying the patient pays no more and the burden is on the provider. Again, you could come up with some variations on those.

So you might actually think of these as just the same thing with two parameters that you can move around in different ways, and if we don't like quite the mix on either one, try to come up with a better mix.

MR. HACKBARTH: So if I could, I want to sort of follow Jack. My mind was sort of working on a similar track. I won't be as good as Jack in articulating it, but what I'm trying to do is figure out a path for us to explore here. And I think Jack is right. We've got a variety -- several different types of issues here that we've touched on, and I think we now need to start sort of sorting them in order to make progress.

You know, the categorization I was using, Jack, I think is similar to yours. There's this discussion about the incentive for physician and whether the percentage add-

on should be converted to a flat fee. That's sort of one path to pursue.

A second involves methods that require some determination of equivalency, whether it's LCA or consolidated codes or Jack's sort of middle option between the two. That's sort of another basket of things. You are making a judgment about equivalency.

And then the third basket that I was thinking of is the sort of bundling payment reforms that go beyond just paying for individual -- how you pay for an individual drug to wrap it into broader changes in incentives, and here, I'm sorry, Craig, I'm using "bundling" to encompass things that have ACO-type structures as well.

And those are three paths that are actually not mutually exclusive, and, you know, they all have potentially some merit. When I say "merit," I don't necessarily mean to imply that I hear consensus about what we should do in each of the three categories, but I do think there are three distinct paths.

So let me pause there.

MS. BUTO: Just on that point, Glenn, I think, you know, the flat-fee approach, depending on how you set the

flat fee, could in a sense mitigate the need for an LCA or consolidated billing code approach if what you're trying to do is level the incentive. So it could really move in that direction in a way that, you know -- again, it would depend on the methodology.

The one thing I wanted to mention that I'm not sure where it fits -- and I have no data behind this, and maybe Kate has a sense of this -- is whether there's any impact on either the development of follow-on biologics or other source -- other of the multiple source, you know, originator type drugs. Once you establish an LCA grouping or a consolidated bill groups -- in other words, once you've established a lower payment level, do we care? And is there any impact on the incentive for a generic or for a follow-on biologic to come in? Maybe we don't care because maybe it's those drugs already have multiples in them. But I'm just raising it because if we do care, if we want more competition, that's just something that we could look at. But I don't know that there's any data on this one way or the other. There's not enough experience really with follow-on biologics, even in Europe, to know what the impact would be.

But, anyway, I do think that one of the approaches could actually mitigate the second issue somewhat if you go to a flat fee.

MR. HACKBARTH: So let me just think out loud about that. So going to a flat fee eliminates the incentive to order a higher-cost drug in order to maximize your payment as a physician. It does not create an incentive to use a lower-cost drug that may be equivalent. So it neutralizes the incentive to go higher, but it doesn't create the incentive to go lower.

MS. BUTO: Right, and I was going back to Kate's point about, you know, where do you -- which side do you fall on. Is it the side of at least wanting to leave that room so that the clinician can make that decision? Or is it that we really think these are so equivalent that there's no reason really for the clinician to prescribe the higher --

MR. HACKBARTH: I also want to give Mark a chance because he's been scribbling thoughts.

DR. SAMITT: I have one quick comment, and I'm actually representing Alice in this comment, who -- it's as much about the optics of how we describe this, but her recommendation was that if we have the ability to influence

the language, we shouldn't say LCA, that it shouldn't be least cost alternatives, that it really is least cost equivalent, that alternatives suggests that it doesn't have an equal level of effectiveness, and so maybe we should be describing it as LCEs as opposed to LCAs.

DR. HOADLEY: Yeah, that's a nice amendment. I think on Kathy's point on the flat fee, we've got to remember that there's still a margin profit potential, so in the sort of Lucentis, Avastin, where it's a 40:1 difference, if they can get -- find a supplier that gives them a 1 or 2 percent discount, they've still got a lot of money to make on that margin.

So it's not only the percentage add-on. It's the potential to use margin on that. So it does fix it partly, but it doesn't fully sort of solve that other issue.

MR. ARMSTRONG: And I just briefly wanted to affirm, I thought the way you characterized or packaged the issues into those three categories was a really nice and useful way of getting us organized for going forward.

And then one brief point -- it's kind of a semantic point as well -- the title of the chapter is "Developing Payment Policy to Promote Use of Services Based

on Clinical Evidence." And I think maybe to the degree there's evidence that creates equivalence, that's really a fairly limited, actually, application of clinical evidence to this whole topical area, particularly given some of Rita's points about if you're really applying clinical evidence, you would be imagining all sorts of other much bigger questions about the use of these various medications.

And so I just would challenge us to really look at the language in the title itself.

DR. MILLER: This is going to be anticlimactic. I wrote three things out. They were the same three that you wrote down.

MR. HACKBARTH: For this we're paying you [off microphone].

DR. MILLER: Well, no, there was a fourth one about extra vacation time for the Executive Director. I thought I heard that.

[Laughter.]

DR. MILLER: So with your list of three, I saw two of them as ASP oriented, looking at the consolidating or thinking about, you know, a reference, you know, a flat fee -- sorry. Thinking about consolidating the ASP codes, and

then the kind of buy-up arrangement there. Then there is still within general ASP a flat-fee type of approach and variance on that. And then you have the bundling, and I want to be really clear, I think if we go into the bundling conversation, we're talking about oncology and kind of building off some of the -- and I shouldn't say -- you know, shared savings -- well, what I would say from a staff perspective is we would probably try and come back to you and say, okay, let's work through the mechanics of how it would happen and, you know, how this would work, and we would probably try and work through an oncology example as the first and most obvious place to go just to kind of cut the playing field down to something.

Now, what I didn't hear -- and I'd be happy if you want to say, you know, just go figure this out. You know, I could huddle with the staff and figure out what could come online more rapidly if you're indifferent about which order. But if you have an order, then you should speak to that.

MR. HACKBARTH: Well, as I was saying in the exchange with Craig, I do think an important part of this thinking is, What are the resources required to do various options? Are there some of these that are lower-hanging

fruit, both in terms of our time and effort, Congress and CMS, and we may want to have some explicit staging that says, you know, let's focus on these, these are incremental improvements, but they are improvements, while these more, bigger reforms are moved to later. Or in some cases, we may decide the big reform is just too big, too complicated to do, it's better to do it through Medicare Advantage plans or some other vehicle. So some staging I think is a useful part of the framework as well.

MS. BUTO: Is this the universe of things we are going to be talking about, though, in terms of reforming Part B? Because I think you started out by saying we are only looking at a certain number of these. If you are going to stage, it seems to me you would want to make sure we thought of --

MR. HACKBARTH: Well, if you want to add -- I didn't mean to say this was --

MS. BUTO: I mean, there are risk sharing arrangements.

MR. HACKBARTH: This is what I had heard in this conversation.

MS. BUTO: There are things that could be done

that are much more -- there is more accountability around outcomes and so on that are also changes in reimbursement, but I don't know if you want to go there.

MR. HACKBARTH: Just say more -- [Off microphone].

MS. BUTO: I can't lay anything out right now, but you probably know there have been experiments with government and providers or manufacturers engaging in an agreement that payment would be made in relation to outcomes produces.

MR. HACKBARTH: Yeah. So UK has experienced with that.

MS. BUTO: UK has experienced with that in cancer car -- well, Velcade. There are other countries. France has experimented in looking at different drugs in categories and essentially trying to figure out whether you pay in increment or not and how you code for that and so on. So there are different approaches, and I don't have it all in my head.

If we wanted to look more comprehensively at, so what's the end game in fee-for-service, what is the best we can hope for in terms of drug treatment and payment, I don't know that this is a universe of possibilities.

DR. SAMITT: And just so that we don't create the wheel, as we think about bundling or game sharing in oncology, are there other examples like ESCOs that can accelerate that thinking to say, "All right. Well, what if we took an ESCO-type model and applied to oncology as an alternative?"

DR. REDBERG: What's an ESCO?

DR. MILLER: This is the ESRD ACO?

DR. SAMITT: ESRD ACO.

DR. MILLER: Yeah.

DR. SAMITT: So an alternative diagnosis but still the same framework.

MS. RAY: Right. Included in the mailing materials, CMMI is currently developing an oncology payment approach, and we could come back to you with more specifics about that, as well.

DR. BAICKER: Just to come back to the specific question of the incentives on the incremental payment, because I think you have raised the very important points about the balancing of the -- clearly, we are at one extreme now where we are heavily incentivizing the use of expensive stuff.

The other extreme, where you pay, you know, the model that we have been looking at here would pretty heavily incentivize the use of the least expensive. And then the flat fee is neutral about whether you use the more expensive and least expensive.

I think everyone seems to be of accord that the right thing is somewhere between the flat fee and incentivizing the cheaper one. We don't want to be on the side where we are incentivizing the expensive one, and it comes back to this point of Craig channeling Alice, to me, in calling something -- I'm blaming you from now on -- in calling something equivalent, and that in some cases, we delude ourselves in thinking these things are exactly the same. That's such a small set of cases, and as soon as you start saying, "Well, but this one has different side-effect profiles and patients have different tolerances for that," you pretty quickly get into the muck of making it a really heavy lift to implement.

So the more you are on the strongly incentivizing the cheapest one, the more I think you have to grapple with the many exceptions. Obviously, in each case along that side of the spectrum, there is the potential for having to

manage the exceptions, the medical necessity, the odd case. That is always going to be the case, but the stronger you push it in this direction, the more I think you have to rely on really close equivalency. And I think the narrower the set of cases and, in some ways, maybe the less of the bang-for-the-buck that you get when you have to limit it to such very specific buckets, whereas coming a little more towards the neutrality, then it takes a little of the string out of that. So that's how I think of that end of the spectrum.

DR. MILLER: If I could just say this quickly about that, and I know there are other people on deck, so I will be very fast here.

If that were the framework that you thought through -- and I know you were talking about a staging thing more from a policy in a large view -- from a staff point of view, if we were to follow this, we would come back with flat fee as more neutral and less muck to implement and start thinking about bundling, where you don't go through all the equivalency calculations. The clinician does that in bundling and shared savings -- I'm sorry, Craig -- do that in his or her head as they are working through with the patient.

DR. CROSSON: Just two comments. First, on what Kate said, I think the further along you get on that spectrum of strong incentives or strong disincentives, the more important it is to incorporate a process of allowing clinical judgment to take place, and that exists more robustly in a situation where there is broad flexibility in terms of making a whole bunch of clinical decisions.

But in answer to the phasing or prioritization question, is the assumption that the whole spectrum of things that we have discussed so far would require legislation, or are some of these things that could be done on a regulatory basis?

MR. HACKBARTH: There may be some regulatory opportunities, but I think in general, what we have been talking about here requires legislative action.

Kathy, I think you are absolutely right is that there is a whole, much larger universe of potential options that goes way beyond what we have talked about here, so your point is very well taken.

What I am wrestling with is how do we get traction.

MS. BUTO: And I didn't mean to say we shouldn't

try to bite off what we can chew.

MR. HACKBARTH: Yeah.

MS. BUTO: It's just that when you presented it, it was sort of like, you know, these are the things we're going to be moving to.

MR. HACKBARTH: Yeah. Again, I concede your point is a good one.

My fear is that if you open the door too wide, especially meeting as infrequently as we do and having the limited time we have, that it's a formula for never being able to make progress. So I would be inclined to go with the shorter list and see if we can use that to make headway here.

Jack.

DR. HOADLEY: The only thing I would add to that, I mean, one point I'd add on top of Kate's point is sort of pushback, the political pushback, on the examples we are looking at are ones where things were done and then people went to court or went to Congress to get them overridden. So, I mean, it is just another consideration to keep in their minds.

But the more substantive point is -- I keep coming

back to the follow-on biologics, because these were -- the legislation has created the pathway for these to get approved, and FDA is working along that path. There are a lot of other issues, especially on the Part D side, of the oral follow-on biologics about what are the prescribing rules going to be. Those have mostly been a matter of state policy, nothing something I suspect we would get into.

But the coding options really may play heavily into that. The percentage add-on issue can play into that. I think thinking about that maybe has some urgency because it's not that far away, and in fact, there is a lot of activity already at state legislatures and things trying to anticipate and protect the original manufacturers' interest in these.

So I think there is a lot of money, potentially, to be saved along that path, and even that one number that you had in the paper about the difference in those two estimates, even though that was old and out of date in terms of the specific numbers says there is a lot of money on the table, depending on what we do to encourage their use once they are on the market.

MR. HACKBARTH: We are just about at time. Any

concluding comment that anybody wants to make?

[No response.]

MR. HACKBARTH: Do you have a sense, Mark, of where to go from here on any questions you asked?

DR. MILLER: I do.

MR. HACKBARTH: Nancy, Katelyn, any questions that you want to ask here in terms of getting guidance?

[No response.]

MR. HACKBARTH: Okay. Then we are done. Thank you very much. This is a challenging area.

We will now have our public comment period.

[No response.]

MR. HACKBARTH: Seeing nobody at the microphone, we are adjourned.

[Whereupon, at 11:29 a.m., the meeting was adjourned.]