MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, NW
Washington, D.C. 20004

Thursday, April 7, 2016
9:49 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[9:49 a.m.]

DR. CROSSON: Okay. Can we take our seats, please? I do have a request from our recorder here. Maybe the microphones are not quite as vital this morning as they normally are, so I ask the Commissioners as well as the presenters, keep the microphone near you and try to direct your voice into it so she doesn't miss some of the things that are said here.

Okay. So Carol Carter is back with us, and we are going to be going over again the response -- our mandated report on a unified PPS for post-acute care. At the end of this discussion we will ask for support of the Commissioners to forward this report to Congress as we are required to do.

So, Carol, you have the microphone.

DR. CARTER: Great. Good morning, everyone.

The IMPACT Act of 2014 requires the Commission to prepare a report considering the design of a prospective payment system spanning the four post-acute care settings: home health agencies, skilled nursing facilities, inpatient rehabilitation facilities, and long-term-care hospitals.

Aware that similar patients were treated across the four post-acute care settings yet Medicare pays very different rates depending on the setting, the Congress requested the Commission to prepare two reports. The first (due at the end of June) must evaluate and recommend features of a unified payment system to span the four settings and, to the extent feasible, estimate the impacts of moving to such a system. After the Secretary issues her own report, most likely in 2022, the Commission must propose a prototype design in a second report, most likely due in 2023.

Just as a reminder, mostly for the audience, the report is the culmination of a lot of work that you have discussed at many meetings. Since last September, we've reviewed the various pieces of the report, and you provided feedback on what was presented and what else you would like to see in the report. In March, we discussed the draft of the entire report and how the different pieces fit together.

The draft report has the sections listed here on the slide. Based on your comments last month, several revisions were made to the draft. Of note, Mary, you

thought a summary table would be helpful for the takeaway points of the report, and we added that to the introduction.

Susan, you asked about what policies have been waived by CMS' bundling initiatives and ACOs, and so we added that information.

Alice and Mary, you both noted that outcome measures could be tracked over a longer period of time, more than 30 days and that hospital admissions would be a good measure for looking at patients without a prior hospital stay, and so we included both of those sets of information in the chapter.

Herb, you asked for more discussion of the finding regarding IRFs and their low-income shares, and so we expanded that discussion.

I'll briefly summarize our findings on each topic. Our findings should be seen as guideposts, not as a prescription, for CMS in its own design. We've identified features that should be included in the design, those that appear to not be needed, and a third set that needs more work before deciding whether or not to include the feature.

First, the overarching design features. Our work

confirms that it is possible to design an accurate payment system spanning the four settings that uses a common unit of service and a common risk adjustment method based on patient characteristics to establish payments. The design should adjust payments to home health agencies to reflect this setting's considerably lower costs, and given the differences in benefits across the settings, the design should separately establish payments for nontherapy ancillary services (such as drugs) and payments for routine and therapy services. The design should include two outlier policies: one for unusually high-cost stays and one for unusually short stays.

We did not find strong evidence for adjusters for IRF teaching facilities or for either a broad rural adjuster or for providers located in frontier areas. It appears that a robust risk adjustment, especially in combination with outlier policies, can predict the costs of these stays.

That said, there are areas for the Secretary to explore further: first, whether low-volume, isolated providers need protection. Also, more work on the risk adjustment for the highest acuity stays would help ensure

these patients' access to post-acute care and protect the providers treating them so they are not disadvantaged by the payment system.

Recall that we examined how well the model worked for over 20 different clinical groups, and we also looked at four different definitions of medically complex patients. The model worked well for most of these groups, including three of the medically complex definitions that captured the vast majority of these patients, and the model predicted the cost of these stays as well. The Secretary should also examine the need for adjusters for providers treating high shares of low-income beneficiaries. We did not have the data to do this analysis across the four settings.

Turning to the impacts of a unified payment system, our estimates should be considered as directional and relative rather than as point estimates.

We found that a unified payment system would result in more uniform profitability across different types of stays, and this would decrease the incentive to selectively admit certain types of patients over others. Payments would shift between different types of stays,

generally increasing payments for medical stays and lowering payments for stays that receive physical rehabilitation services that are unrelated to patients' conditions. For example, we estimate that payments would increase for patients on ventilators and for most medically complex patients.

In general payments would be lowered for providers with high costs that are unrelated to their patient mix. A high-cost outlier policy would help align payments to a provider's cost and a transition policy will give high-cost providers time to lower their costs in line with the new PAC PPS payments.

In implementing the payment system, the Secretary will need to consider the level of payments. We estimated that in 2013, payments were 19 percent higher than the costs of the stays.

Another issue is how long the transition will be from the current setting-specific payments to the new PAC PPS payments. A transition could also contemplate moving ahead earlier with a PAC PPS that uses only administrative data and refine the payment system when patient assessment data become available.

Finally, the Secretary will need the authority to recalibrate and rebase payments over time so they continue to be aligned with the costs of stays.

Because a PAC PPS would eliminate payment differences across settings, Medicare should move away from setting-specific regulation; this would give providers the flexibility to offer a range of services across the PAC continuum. We know that overhauling Medicare's conditions of participation is a complex undertaking, so we outline a possible near-term and long-term strategy. In the near term, when the PPS is implemented, the Secretary should evaluate whether and which regulations could be waived. The report mentions some possibilities to consider, such as the 60 percent rule and the intensive therapy requirements for IRFs and the 25-day length of stay for LTCHs. In the longer term, CMS could consider developing a core set of regulatory requirements that all PAC providers would meet and additional requirements for any provider opting to treat patients with highly specialized care needs, such as ventilator care. Requirements would, thus, shift away from being setting-specific to being condition-specific.

A PAC PPS retains some of the undesirable

features of fee-for-service, so the Secretary should implement companion policies to protect both beneficiaries and the program. We want the policies to encourage care coordination and high quality care for beneficiaries, and at the same time, we don't want the program to incur unnecessary spending. Companion policies could include a readmission policy to promote high quality of care and encourage good care coordination. A resource use measure, such as a PAC Medicare spending per beneficiary, would counter the incentive to generate unnecessary service volume, such as serial PAC stays. Both policies could be organized as part of value-based purchasing that includes both quality and resource use measures. Other quality measures could include the rate of discharge to community, changes in function, and measures of care coordination.

It will be important for CMS to monitor provider responses to the new payment system, including indicators of quality of care, selective admissions, unnecessary volume, and the adequacy of Medicare's payments. Measures of each, using existing data, are discussed in the chapter.

Given the shortcomings of fee-for-service, Medicare needs to move towards episode-based payments as

soon as feasible. Providers should be at risk for quality and spending over an episode of care, thereby reducing the need for companion policies aimed at dampening undesirable provider responses to fee-for-service. Thus, a PAC PPS should not be considered the endpoint but, by beginning to align PAC providers' payments, represents a good first step towards broader payment reforms.

The Commission's work on a unified PAC PPS and related policies will continue past this June's report. As you know, we're required to develop a prototype design after the Secretary has proposed her own design. We will also look for opportunities to integrate our findings into our annual update discussions, examining changes that would align policies more closely to the broad PAC agenda. And we will continue to develop and track outcome and resource use measures across the PAC settings.

And with that, I would like to turn the discussion back to Jay.

DR. CROSSON: Thank you, Carol, for the presentation, and thank you again for what is a considerable and excellent piece of work that you have brought forward over these last months.

We will now have the floor open for questions of Carol.

MR. GRADISON: Let me join with you in complimenting the staff on the quality and depth of this excellent report.

The Secretary is supposed to make recommendations regarding the collection and analysis of common patient assessment information and report in 2022. That is six years off. Do you have an opinion as to whether it could be done in less than six years? I appreciate that's the statutory requirement, but just--

DR. CARTER: Well, as we have indicated in the chapter, it looks to us like the payment system for most of the patient groups we looked at does pretty well in predicting accurately the costs of stays. So one could proceed sooner using administratively available data that's already available now, and then refine a payment system over time to include the functional assessment data. That would improve the accuracy of the predictions, particularly for certain groups of patients. But I think especially as you think about a provider's book of business across all of its patients and the averaging that is always implicit in a

payment system, it looked to us like you could move more quickly using existing data.

MR. GRADISON: Thank you.

DR. CROSSON: Other clarifying questions?

MS. BUTO: Carol, would you say that that's true even if the Secretary were to proceed to refine the existing PPS systems that there still could be -- in other words, does your statement apply only if they were to go somewhat more immediately to a PAC PPS rather than to refine the existing individual PPSs?

DR. CARTER: The recommendations that we've made about refining the payment systems are completely consistent with what we've scoped out here. So doing one actually would facilitate the other, and I see they're moving providers in exactly the same direction, which is basing payments on patient characteristics and moving away from therapy-based payments. I think both need to be done. The payment system changes we made back in 2008 for the SNFs, so that one's out there. It could be done pretty quickly.

So I do think even in the interim you could move forward with the refinements to the individual PPS payment

systems.

DR. COOMBS: Thank you so much, Carol. This was superb.

I notice on page 64 the -- we talked about this, about the whole notion of cost sharing for the beneficiary. We're not making really any kind of recommendations to the Secretary as to, you know, looking into the future as to what might be a reasonable adjustment or reconciliation between SNFs, the LTCHs, the IRFs.

Do you have any kind of idea going forward if that was a question to come back at us?

DR. CARTER: So the short answer is we really haven't done that work. I think when we did the benefit redesign work a couple of years ago, we talked about having more uniform cost sharing across the different types of services being used. The post-acute care is a ripe candidate for that because the cost sharing is different across the settings, but we have not done the work to sort of construct what one might look like.

DR. CROSSON: I see no further hands for clarifying questions. So now we're going to engage in a discussion about the content of the body of the report that

we'll be sending to Congress. We will be, as I mentioned before, asking for consent at the end of this discussion, and, Mary, I would like you, if you would, to begin the discussion.

DR. NAYLOR: So over the course of many, many months, I think we have started each of these reactions, Carol, to the work that you and your team has done, in collaboration with Urban and partners, with how extraordinary it is. But I have to tell you, when I read this version, I was just blown away by the comprehensive and extraordinarily clear description of the design features, the path forward, the implications. And I really think in so many ways this is not just a model for the ways in which the staff and Commissioners optimally interact, but it is clearly a model for how it is that the Commission and its work can go forward in strengthening changing the fee-for-service system. So I just want to start with and I will end with congratulating you. It's just really beautiful, beautiful work.

Of course, you give me one more chance to offer a couple of ideas, and knowing me, let me fully do that, and I'll be brief. But on page 54, when you talk about

defining the stay, it really helps to raise the challenges, the conundrum, when you're talking about how to do this in an effort to try to build a PAC continuum of services, you know, when you talk about institutional PAC, et cetera. So if anything, I would just say how just that dimension reflects a real need to move as quickly as possible to episode, because we're just not going to be able to move Mr. Smith from hospital to skilled nursing for as short a time as necessary to home health in one and consider that a PAC continuum of services until we do that.

On page 55, alternatively, CMS could require physicians to attest that the continued PAC, so, look, I have two more days here, physicians and other health professionals --

[Laughter.]

DR. CARTER: I'm channeling you. I'm sorry

DR. NAYLOR: No, no, no. But I get that. But the science here is pretty robust that other health professionals can really make great decisions about the kinds of PAC services, et cetera.

On page 59 -- and I really appreciate a response to Bill's earlier question how this positions much more --

much quicker movement toward this benefit. But I would also say that equally push the Secretary to move functional status data in as early -- much earlier than suggested in order to be able to get it.

And, finally, on the measures, just to remind, I think that the readmission measure -- thank you for all of this and for all of the ways in which you incorporated, but readmission measures here can equally include readmission to PAC as something we should pay attention to.

All of that said, just really extraordinary blueprint, outstanding work, just a joy to be a part of it. So thank you and congratulations.

DR. CROSSON: Thank you, Mary.

Let me see hands for comments. Let's start going down this way.

MR. ARMSTRONG: So, Jay, I would just briefly echo Mary's comments and acknowledge that here we are -- Mary and I and a few of the rest of us -- 6 years on MedPAC, and we have been talking about this issue for a long time. I am very proud to be associated with this and look forward to endorsing it.

In particular, moving payment policy from paying

post-acute services for how they've been structured over time instead of for how beneficiaries need to be cared for, and really underlying this, this is a way to reinforce through payment policy the fact that the Medicare program can do a better job than it's been doing, particularly in the post-acute area, of actually reducing unnecessary costs, saving the program money, but doing it through a system that is reinforced -- that is focused more on the beneficiaries' individual care needs. Wherever we get the opportunity to make changes like that, we're doing our best work, and I think this is a great example of that. Thank you.

DR. CROSSON: Kathy.

MS. BUTO: Carol, thank you for this work. It is really stunningly put forward. Given I think the size of this job, I think it's really amazing, and I hope we can look for ways to accelerate the adoption of a single approach to PAC PPS and an episode-based one.

I have two somewhat minor comments. One is on page 60 at the top where you talk about over time CMS should consider specifying regulatory requirements by patient type rather than by PAC setting, and I understand

what you're getting at, the core set of requirements. I'm just thinking to things like licensing facilities and how difficult that would be if the requirements were really by type of patient, and I'm just not sure how those two work together. So it's just a question.

I think elsewhere in the paper, you really talk about core requirements that would apply, and it would allow for different kinds of patients and even suggest that we might want to look at policies that -- facilities that want to specialize in certain kinds of patient acuity would be asked to meet. So I just question how that would work.

And then the second one -- and I think I understand why you didn't try to take this one because I think it's difficult -- is the three-day prior hospitalization stay in SNFs; if you go to a core requirement, how that's going to work. I understand that when we've talked about obviously counting observation days, but how if you remove that requirement, then it becomes just an open-ended benefit. So I don't know if you thought about that or how we might deal with that in a core set, once you get to the longer term.

DR. CARTER: So we have thought about it just a

little bit to note that one could. I don't want to scare anybody. There are 10 to 15 percent of IRF and LTAC patients that don't have a prior hospital stay, so one could think about having that as a uniform requirement and then think about the Commission has already recommended counting some observation time towards the three-day requirement but requiring at least one -- to be one inpatient day. So you could make the requirement more uniform across the settings.

The other I noticed in the BPC waiver, the three-day stay is still required for nursing home residents, and if that's the population you're most concerned about in terms of generating additional revenue for a facility by requalifying patients for a Part A stay, you might be able to use that policy lever a little bit to at least dampen that concern. So we haven't thought through all of that.

MR. KUHN: Carol, I am going to join in the chorus of others. Just terrific work. This is the fifth meeting we've taken this up. We have tortured you along the way, and you have come back each and every time with just great information, so thank you for that.

I think in the past, we've described this report

as a set of guideposts to help inform the Secretary as she moves forward to think about this, but as I looked at this last iteration, I think it's more than a set of guideposts. It really is a more thoughtful roadmap to get us there, and I think that's a tribute to you and the team's work of putting this together.

What I like particularly about it is that, as you've kind of enumerated here as you went through your slide deck, it looks at all these key issues, whether it's implementation, whether it's regulatory changes, whether it's impacts, just a variety of different things that captures that. But what I like mostly about this report, above all else, it continues to focus where I think the Commission's work has always been about, is on the patient, and to make sure that we really focus on the access, ultimately the quality and the value of these services as we go forward.

I know when I was at CMS, I was part of the team that I think implemented the last PPS system in kind of the post-acute care settings out there, and I think even back in '06, we were talking about when we were going to be able to move to a unified payment system. And I think Bill

captured it right when we think about is it going to be now in the 2020s, so that's 15 years after we talked about it.

My only observation -- I think I've made this before -- I'll probably be on Medicare by the time we get to this, and I look forward to benefitting from this program in the future.

DR. NERENZ: Let me also say great, great, fabulous work. Thank you.

My question is like Kathy's, about the folks who may enter into the system without having had a prior hospital stay. You mentioned that may be part of the regulatory change. You talk about that on page 61. Then you talk about perhaps an admission measure linked to that.

My question is a little more technical. Are stays like that in the data set from which all this modeling was done, and are there any known differences or suspected differences about that particular class of stays that would require some additional special attention, lower cost, higher cost, different stay length? Do we need a little asterisk for those if they are going to happen in the future?

DR. CARTER: So we did look specifically at stays

with a prior hospitalization compared with stays that were community admitted, and the model was equally predictive of both classes of patients.

DR. CROSSON: Let's finish this side. Warner.

MR. THOMAS: Just real briefly, given the magnitude of work here, I think it is very, very good. I guess the question I have is, what do you see as the downside of accelerating the potential change here, and do you see any downside to potentially trying to accelerate the change in these policies?

DR. CARTER: So we know the kinds of patients that the model does not do as good a job predicting. So if you were a facility that had a disproportionate share of those patients or if you were small -- and all the payment systems always deal with averaging, and when you are small, that's harder. So that would be the downside, is for smaller providers or providers that specialize in the absolutely highest acuity.

And I want to emphasize here, the group that this model didn't do well for represented 3/100ths of a percent of states. So they're way at the tail, and not surprisingly, we couldn't predict the costs of a tail very

well. But if you looked at severity of illness, Level 4, chronically critically ill patients, or patients that had conditions that involved five or more body systems, the model did very well for all of those. And so I'm saying the highest acuity patients are maybe a group we need to focus on, but medically complex patients in general were not a hiccup, and so I don't see that as a particular problem.

Size for small providers. I mean, a payment system was always averaging, and so that could be an issue.

MR. THOMAS: And then on page 61, really the same thing David brought up, on the regulatory changes, I mean, I think there's a comment in here about there's a concern if some of these regulatory reliefs are put in place that it could escalate the cost of post-acute care. But I think there is also a concern that if there's not a regulatory relief, then the change is really going to be difficult to implement. So any thoughts on that?

DR. CARTER: Well, we do think that if you're -- as a short-term strategy, when you implement the PAC PPS, I think CMS needs to think about what regulations need to be waived, not after, but at the same time. And then as a

longer term strategy, we are proposing this idea that we don't license by setting. We license by do you want to treat ventilator patients; this is the requirements to do that. If you want to treat patients with serious wounds, this is the capabilities you need to have, so moving towards patient-defined requirements as opposed to setting-defined requirements.

But when this payment system is implemented, given the conditions of participation are unlikely to be changed quickly -- that is a complex undertaking; we appreciate that -- I do think it's important to waive certain requirements.

MR. THOMAS: Okay. Jay, I just wonder, given the issue, the duration of this implementation, should we have comments in the chapter just around the idea that people could opt into it or organizations could opt into it if they were larger and maybe have less likelihood of being negatively impacted, or is there a way to recommend kind of quicker adoption? So it's just a general comment. Thank you.

DR. CROSSON: Herb, do you want to comment on that?

MR. KUHN: Yeah. Just on that, if I recall right, when the ESRD PPS system went into place, there were options for them to opt in early, and because CMS got it right, they almost had 90 percent opt-in the first year as part of that. So it's not unprecedented, what he was talking about.

DR. CARTER: Yeah. I think the SNF PPS was like that also.

DR. CROSSON: Yeah. I mean, I think, just generically, you probably need to have some parts of the regulatory relief set of issues in place in order for that to happen, but were that the case, sure.

DR. MILLER: I've been trying to think about it, and I think we said some of this to each other, Carol.

DR. CARTER: Uh-oh.

DR. MILLER: This is always awkward.

And it goes right to where the comment started over with Bill and Kathy and comments that they've made and others have made of is there a way to move along on this, and I wanted to make sure that Carol held the floor. And in responding, she said either you could change the system in a way that we have recommended, which is more patient-

oriented, silo-by-silo, or begin to think about this thing, to try and respond to an array of questions there.

To me, one of the next generations of this work is for us to think about if the "it" can be built -- and we have done a prototype. The Secretary has to do her version of it. What you could almost begin to do is blend payment between each of the individual settings and this thing and say -- start to move a transition and say part of your patient will be based on your current silo-based thing and part of your payment will be based on this, which will help the transition also begin to change the underlying incentives more towards the patient-oriented. And then when you had something like that -- and I really think this responsibility thing is a difficult set of issues to work through, but if you could get through that, then I think you might be able to say -- and if you want to move faster and go instead of '20, 2020 to something that's faster, then maybe you'd be in a position to do that. And that's the way I've been trying to think about our next generation of work on this.

And I can't remember how much of this I mentioned to you, Carol.

DR. CARTER: We've talked about it, yeah.

DR. MILLER: Say it again?

DR. CARTER: We've talked about kind of different versions of the transition in thinking about that.

MR. THOMAS: Just an add-on to that, Mark -- and that's why my concern is -- I mean, I think all of this work is great. It's just if the regulatory relief doesn't occur appropriately, then really all the other great ideas are going to be extremely difficult to implement. I just wonder if we need to be more pointed about our thoughts on that specific issue, so --

DR. CARTER: The chapter does say these need to be happening at the same time, but I'll look for places to emphasize that.

DR. CROSSON: Okay. Moving over to this -- I'm sorry. We are going to work down. So I've got Jon, Kate, Bill Hall, Jack, and I saw Alice's hand, so let's go down this way. Jon?

DR. CHRISTIANSON: Carol, remind me of how this payment work will interact or be integrated with the work to move more patients, more beneficiaries into ACOs and other organizations like that.

DR. CARTER: I'm not sure I understand your question, but let me give it a shot. So the ACOs use fee-for-service as what's kind of that platform, and so having more accurate payments across the different settings would be built into the ACO benchmarks, if you will. Is that --

DR. CHRISTIANSON: I was impressed with all of the complexity of what you're trying to do, and then I really thought probably episode-based payment would be where we would want to end up. I don't know where the rest of the Commissioners are on that, but you've noted it a few times in the paper and in your slides.

I guess this is a question for the Commissioners. Do you think we should be more aggressive in terms of advocating for that than we are now, or, Carol, do you think that we're not there yet in terms of the data and analysis?

DR. CARTER: Well, the Commission did a block of work on episodes a few years ago, and we looked at an episode that's PAC only, a PAC-only plus hospital stay, long and short. So we've looked at that. I think the Commission didn't come out -- I mean, we didn't come to any recommendations about sort of which bundle type and

duration type it had a preference for.

I think if you used kind of fee-for-service running -- one of the issues with bundled payment is who gets the money, but if you pay providers as they go based on fee-for-service with using some of the payments as sort of a benchmark, you can sidestep, I think, some of the issues about who's getting the money. We talked about that as sort of virtual bundling, if you will, but that would be maybe a conversation for the summer at the strategic planning meeting about if we were to do another round of bundling work, what would that look like.

DR. CROSSON: Okay. I think we've got Kate; is that right? Yeah.

DR. BAICKER: Yeah. I'm very supportive of this direction. I think it's moving us along a path that we all would like to travel down, and the question is how quickly. And one of the things that you've been helpful in surfacing and that echoes something Mary said is that really, I think ideally, we would want the payment structure to be based on the efficient delivery of care in the right site of care for that patient rather than the patterns of locations at which patients are getting care now, but we don't yet have

the data we would need to do that more globally optimal payment mechanism across sites. And so this moves us great steps in that direction and also highlights the need for greater data collection that can then be incorporated to have a more tailored payment plan, not just to be site-neutral, but to prefer the right site for the right patient. And that's a great direction to be going in the future.

DR. CROSSON: Bill Hall.

DR. HALL: Carol, I send you my congratulations as well. When I was reading this over for -- I don't know -- the nth time, this time, for another reason, I had to look at the history of Medicare, and there' the famous picture of Lyndon Johnson signing Medicare into being in 1965 and presenting to Harry Truman and Bess Truman, Medicare Card No. 1 and Card No. 2. In that picture, Harry Truman seems to have some hesitancy of signing, and the reason is that Johnson explained to him. He said, "What's this other part here? I understand the hospital part," and Lyndon Johnson said, "Well, Harry, that's for health insurance." "How much?" And the price was for him $3 a month, and for Bess, it was $3 a month. They looked back

and forth at each other, and they weren't sure that they really wanted that type of coverage.

I think that reflects kind of the paradigm we've been in, in health care, with the inception of Medicare. If you got sick, you went to the hospital, and you either lived or you died. And you paid your doctor in any way you could, sometimes with barter, sometimes with money. Sometimes you didn't pay at all. And we're stuck with that. Our vocabulary is still in the 1965 mode: post-acute care, long-term care, intensive care. Everything is presumed to start with somebody getting sick and going in the hospital, and then what?

I mean, if anything we've learned on MedPAC is that this is probably an old idea that has to change, as several people have mentioned, as Kate just mentioned here. And so I think this is what we're doing here, is actually more than just looking at post-acute care. It's looking at what is going to be the package of health care for this burgeoning population of older adults, the 10,000 a day that turn 65.

And as pointed out, I think there are some real roadblocks and danger points along the way. I think the

biggest one is, what are the new metrics that we're going to use? Mary mentioned the importance of function, and I think that's going to have to really be pushed very, very hard. Health care that is patient-centered has to be for older people on what you can do, how you can stay independent. It has very little relevance, in a way, to the chronic disease models that we've looked at, and I think this is a wonderful first step.

But I do think we're going to have to be very -- have a lot of surveillance here. This isn't going to be easy. It's not going to be easy for systems to change this rapidly, as has been mentioned here, but if we keep the goal in mind that the purpose of health care -- who knew? -- is to really help people stay independent, I think that's one of the guideposts that we can use, and I think this is going to be great work, great work for the future of our enterprise here. Thank you.

DR. CROSSON: Thanks, Bill. I have that same picture. As a matter of fact, it's the screensaver on my laptop, believe it or not.

[Laughter.]

DR. CROSSON: A lot of that has to do with

technical incompetence, by the way.

[Laughter.]

SPEAKER: [Off microphone.] It's been there since 1965.

DR. CROSSON: Yeah, right.

[Laughter.]

DR. CROSSON: Oh, no. That was unkind.

[Laughter.]

DR. MILLER: Wait a minute. You had a laptop --

[Laughter.]

DR. CROSSON: The only thing I would point out is on the other side of the picture is Wilber Mills, and if I can interpret the look on his face, it is, quick, sign it, before I lose the political deal that I've just made.

Anyway, Alice.

DR. COOMBS: First of all, Carol, great job, and although we've done this five times recently, we've actually had little children of this coming together to form the big one, and I think the first time I was on -- the first year, actually, on MedPAC, and we did the presentation on LTCHs and we started talking about this site neutral and we talked about strokes, and I think this

is a really good product to deal with what we called then the stroke syndromes, because all strokes are not the same. And, so, having something that's really tailored to the condition and the resource utilization at the various sites is really important.

That being said, I think one of the things is that ICU doctor, me referring a patient to a certain facility, it has a lot to do with the relationship that's established and what kind of results we see from those entities.

It's going to involve a culture change, as Bill has said. It's not going to be something that's overnight. But, it's a culture change that will result in industry changes within the various institutions, and I think that's actually good when one institution says, I'm going to increase my breadth so that I can actually take care of these type of patients, so we have to actually educate ourselves.

And, it will be interesting to see the transformation that will occur that actually will result in better quality, I think, for all patients in all areas, because you will have almost like a cross-training in a way

that diversifies the health care workforce within the various different entities, whereas now they're pretty much siloed into, no, we don't do vents. No, we don't do wounds. We don't do dialysis. There might be some transformation that happens that says, oh, yeah, now they're taking vents and they're doing a pretty good job. They're doing the wound vacs and, guess what, this one was a diabetic, went in there and came out and did very well.

So, I think that there'll be a transformation. I'm hoping there's a trickle-down effect that people will begin to see the potential that they can have within their institution. So, I'm really, really encouraged by that and I'd like to say that this is something that I feel like the others. Mary said it better than anything I could ever say, which is that this is a good thing for patients in the big picture and I think it's something that I'm proud to be associated with as a Commissioner.

DR. CROSSON: Thanks, Alice.

DR. CARTER: Thinking in terms of one thing Warner was talking about in terms of, you know, who -- what kinds of providers would this be hard for, and what you're saying made me realize, if you're small but you have the

flexibility to treat a broader range of patients, it sort of counters, maybe, the problem of averaging, because right now, you're only averaging within sort of the types of cases you can treat sort of by your setting requirements, whereas if those are relaxed, you can treat a broader range of patients. So, even though you're small, you might -- it would help, I think, with the averaging.

DR. CROSSON: Jack, I think the last word is yours.

DR. HOADLEY: So, I'm not sure I have anything really to add beyond sort of reiterating, first of all, the excellence of this report and its clarity, and I think we've used up most of the positive adjectives in going around the table.

But, I hope that because it's so clearly written, it will be very clear to our various audiences that changes of the type that this report discusses are very much doable and that they're very much urgent, and I think we've said that very clearly, and I think it really does hit the right points, and people have talked about these, that we have set these guideposts, road map, different terms that people have used, about feasibility and companion policies. We're

not recommending the details, as has been emphasized numerous times, but we really have set out a feasible road map that can be followed.

And, I think the second point that's been made several times already is the urgency point and that there are potentials, and we've identified these, for moving forward more quickly. And, some of it, I think, you know, Mark talked about sort of the blending. There's a lot of precedence for that back years ago in the original Medicare fee schedule and PPS systems were done -- started out through blends of old systems with new systems. And, we will have the opportunity in the next couple of years, as we talk about our annual updates on the different sectors, to potentially identify places where the principles that we've laid out here, we can find ways to push towards finding that starting point on the guidepath and sort of thinking about all these issues that we've raised about the companion policies and the right kinds of transitions and things.

And, so, I think this really does create the basis for those conversations to happen, and let's hope it happens -- hope that it does happen, and hope that it does

happen as quickly as possible.

DR. CROSSON: Okay. Thank you to the Commissioners for your comments. As you are aware, I think you'll have as individuals one more chance to look at this. We've had some suggestions for perhaps a few changes in emphasis or additions in this discussion. We will be getting the report to you, Jim, in some time --

DR. MATHEWS: This one can go very, very soon, potentially as early as tomorrow afternoon.

DR. CROSSON: Okay, great. So, you'll be seeing it in time to work on it early next week. If you have additional changes, please get those off to Jim.

On the basis of that, I'd like to have an informal show of hands for those Commissioners who are in favor of forwarding this report to the Congress.

[Show of hands.]

DR. CROSSON: I see that as unanimous. Thank you very much, and again, thank you, Carol, for this terrific work.

[Pause.]

DR. CROSSON: I'm just waiting for the crowd to settle a little bit here.

[Pause.]

DR. CROSSON: Okay. I think we can proceed. We're going to move to the next agenda item, which involves Medicare Part D and a series of recommendations, the original version of which we reviewed at the March meeting. We're going to see the final version today, and we will be taking a vote on these three recommendations.

Rachel and Shinobu have done this work, excellent work also, and they're going to start by presenting to us now.

DR. SCHMIDT: Good morning. Today Shinobu and I will walk you through draft recommendations aimed at preparing Medicare Part D for the challenges ahead. Policymakers consciously designed Part D to use a market-based approach. Private plans deliver prescription drug benefits to enrollees, and the plans negotiate with pharmacies and drug manufacturers over prices. Medicare subsidizes nearly 75 percent of the cost of basic benefits, and Medicare shares insurance risk with the plans. There are currently about 39 million enrollees in Part D and about 30 percent receive Medicare's low-income subsidy, which pays for most of their premiums and cost sharing.

Eleven years in, Part D has begun to face challenges that require some restructuring. I'm not going to go over all of the bullets on this slide because Shinobu will pick up on some of them in a minute, but let me address a few. Medicare's population is growing rapidly as the baby boomers retire. Growth in program spending is increasingly driven by enrollees who reach Part D's out-of-pocket threshold. We refer to these as "high-cost enrollees." When an enrollee reaches that threshold, under Part D's current structure, Medicare starts paying for 80 percent of benefit costs through reinsurance. Since 2010, the number of non-LIS high-cost enrollees has been growing very fast, and so has their drug spending. Meanwhile, most high-cost beneficiaries are LIS enrollees. About 70 percent of total Part D program spending is for the 30 percent of enrollees with the low-income subsidy. We've seen substantial growth in prices for older drugs, and many new drugs launched at "orphan drug" levels of prices. We need to find a balance between beneficiary access to appropriate medicines and financial sustainability for taxpayers, but the factors on this slide make financial sustainability an enormous challenge.

MS. SUZUKI: I'm going to walk you through three parts of the first recommendation. They all relate to the out-of-pocket threshold. The first piece has to do with the amount of reinsurance protection Medicare provides to plan sponsors. This is driven by a few observations.

For several years, we've been pointing to the aggressive growth in open-ended reinsurance spending that is unsustainable. It has grown by about 250 percent between 2007 and 2014. Our report last June describes a bidding incentive that pushes more spending into the catastrophic portion of the benefit, where Medicare bears the vast majority of the risk. This has resulted in Medicare's subsidy that's above the 74.5 percent specified in law.

Another observation is that although plans are on the hook for 15 percent of spending, that amount may be less than the rebates plans get on brand-name drugs, so they may not have strong incentives to manage catastrophic benefit spending.

Reducing Medicare's reinsurance from the current 80 percent to 20 percent addresses these issues by putting greater pressure on plans to negotiate lower prices and

manage benefit spending. This would tend to lower costs. But some plan sponsors, particularly the smaller ones, may need to build in risk premiums or purchase private reinsurance, and this would tend to raise costs. On net, we expect this policy would produce a small savings to taxpayers and to Part D enrollees, particularly when plans are given more flexibility with their formularies.

The second piece relates to how manufacturer discounts are treated for the purpose of determining when a beneficiary reaches the out-of-pocket threshold. PPACA gradually eliminates the coverage gap, and one part of that includes having brand manufacturers provide a 50 percent discount to non-LIS beneficiaries. That discount is treated like beneficiary out-of-pocket, and this has a significant implication for the program costs.

While we understand the goal, this leads to inequitable treatment of brand and generic drugs and reduces incentives for non-LIS beneficiaries to seek generics when they are available. And with more high-cost drugs and general growth in prices, when beneficiaries use brand-name drugs, this policy moves more of them into the cap, and that increases costs to the program and taxpayers.

In 2016, an enrollee using only brand-name drugs in the coverage gap would reach the cap at about $7000 in total spending compared to about $10,000 for an enrollee using only generics in the coverage gap.

A remedy would be to no longer count the 50 percent discount toward the cap. In 2013, this policy would have resulted in about half of the high-cost, non-LIS beneficiaries no longer reaching the cap. Those beneficiaries would pay more cost sharing, and manufacturers would pay more in discounts. The other half of beneficiaries would also see increases in cost sharing and manufacturer discounts, but when combined with the catastrophic protection that we'll talk about next, many will come out with lower out-of-pocket spending overall.

This policy puts brand-name drugs on more parity with generics. Without this change, the manufacturer discount effectively works like a copay coupon. By filling in the cost-sharing liability for the beneficiary, it disconnects his or her choice from drug prices, and that situation allows drug prices to be set higher without facing backlash from patients. Because fewer non-LIS enrollees would reach the cap under this policy, it results

in savings to taxpayers and to Part D enrollees.

The last piece would give "real" catastrophic protection by eliminating the 5 percent cost sharing above the cap. Currently, non-LIS beneficiaries have unlimited liability for 5 percent of all spending even after they reach the cap. This is concerning because of the expected influx of new high-cost drugs and biologics coupled with the general rise in prices. It is also concerning because they are exposed to 5 percent of the full price since the 50 percent discount in the gap no longer applies, and 5 percent of an expensive drug or 5 percent of a lot of drugs can be a substantial financial burden.

In 2013, a quarter of the high-cost, non-LIS beneficiaries spent about $2,600 in cost sharing above the cap. That amount accounted for about 62 percent of their total cost sharing because their drug costs above the cap were very high -- about $32,000 on average.

Adding a real catastrophic cap would protect all beneficiaries from unlimited financial liability, and because this makes the benefit more generous, this policy would increase costs to taxpayers and to Part D enrollees.

With that, here is Draft Recommendation 1. It

reads:

The Congress should change Part D to:

Transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent, while maintaining Medicare's overall 74.5 percent subsidy of basic benefits;

Exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending; and

Eliminate enrollee cost sharing above the out-of-pocket threshold.

CBO estimates that the combination of all three recommendations would lead to a one-year savings of more than $2 billion and savings of more than $10 billion over five years. Separate estimates of each recommendation are not available. Again, the CBO estimate is not just for the recommendation I just described, but also include two others we'll cover next.

Lower Medicare reinsurance would have offsetting effects on plan costs and enrollee premiums. Some plan sponsors may need to purchase private reinsurance which would raise costs, but sponsors may also manage spending more effectively and negotiate lower prices.

Changes to the "true out-of-pocket" treatment of

brand discount would result in higher cost sharing for all high-cost, non-LIS enrollees. In 2013, roughly half of those individuals would no longer reach the cap, and the other half would reach the cap and receive catastrophic protection. All non-LIS enrollees would benefit from more complete insurance protection provided by the real catastrophic cap.

The second draft recommendation relates to LIS copays that are set in law. This is motivated by a few observations.

Claims data suggests that generic use is lower among LIS enrollees who incur high costs than for other Part D enrollees, even in many common classes such as drugs to treat high cholesterol and diabetes. In 2013, generic use rates were 71 percent for the 17 to 18 percent of LIS enrollees who had high spending, compared with 86 percent for those who had lower spending. Some of that is for clinical reasons, but some of it may also be their limited financial incentives to use lower-cost drugs.

Use of brand-name drugs when generic substitutes are available increases program costs because Medicare pays for most of their cost-sharing, and it also increases the

number of people who reach the out-of-pocket threshold, increasing the reinsurance costs for the program. A concern going forward is that the current LIS copay structure makes no distinction between biosimilars and their reference products; they would pay the same brand copay. Studies show that financial incentives do matter, and a recent study by CMS confirmed that the effect is true for both low-income and non-low-income individuals.

In 2012, the Commission recommended giving the Secretary authority to change LIS copays to encourage the use of generics. The idea is that cost sharing can be lowered for generics and preferred drugs, coupled with higher copays for nonpreferred drugs. We may want to also encourage the use of biosimilars when it is clinically appropriate. This may lead to lower prices for biologics over time.

The key is to give the Secretary the authority to apply this policy when it's clinically appropriate and at copay levels that balance affordability with financial incentives. And it would only be in classes where generic substitutes are available.

This brings us to Draft Recommendation #2. It

reads:

The Congress should change Part D's low-income subsidy to:

Modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multi-source drugs, or biosimilars when available in selected therapeutic classes;

Direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multi-source drugs, and biosimilars; and

Direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.

The budgetary effects of this recommendation is part of the combined estimate, and a separate estimate is not available. Greater use of generics could lower copays for LIS enrollees, particularly if copays were reduced or eliminated for generics. Enrollees who choose not to switch to generics may pay higher copays for brand-name drugs or might not be as adherent to treatment.

DR. SCHMIDT: If plan sponsors are going to bear

more risk than they do today, they also need greater flexibility to manage benefits through their formularies. Part D has more restrictions on formularies than what you see in commercial plans. We're going to walk through ways in which Medicare could allow more flexibility with formulary tools, which could give plans more bargaining leverage over drug prices.

Today, plans have to cover two distinct drugs in each therapeutic class and all or substantially all drugs in six protected classes. In 2014, CMS proposed removing two classes from protected status -- antidepressants and immunosuppressants for transplant rejection -- based on objective criteria. However, the proposal was never implemented. Both of those classes have a number of generic drugs in them, and when generics are available, commercial plans are more likely to offer several distinct drugs on their formularies.

A second area for flexibility relates to when and how a plan may change its formulary. Plans submit their formularies to CMS in June before the start of a benefit year, and CMS reviews the formulary to make sure it doesn't discriminate against certain groups of beneficiaries.

While CMS wants plans to keep the formularies that they used in their bids, there are situations that could warrant a formulary change, such as if new clinical information came out about a drug's effectiveness. There's a very limited window of time for plans to make changes before the start of the benefit year. We think it would be reasonable to give plans more opportunity to make changes between June and the start of the open enrollment period in October. Midyear changes are when a plan wants to make a formulary change during an ongoing benefit year. Plans can add to their formulary without CMS' approval, but they have to first get approval from CMS before making other changes, and they must give affected beneficiaries 60 days' notice.

CMS says that it would generally approve maintenance changes. An example is if a generic enters the market and the plan would like to replace the brand-name drug on its formulary with the generic. One flexibility would be to allow plans to make maintenance changes, the type CMS says it would normally approve, without first obtaining CMS' approval. The plan would still have to give notice to affected beneficiaries and to CMS, and the plan would be subject to enforcement action if it didn't provide

sufficient coverage in a drug class.

Medicare beneficiaries are starting to use more specialty drugs to treat certain conditions. Because of their high prices, commercial plans use additional tools to manage those medicines. Medicare could permit Part D plans to use selected tools to manage specialty drugs so long as plans maintained appropriate access to those medicines. One example is split fills: dispensing a 15-day first fill of a drug, and then thereafter regular 30-day supplies if the patient does not discontinue treatment. A split fill can reduce waste.

Another example involves using two specialty tiers: a preferred one with lower cost sharing and a nonpreferred one, so that the plan can encourage enrollees to use lower-cost biologics. Some plans in the Federal Employees Health Benefits program are doing this.

We also think it would be useful to lay out clearer expectations about the clinical rigor that prescribers should use when justifying a formulary exception. Some plans believe that when enrollees appeal, the plan's coverage decisions are reversed routinely, even when the supporting justification is extremely general.

This tends to undermine plans' formulary management, and it can affect plans' negotiating leverage with drug manufacturers over prices. At the same time, we want to try to reduce delays that beneficiaries face when they seek an exception for a drug. A beneficiary might not need to appeal if there was a clear supporting justification from the prescriber. We think Part D could use a more standardized approach toward prescriber justifications, including the requested medication, the patient's diagnosis, and the rationale for the exception. If this process were standardized and more predictable to the prescriber, it could limit the administrative burden and ultimately reduce beneficiaries' delays in receiving medications.

Part D plans are required to have exceptions and appeals processes for enrollees to help ensure that enrollees have access to appropriate medications, and we know that all stakeholders are concerned about these processes. We recognize that any recommended changes to formulary tools need to be accompanied by steps to improve Part D's exceptions and appeals processes. We've looked at data in the past, and we've seen very low rates of rejected

claims and appeals. But we were unable to say whether those findings were cause for concern. Sometimes claims can be rejected for valid reasons, such as exceeding quantity limits based on the FDA label. Sometimes the beneficiary ultimately get an appropriate drug by finding an alternative drug on the formulary. But low rates of rejection and appeals are more of a concern if an enrollee is discouraged from submitting an appeal. We believe there is a need to streamline these processes and make them more transparent.

CMS has run a small pilot with plan sponsors to test different approaches at trying to resolve beneficiary issues related to rejected claims at the point of sale. The pilot had mixed results, and plans found the process to be labor intensive. Beneficiary advocates would like enrollees to be able to receive clearer information at the pharmacy counter about why a drug was denied and what steps the enrollee needs to take next.

Another longer-term approach is to provide more information about plan formularies at the point of prescribing to help avoid the need for exceptions and appeals. Part D plans have to support electronic

prescribing, but e-prescribing is optional for physicians and pharmacies, and electronic prior authorization is not required.

Our third draft recommendation reads as follows:

The Secretary should change Part D to:

Remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern;

Streamline the process for formulary changes;

Require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions; and

Permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

Again, CBO estimates that the combined effects of all three of these draft recommendations would be to reduce program spending by more than $2 billion in one year and more than $10 billion over five years. This is a combined estimate. We don't have separate estimates for the pieces.

Dropping the two classes from protected status may, to the extent that enrollees use brand-name drugs, allow plans to negotiate lower prices. In turn, this could

help constrain growth in enrollee premiums. Some beneficiaries would need to switch medications, and those who choose to not take the formulary drugs in those classes would need to apply for formulary exceptions.

The other parts of Draft Recommendation 3 aim to give Part D plans greater flexibility to manage their formularies, but also improve the exceptions process so that it becomes less burdensome for everyone. If plans are able to manage the formularies more flexibly, it could reduce costs and help to constrain enrollee premiums. However, we recognize that some beneficiaries would need to apply for formulary exceptions and appeals, and some prescribers may find the transition to a more standardized approach to providing supporting justifications as burdensome.

Here is a summary of all of the draft recommendations. The recommendations make an interrelated package that's designed to improve Part D's market-based approach for the challenges that lie ahead.

DR. CROSSON: Thank you. Rachel and Shinobu, we'll take clarifying questions, starting over here with Craig.

DR. SAMITT: So in Draft Recommendation No. 1, all of the materials reference a reduction of Medicare subsidy from 80 percent to 20 percent, and I wonder why we don't reference it as plan sponsor increasing from 15 percent to 75 percent. And Jay and I talked about this. It's not clear, especially with the 5 percent above threshold beneficiary percentage. If that goes away, who assumes that 5 percent?

So if we use language, 80 to 20, it implies that 5 percent shifts to plan sponsors? If we say plan sponsors increase 15 to 75, it implies that that 5 percent shifts to CMS. Can you clarify that?

DR. SCHIMDT: Yes. If you have the hard cap, we are assuming that it would shift to the plan sponsors.

DR. SAMITT: Okay. Jay and I actually had a reverse discussion, so I think it would be helpful to clarify. Is that 5 percent out of pocket to plan sponsors, or is it to CMS? I think I hear you saying plan sponsors, but I thought Jay had specified CMS.

DR. SCHMIDT: If there were a hard cap in place, that means the Part D benefit would become more generous, and so the overall benefit, it still has the 74.5 percent

subsidy of the government, right? So that's Medicare's contribution. That's still heavily subsidized. It's just that the amount of spending above that out-of-pocket threshold, now Medicare would be providing 20 percent to reinsurance. The plan would have 80 percent insurance responsibility for that spending.

DR. MILLER: The reason I think it might be a little tricky is because to the extent that the cost of the benefit is built into the subsidy that comes from the government, 74-point-whatever percent, and then the beneficiary's premium. Ultimately, the cost of the benefit is paid from those two pods. So exactly who is sharing the cost, depending on what perspective you take from it, whether it's, all right, when you hit the cap, how is this allocated versus what is the cost, where does the cost come from in paying for the benefit, you can get slightly different answers.

DR. CROSSON: Jack.

DR. HOADLEY: I just want to ask a couple of clarifying questions where I think I know the answer, but I just want to get a little more clearly on the record.

On the first recommendation -- and it's

specifically the point that came up on Slide A -- the higher level copay for the biosimilars, is that due to the way the statute today is worded as opposed to a policy that CMS has set?

DR. SCHMIDT: I think that's correct, yes.

DR. HOADLEY: It's a statutory basis. So that's, thus, the recommendation, incorporates making that change to statute.

On Recommendation 3, the --

DR. SCHMIDT: Jack, actually we're --

DR. HOADLEY: Sorry.

MS. SUZUKI: We'll get back to you on exactly where that comes from.

DR. HOADLEY: Okay.

MS. SUZUKI: It may be because of the language, the definitions of multisource drugs, that's included in the lower copay category, but we'll double-check.

DR. HOADLEY: Okay, thank you.

On Recommendation No. 3, on the second bullet of that, is there any intent in the wording of this recommendation to change the current standards that CMS establishes for allowing formulary changes and particularly

the negative formulary changes, the non-maintenance ones, or is it just a matter of the process that plans would go through to request and get those changes approved?

DR. SCHMIDT: So we talked about -- we described two varieties. One is for the upcoming benefit year, but for the midyear changes. So that the change in process that we're envisioning is that the plan would be able to go ahead and, for example, if a generic comes out, put the generic on its formulary, remove the brand without getting CMS approval first. Currently, they're supposed to get CMS approval. CMS says if they would generally approve those situations, if they're silent about that for 30 days, they could go ahead. So this is -- that's what we're envisioning there.

DR. HOADLEY: Right. So it's things that normally seem as would have approved but may not have done so on a timely basis.

On the third bullet on this recommendation -- and again, you talked some about this in the presentation, but I'd just like to hear it again as a statement -- is there any intent to make these exceptions harder to obtain, or is it more about the process and the standardization?

DR. SCHMIDT: Yeah. I think the goal is to have broader consistency across prescribers in terms of what sort of clinical information they need to provide, so that the process becomes easier for everyone, so that there is less delay for the beneficiary in getting the medications.

DR. HOADLEY: And then on the last bullet on that recommendation, I just want to get it again and say whether the notion of this recommendation is to permit the specific tools that you've talked about in your examples or it's more about encouraging the Secretary to look for -- to add to the arsenal of tools that would be available to plans.

DR. SCHMIDT: We would certainly hope that the Secretary investigates these things. We did in particular write about a couple of ideas, split fills and a couple of specialty tiers, but we would expect that the Secretary would investigate these first.

DR. HOADLEY: Right. Thank you. That's very helpful. Thanks.

DR. CROSSON: Clarifying questions?

MS. BUTO: So, Rachel, I'm not sure I totally got, in relation to Jack's question, are the midyear changes for non-maintenance changes in the formulary -- are

we recommending that the plans have the flexibility to proceed with those, or is there more of just a streamlined process?

DR. SCHMIDT: We actually are silent as to the non-maintenance changes. We have only spoken to streamlining the approach for the maintenance changes.

MS. BUTO: Okay. Because I have a concern that the non-maintenance changes could be one of those bait-and-switch kinds of situations where the beneficiary actually went to the trouble of looking at plan finder, finding their drugs, and then something significant happens to take some of those drugs off midyear. So that would be a concern. At least for now, I think it's appropriate that we're silent on that.

The second one is for the appeals process. I have to believe that although we would like to see a standardized approach, there would be likely more rigor attached to the appeals. So I guess I'm thinking there would be some reduction in appeals granted, but I think that's, in a way, the purpose, which is to make sure that they're appropriate, if I get that right. And do those appeals approaches also apply to the midyear changes or

not? Is that not something that is subject to appeal?

DR. SCHMIDT: I think if there were a clinical reason for -- and to take the example of replacing on a formulary, the generic, a new generic that comes out and removing the brand.

MS. BUTO: Right.

DR. SCHMIDT: If there were a clinical reason to continue with the brand, yes, you could apply for it.

MS. BUTO: Okay. Thank you.

DR. CROSSON: Rita.

DR. REDBERG: Thank you.

On page 12 in the mailing materials, there was a reference that the majority of Part D plans in the last eight years are in substantially higher profits than they had built into the plan bids. Do we have any understanding of what was going on behind that?

MS. SUZUKI: So one of the things we wrote in the June report last year is that plans receive two subsidies, direct subsidy which covers the lower portion of the benefit primarily, and then there is the reinsurance, which is a cost-based reimbursement. And around the direct subsidy, there is a risk corridor, which protects plans

from unusually large losses, but it's symmetric, so that CMS recoups a portion of the payments that are higher than what they had bid for. And the bid includes built-in profits, but plans on average were getting money back, paying CMS back for the extra profits they were making in that direct subsidy portion of the benefit. So that's what we've been observing for pretty much all of the years from 2007 through 2013, '14.

DR. REDBERG: In the aggregate.

MS. SUZUKI: In the aggregate.

DR. REDBERG: Maybe I need to work more on it because that kind of relates just to my other question, which was on page 15 on the mailing materials, which then in that second paragraph, it says that the direct subsidy payments on which sponsors bear the most insurance risk has grown slowly, while the other, the benefit spending on which sponsors bear no insurance risk, like the LIS cost sharing, or the limited risk, catastrophic portion, has grown much faster. And I was wondering what was behind that.

DR. SCHMIDT: So that's just an observation from looking at growth in program spending. So the pieces of

Draft Recommendation 1 related to the reinsurance and changing, putting plans more at risk for some of the higher spending, reflects our reaction to this past work that we had done that we have written about in the June 2015 chapter.

So we've seen very flat average enrollee premiums over time, especially in recent years in Part D, at the same time that we've seen reinsurance spending growing fairly dramatically, and so that's the genesis behind the first piece of Draft Recommendation 1.

DR. MILLER: The three dots that I kind of organize in my head is that if there are price increases and more people becoming eligible, that's going to drive more of your catastrophic cap.

The second thing -- and I thought this was her first question, and I wasn't quite sure I followed the exchange, and so I apologize. Based on that work you did last year, we found the structuring of the bids that was also pushing some of the expense into the catastrophic cap and resulting in the government paying more than its fixed percent in loss subsidy.

And then the third piece that pushes things into

the cap is the discount that we've been talking about, and that accelerates it.

At least when I think about this, right before I go to sleep each night, that's the three things that motivated -- and I thought her first question was about the structuring of the bid, but I may not have understood your question.

DR. CROSSON: Scott.

MR. ARMSTRONG: So my question actually is kind of in the same neighborhood, and I realize what I'm thinking about and you've given a lot of attention to. So how do these changes have an impact on different groups of beneficiaries' out-of-pocket costs?

And the way in which these different component parts come together, we know that for a beneficiary who gets into the donut hole that then moves through the spend and the donut hole, they're going to be spending on average more than they otherwise would have under this proposal. But then they get to the end of the donut hole, and they're protected from that point forward, and so there's a smaller number of beneficiaries who would have been paying much more out of pocket if they had gone past that level in the

old -- before this proposal would be implemented.

But you've made an illusion to there's a third out-of-pocket cost that we haven't really spent much time talking about, and that's the premium that the beneficiary would pay for the insurance to begin with. My understanding, my sense is that, given these exchanges, you would expect that there would be some upward pressure on those premiums themselves, but we don't make any estimate around, well, what kind of pressure would that be, and so I'm just wondering, first, is my assumption right? Am I thinking about that correctly? And then, second, do we have a feel for what that upward pressure would look like? Because that does become a new out-of-pocket cost for beneficiaries who are rolling in the plan.

MS. SUZUKI: So the first 80 to 20 percent reduction, that we think is a net reduction in benefit cost. So on net, there would be a lower premium that Medicare beneficiaries would pay from that provision.

The two others -- so the true out-of-pocket provision, we said that it reduces the number of people who reach the catastrophic phase, and that is on net a lower cost for the Part D program. So that tends to reduce the

premium for the Part D enrollees.

The third one is making the benefit more generous, that as to the cost of the program. When we look at the 2013 claims data to see what the magnitude of change would be, it was fairly small, but the two changes in the premiums from the second and third parts of the recommendation, they're about the same size in magnitude, at least with the 2013 data. So on net, for those two things, I think it's a wash.

There is the 80 to 20 percent reduction that we still think is a net reduction in benefit cost that lowers premiums.

DR. MILLER: Your whole exchange so far -- and again, I want to be sure I'm following your question -- is about the puts and takes of the first recommendation. Across the three recommendations, the net impact is to lower the cost of the program, which should -- did I miss this? -- lower the cost of the premium.

So it depends that if your question was, narrowly, tell me about the puts and takes of the first recommendation, that's what she just answered. If you were saying what's the net effect of these three

recommendations, it's to lower the cost of the program and should take the premium down for the average beneficiary. Am I correct on this?

MS. SUZUKI: Yes.

MR. ARMSTRONG: I was thinking just about the first recommendation.

DR. MILLER: Okay. Then I apologize.

MR. ARMSTRONG: I have actuaries who I love but rarely really fully understand --

[Laughter.]

MR. ARMSTRONG: -- telling me that the plan responsibilities for above the catastrophic level will create significant pressure to increase the premiums for the insurance product itself. So what you're saying is, well, not necessarily, and all I'm saying is it just might be an area worth making sure we're really tight on.

MS. SUZUKI: One thing that I'll clarify is reinsurance that government provides currently is in the premiums now. Beneficiaries pay for that. The only portion that they haven't paid for is the net payment that Medicare makes at the end of a year because the estimated reinsurance that plans submitted were lower than the

actual. So that's the part that's not in the premium currently.

DR. MILLER: I'd like to say for the record, I appreciate you getting that actuary shot in right before the end of her last meeting.

[Laughter.]

DR. CROSSON: Of course, of course.

MS. UCCELLO: I'm going to butt in. Aside from the character issue --

[Laughter.]

MS. UCCELLO: I just want to bring up the slight -- I think the idea here is that in terms of net claims, there's not going to be all that much difference with under just the Recommendation No. 1. The one thing that might just slightly put more upper pressure on would be if those plans now have to increase their risk premium, purchase their own reinsurance coverage on the side. So that I don't think that's going to be -- the magnitude of that, I don't anticipate would be huge. So on net, I think it's going to be kind of close.

DR. CROSSON: Just to be clear, there is no anti-actuary atmosphere here on this Commission.

MS. UCCELLO: Good.

[Laughter.]

DR. CROSSON: Further clarifying questions? Warner.

MR. THOMAS: In Recommendation 3, with the removal of the antidepressants and immunosuppressants, do we have an idea of how many people that impacts? And as we've thought about that, I mean, obviously you could -- as Commissioner, you could be concerned about the impact on beneficiaries, and I know you've done a lot of review and study on this. So why do you feel comfortable with that recommendation, and how many people do you see potentially being impacted?

DR. SCHMIDT: So I guess our comfort comes from CMS having done a review itself internally with its own chief medical officer and pharmacist to review all of the protected classes and looking at treatment guidelines that are available and the degree to which those treatment guidelines mention specific drugs versus subclasses of drugs, and in these particular cases, that's the part of the justification that they used to make the recommendation that they did. Ultimately, it wasn't implemented, but that

was their position at the time.

In terms of numbers of people affected, the immunosuppressants, I don't have an exact number, but it would be very small.

For people who had their transplants paid for under Medicare Part B, their drugs are going to be paid for under Part B. There's going to be a small share of people who are going to get them under D. So it will obviously affect them.

I think about one in four Medicare beneficiaries has taken an antidepressant according to a CMS study I saw. So it's a large number of people. There are a large number of generics available in that particular class. Again, the treatment guidelines did not mention specific drugs so much as subclasses of drugs, and when we took a look at some of the commercial formularies available and looked at the antidepressant classes, they tended to include several different generics within subclasses.

DR. CROSSON: Just parenthetically, Warner, the exception process, of course, is still in place for the rare individual.

Alice.

DR. COOMBS: With the immunosuppressives, it's, like, we just have a blanket immunosuppressive, but there's subsets of the immunosuppressives, as Nancy pointed out earlier. With the renal failure patients, if they have transplantation, they may get the drug for a defined period of time but may be on lifelong immunosuppressive therapy. But, they lose their status as Medicare beneficiaries because they no longer have end stage renal disease. They are now with a functioning kidney. It might be to our advantage to just look at how small that number is. It may be infinitesimally small, but if it's a significant number, it means a burden, a lifelong burden of having to be in a high-risk drug class.

And, the appeals process is another way to address that, but I'm not sure that, you know, the -- it may be burdensome for this particular subset of patients.

DR. CROSSON: Okay. I think that is the end of the clarifying questions.

So, how we're going to proceed here, as is our custom when there are recommendations on the table, I will start the discussion. We're going to have the discussion focus on one recommendation at a time, and then we will

proceed to vote on that recommendation and then we will discuss the second recommendation and then on into the third.

So, the Chair is open to comments with respect to recommendation number one. Let's go down this way, then. Craig.

DR. SAMITT: Thanks, Jay. So, especially with the clarification that the degree of shift of risk to the plan sponsors is really increasing from 15 percent to 80 percent, I think it further underscores the importance, and I know that the recent addition references language of transition. What I'm concerned about is that we don't specify more fully sort of the terms of that transition. This is quite a dramatic change. In prior meetings, we talked about sort of a ten percent transition over a six-year period. I would advocate for us to be a bit more specific because this is such a substantive reversal in risk sharing.

And, I also think that it will be very important over that transition period that we very carefully monitor the impact of this, because I think one of the weaknesses of this recommendation is we haven't really studied the

impact of this provision on plan sponsors and whether this will significant impact premiums or beneficiary access.

And, so, I will reluctantly vote in favor of this recommendation, but I'm not sure we fully understand the impacts of what this global recommendation will do and most certainly feel that we need to have a very careful transition process so that we can measure it, monitor it, and let it settle out appropriately over time.

DR. CROSSON: I think, without going back to the text, I think in the discussion of the transition, we can add some of that verbiage, careful monitoring, and make sure that it's not a superficial proposal.

Kate.

DR. BAICKER: So, I think the package together has some really nice features, and one of the things that I think is important is ensuring that beneficiaries have protection against catastrophic out-of-pocket exposure. And, so, I think it's important not just to think about the average change in spending per person, but think about what's happening out in the tail of potentially very high spending and how that protection is especially valuable relative to changes in the middle of the distribution.

So, while I have some concerns about exposing people in that doughnut hole to more out-of-pocket costs, and in isolation, I'm not sure that I would support that, in combination with providing the much greater financial support at the high-spending end of the distribution, I think the combination makes a lot of sense, and I think that the reinsurance -- the reframing of the reinsurance is supported by the data analysis you've done about the predictability of the basket of expenses to the insurer over time.

So, as a whole, I think that the package works well, even though any individual component might raise some more concerns.

DR. CROSSON: Cori.

MS. UCCELLO: So, I agree with Kate, and I'll pick up on the second part of this recommendation. So, in terms of the increasing the exposure on the beneficiaries, I think what we need to keep in mind -- and the chapter addresses this and frames it, I think, perfectly -- really putting on a level playing field the generic treatment and the brand name treatment, and the idea here isn't just to

simply increase out-of-pocket costs for beneficiaries, but to use their money more effectively, more efficiently, lower program costs. So, when possible, move more to generics.

And then, also, providing more pressure on plans and more encouragement for them to negotiate the price. What was added to the chapter about the manufacturers' coupons and how that kind of parallels this here, I think, really kind of makes that more clear about how, as currently structured, there's less incentive for those negotiations, but taking that away would.

DR. CROSSON: I could not have said that better if I were an actuary.

[Laughter.]

MS. UCCELLO: I'm not sure what I said.

[Laughter.]

MS. UCCELLO: And, on the reinsurance side -- I say this every time, but I'm going to take one last chance to say it -- this really does increase the pressure on the risk adjustment program. You already mention it in the chapter itself, but I just want to say it out loud. So, that whole program needs to be recalibrated, and also,

especially because we're giving plans additional tools, we also need to monitor how those are being used to make sure that networks, pharmacy networks, formularies, and those kinds of things don't discriminate against folks with especially high costs that aren't perhaps totally adjusted for through the risk adjustment program.

But, thank you. This whole -- I feel like we've been working on some of these issues almost as long as some of those PAC issues. I think it's come a long way. So, thank you so much for your work.

DR. CROSSON: Jack.

DR. HOADLEY: So, I, too, want to thank the staff for all this analytical work and working through this. And actually, you reminded me that well before I joined the Commission, we did an expert panel on the impact of the reinsurance and the risk sharing provisions and that was probably ten years ago. So, yeah, this has been an issue that's been on the agenda of this Commission for a long time.

I also want to thank Jay and Mark and the staff for working through with me some of the potential options and modifications, and I do appreciate a lot of the

improvements that we've seen in the chapter in this round.

On this recommendation, I still have, you know, pretty serious problems with the second piece of this, because I think we are passing along additional out-of-pocket costs, potentially up to a thousand dollars, to a set of beneficiaries, admittedly a small set, you know, 700,000 in total and maybe only half of that who will sort of get net negative. But, those are people who are already facing significant cost burdens, and I think it's unfortunate to be adding out-of-pocket costs to this particular small subset of people.

You know, you think about the fact that at the catastrophic point of $2,700 out-of-pocket, sort of the way it plays out under the current rules, that represents more than ten percent of the median income of a typical -- of a median Medicare beneficiary. So, we are talking about some pretty substantial dollars already incurred, and so people up in this range, I think this is difficult.

The problem is, and I tried to think about options for holding these beneficiaries harmless and talked with folks about sort of options in that direction, and the challenge is that we can't seem to come up with a way to do

that without increasing government costs and giving up some of the dollars from the manufacturer discounts, and so it's a net loss to do it, even though we would be protecting -- so, it right now feels like it would be viewed as too high a cost to protect these people in this particular way.

I mean, I do share the notion that sort of doing the counting the right way is a goal that we liked, and I wish we could come up with a way, perhaps continue to look for ways in the future to see whether there's a way to avoid placing this additional burden on these beneficiaries and that we monitor sort of the impact of this as time goes by, because it is clear that, and you guys were very clear about this, you're using the 2013 data, the most recently available data that you have, but the dynamic changes that are going to happen both from the continued phase-out of the coverage gap and the behavioral response of beneficiaries, plans, manufacturers, everybody to these changes will mean that the numbers in the future will look different. We just don't have a good way to tell how. And, so, I do think it would be ideal if we could come up with a way not to add this cost to the beneficiaries.

Having said that, I think that pieces one and

three of this -- the first and third bullets of this recommendation -- are good ones. As I said, we've been thinking about the reinsurance issue for a long time. I completely agree with Cori that there are corresponding changes in risk adjustment, and you do talk about that in the chapter.

I also would point out, because it hasn't been said out loud here today, that we are not proposing any changes to the risk sharing, the risk corridors, and I think we could even maybe make that point more clearly right in that same context, and that continues to provide a protection, both for the government, but also for plans that face unexpected risk, and specifically the kinds of things we saw with Hepatitis C, where a new drug came online after some of the bidding was already thought through, and that's going to happen again in the future at some point, we can be pretty sure of that. So, we are maintaining that system as another protection.

I will support this recommendation as the collective package, because I think the net effect of the three policies is a positive one. And I really do think that removing the cost sharing after the catastrophic

threshold is going to make a big difference. There are people up there -- you know, we talk about the averages, but as Kate and others have talked about, there are people up there at the tails of the distribution for whom the costs are very, very high, and this is going to be a huge benefit for people at that end.

So, yes, I will support this, but I do want to continue to make the point about my concerns on the second piece of it. So, thank you.

DR. CROSSON: So, I'm going to interject here for a second. I think this Commission has had a compelling interest, at least for the last two years since I rejoined the Commission, in addressing the cost of pharmaceuticals. It's a public interest. It's also an interest of this Commission. And the concern is, of course, not just with the current costs, but the costs coming down the line with the introduction of new pharmaceuticals, and the net impact of that over a period of years, both on beneficiaries' costs, direct and indirect, and also on the long-term sustainability of the Medicare program.

In this session and with this set of recommendations, we are addressing one part of this, the

Medicare Part D prescription drug benefit. In other work, which is continuing, we'll be addressing issues with respect to Part B.

In both cases, however, these deliberations and the evolution of recommendations have been a good deal more complex than other judgments that we traditionally make here about how Medicare pays for care services, because in the other cases, other than pharmaceuticals, Medicare is the direct pay -- price setter and direct payer. In the case of pharmaceuticals, both in Part B and Part D, Medicare pays indirectly and is not directly involved in setting the prices, for the most part.

So, in order to address successfully changes in Part B and Part D, we have much more complicated work to do, and today, in the case of Part D, it involves very complex relationships, in this case, between plans and beneficiaries. And there's no way to escape that.

I think that, in sum -- and others have said this -- not just with respect to recommendation number one, which we're addressing now, but the entire package of recommendations, we have -- the staff has constructed and we have helped construct a pretty well balanced set

together of recommendations that take into consideration the interests of beneficiaries, the interests of the long-term sustainability of the program, and the long-term -- and also the viability of plans.

Now, having said all that, the one area I think, and we've heard it expressed already, of concern about the recommendations is the potential impact on beneficiaries within the coverage gap, particularly beneficiaries who are not LIS beneficiaries, but, as Jack maintained, of low income and potentially vulnerable, particularly financially vulnerable.

As Jack said, we did explore -- I explored with him some potential solutions to that. It happened that those solutions were rather costly and undermined our mission to protect the long-term viability of the Medicare program.

Having said that, I think that there is a valid issue here and I think as we finalize the text supporting this recommendation, I'm going to suggest that we include language to suggest that, assuming that the net, the sum of all our recommendations ends up saving money for the Medicare program, that Congress consider methods to protect

this subset of beneficiaries within the coverage gap.

Okay. So, we're comments on this side. We'll go up this way. Bill.

MR. GRADISON: I'm really picking up on your comment. My understanding is that these are -- not only are these three a package, but the three recommendations are a package, and I'm concerned a little bit about how we can present that. It's easy for people on the outside, and perfectly understandable if they say, well, I like A, but not B and C. Fine. And, maybe what I'm going to suggest is already contemplated, but I would hope that the actual report doesn't say recommendation one, two, and three. It says, here are recommendations, and put them on a single list, which I think will tend to emphasize the idea that it's a package.

DR. CROSSON: Do you want to comment on that?

DR. MILLER: I don't know about the one, two, three, and what we typically do off the top of my head. But, the notion of saying that we've thought about this as a collective set of actions, I have no problem emphasizing that. It was thought about that way. I mean, recommendation three, you know, I don't know why it's

number three, but it's very much because we're asking the plans to take more risk in recommendation one. So, the notion of the connection between these things, I don't have a problem with at all. The actual literal layout in the report, I'll talk to Jim about.

DR. CROSSON: Kathy, and then Scott.

MS. BUTO: Yes. I would just echo Craig's comment about the reinsurance subsidy transition and trying to be a little more explicit about, even though we may not want to put a number on the number of years transition, I think it is important, because it is a fairly big change that requires plans to either get additional reinsurance or make other adjustments that are fairly complex, and the program they need, I think as Cori mentioned, to do some further work on risk adjustment. So, it just seems to me that taking this step-wise would be a good idea.

Like Jack, I have real issues with the second bullet, and what I'm thinking is this, that the additional out-of-pocket cost to the beneficiary, which on average is $1,000, but, of course, there's a range, as Shinobu has pointed out, that that additional cost will lead some beneficiaries to switch to generics, and that's a very good

thing, assuming that they get the same benefit. Some will not be able to switch. And I think that there's a third category of individuals who may not be able to switch and who can't afford it, in which -- and, of course, Medigap does not cover copays in this coverage gap. And, so, they may actually have been in that group that would have reached the catastrophic cap, but won't because they can't afford the medications and so, therefore, won't comply with their medication regimen.

And, there really isn't -- as I thought about this in terms of appeals, there's really no appeal to that, because you're essentially saying, I can't afford the medicine. Now, maybe -- I think Jay has suggested there may be a way to devote savings in some way to mitigating the impact on those beneficiaries. But, it's just something I think either that, first, it would be good to mitigate the impact. I don't know how we would discriminate, but in some way trying to address the issue of affordability, because the original intent of the 50 percent discount was to reduce the beneficiary out-of-pocket by 50 percent. So, what's happening now is it's not reduced. It's just spread out over a longer period of time

and their out-of-pocket will essentially be what it was before the 50 percent manufacturer discount.

So, the other thing I'd like to see us mention is monitoring access as part of this change, that if there are changes, adverse impacts, there be some way that that's -- the plans or the program tries to get a handle on if this is having an adverse impact on access.

DR. CROSSON: Thank you.

DR. HOADLEY: Follow up on that, just quickly?

DR. CROSSON: Sorry. Jack, on this point?

DR. HOADLEY: Yes. I mean, there is an empirical literature that I've contributed to that looked at the original coverage gap and the impact on people stopping their medications. So there's something that we could cite to sort of back up that point, I think.

DR. REDBERG: I want to also commend Rachel and Shinobu for this chapter, which is a very interesting and complex area, but very important to the Medicare program because I think we've all agreed that we're clearly facing higher drug prices, higher program costs, and sustainability of the program. Particularly, we know since 2009 more than half of the FDA's approvals for new drugs

are specialty drugs, and those are very expensive drugs. So I think -- and this trend will continue and become a huge pressure on the program, and so I think we have to think about this in the long term and not just sort of the short term, because in the long term, you know, can we continue the sustainability of the program and providing our beneficiaries what they need?

And so I think the package is a really important step towards moving there. On its face, the idea of 50 percent brand-name discounts counting as spending that they didn't spend doesn't make a lot of sense, and it does encourage high prices and it encourages brand names, neither of which we're trying to do. We're trying to discourage high prices, encourage lower prices, and encourage generics. So it does make sense to me not to continue that.

My hope is that there will be less beneficiaries getting into that coverage gap, because if we are successful in, you know, driving a little pressure on drug prices, which there seems to be very little right now, less beneficiaries would get to that coverage gap, and, therefore, I would hope that they're protected more in that

way.

And my concern, I would say, isn't -- I'm concerned about access, but I think what we need to be really monitoring is outcomes, because also there's a lot in this chapter, and I commend it on polypharmacy and adherence. But, you know, right now more than three-quarters of Part D beneficiaries are on two or more drugs a month. That's a lot of drugs for a lot of people. And I think we just want to be sure that that's really in their interests, and so we really need to be looking at health outcomes, not just adherence and access, and we want to be sure. So I would hope what we're tracking is actual things that matter to beneficiaries is how are they feeling, are they living longer, things like that, in addition to other things we're tracking.

DR. CROSSON: Thank you.

MR. ARMSTRONG: So just a couple of brief points.

First, I just want to generally affirm that I think it's great work, and I'm thrilled that the Commission is advancing this topic. It's overdue, and we're obviously not the only ones paying attention to this right now. But that's just affirming how important this agenda is. It's

messy. Just the complexity of these proposals we're talking about, you know, makes that pretty clear. And yet -- and some things that we will promote will get implemented and will work well. Some things we advance will get implemented and will not work so well. But at least we're advancing ideas, and I'm just thrilled that we are doing that.

I want to just piggyback on a couple of points around -- you know, building off my question earlier on the impact on premiums, I like this idea of being a little more explicit about the need for some kind of transition process, though I don't -- I wouldn't delay it. I mean, I would exercise a lot of impatience about moving this forward, but just a little more clarity around what that process would look like I think is a good idea.

Bill made this point: We're talking about Draft Recommendation 1, but to me 1, 2, and 3 have to be part of a package deal, particularly some of the tools in part 3 are how you make some of these recommendations in number 1 kind of work and make sense. And I thought Rita's point particularly around what are we doing to keep people from ever even hitting the coverage gap and how can we do a

better job of that is really, I think, an important question to put on the table.

And, last, in our comments there has been a lot of concern expressed about the increased out-of-pocket costs for those beneficiaries who get into the coverage gap and who move into it and potentially all the way through it. And I think that is a downside from our beneficiaries' perspective to this package of proposals. But I would just say I'm not that concerned about it. I mean, I would just invite us to put it into perspective and to acknowledge first this is an incredible benefit. I mean, this is an incredible benefit. And, second, relative to the out-of-pocket costs beneficiaries pay in other parts of the Medicare program, whether it's hospital services or premiums for Medicare Advantage benefits or anywhere else, let's remember this isn't the only place where they're incurring costs. It's part of an insurance program. It's part of how it works in our country. And so I think we should be aware of it, sensitive to it, but it's kind of the way the program works, and so let's keep in context. And even comparing Medicare to all the other insurance products in our country, this is still a really excellent

benefit on average.

So I like the sensitivity and the acknowledgment that we ought to attend to this, but I'd keep it in perspective.

MS. UCCELLO: Just quickly, I want to address this transition issue. I know that people are for including more explicit language about a transition, but I just want to caution us before -- you know, I'm fine with it, but I think we also need to consider whether there are any downsides to drawing out a transition, and I can think of a couple, and one of them would be that now this risk adjustment model every year has to really be redone as the plans are taking on greater liability. So you've got some complications there.

Also, in terms of plans -- and Scott and Craig are going to know more about this than I do, but as plans are taking on more liability, is it really better for them to take it on gradually and then kind of gradually have to address these issues of, well, can they handle that themselves? Do they need to get their own reinsurance privately outside the system? What kinds of things go into that? I don't think it's cut and dried that it's necessary

better to lengthen the time of this rather than to get it all over with it once. Just something to think about.

DR. BAICKER: Cori's point about the importance of the risk adjustment rising as you go to this different model is, you know, really important, I think, and it highlights another thing that we might want to be sure to keep an eye on during the transition or the adoption of some of these provisions, and that's the protected classes. We haven't talked much about -- we've talked a lot about concern that beneficiaries have access to the right drugs for them in those circumstances. We haven't talked as much about the implication for cream skimming. You know, part of the concern for the protected classes is that you can try to avoid enrolling particularly expensive beneficiaries by having a stingy formulary in that area, and that's another reason to have protected classes. And we haven't talked much about the implications for that, and that's something that I think the evidence you've presented suggests that that should be not a first-order problem, but that it's something I would want to have in the mix for continuing to keep a close eye on, and also harkens back to the risk adjustment that it's particularly important that

the risk adjusters capture the expected costs of those beneficiaries or the removal of the protected class could lead to further cream skimming.

DR. CROSSON: I think we are going to add -- if I'm wrong, correct me -- language about monitoring with respect to the protected classes.

Seeing no further hands, we will proceed to vote on Recommendation 1. It is before you. I won't read it over again. All Commissioners in favor of Recommendation 1, please raise your hand?

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: The recommendation passes unanimously.

We'll proceed to a discussion of Recommendation 2, if we could put that up on the screen. Comments on Recommendation 2, starting here with Craig.

DR. SAMITT: So, likewise, I am similarly supportive of this recommendation, and, again,

congratulations on the wonderful work with the whole chapter.

The two perspectives that I would bring about this recommendation relate to the notion of preferred pharmacies and the relation -- and the notion of our silence regarding brand drugs in the second subcomponent of the recommendation. So let me take them in turn.

If I recall correctly from our prior work, we suggested that some of the dramatic increases in drug costs in the LIS population were both due to excessive brand use plus -- but also due to excessive use of nonpreferred pharmacies. And so my observation is it feels as if there is an opportunity here, since we're talking about a differential cost sharing for generic versus brand, that we also develop a mechanism here for us to have differential cost sharing for preferred versus nonpreferred pharmacies. And I recognize the fact that we have some concerns about access or geographic limitation to preferred pharmacies, but I would love to see the data that highlights where we actually have access gaps with preferred pharmacies, or at least what we could offer is the recommendation that there's differential cost sharing in markets where there

are adequate network access to preferred pharmacies with exceptions applied to areas where there are not. So it feels to me like we're missing a golden opportunity to influence costs by not including some reference to preferred pharmacy versus nonpreferred.

The second sub-recommendation talks about reducing or eliminating cost sharing for generic drugs, but it doesn't talk about increasing cost sharing for brand drugs. And so don't we believe that this would be a more impactful recommendation if we actually do both?

So, again, I'm favor of the recommendation, but would propose those two modifications to the recommendation to make it stronger.

DR. CROSSON: So, Craig, you're proposing that we alter the recommendation, each of these recommendations? Bullet points. I'm sorry.

DR. SAMITT: Or at least the Commission consider that, yes.

DR. CROSSON: Okay. Let me take the first part.

With respect to preferred pharmacies, I think you raised the point, which is probably the reason that it's not in the recommendation, and that is that at this point

we don't have -- we don't feel, Rachel and Shinobu as well as the Commission in reflecting on our conversations at least at the last meeting, we don't have confidence that we know the impact of requiring the use of preferred pharmacies on perhaps the most vulnerable beneficiaries. And I think you acknowledge that.

So my sense of that -- and I think I would agree with the intent of what you said, which is that that is a reasonable thing for us to pursue. I'm not sure, though, given the fact that we generally feel we don't have enough data, that I would suggest altering the recommendation today with respect to that point.

With respect to the second point, the recommendation is to direct the Secretary to reduce or eliminate cost sharing for generic drugs. If you go into the text, however, that supports the recommendation, it refers substantially to the CBO report, which referenced the potential for the Secretary to do both, as you said. And I think the sense we've had here is that the Secretary, irrespective of what we say in this recommendation, the Secretary, you know, armed with that information from the CBO, she will make the best judgment that she can at the

time as to what course to take. But we have not included it in the recommendation. We have included it in the text. And it is, you know, customary for the Commission to do that given the level of certainty and, quite frankly, support for certain phraseology. And that's my answer.

But if you would like to change the language of one of these bullet points, we'll take time. Write down the change that you would like to see, and we will vote on it.

Okay. Other -- Jack?

DR. HOADLEY: So I do support the recommendation. In doing so, I want to point out that, you know, to me the key part of this recommendation is encouraging the use of generics and adding biosimilars which, regardless of whether -- to my earlier question, whether it's specifically statutory or whether it's a more complicated interpretation of the policy, I suppose the term "biosimilar" would not have been in the statute since it hadn't been in use at that time, but that they do appear to require the higher-level copay and they were not specified in our previous 2012 recommendation on the subject. So I think adding that consideration, I think that's going to be

an important issue going forward.

In contrast to Craig's comment, I like the fact that we focus the recommendation language on the reduced or zero cost sharing for the generics and don't specify the higher cost sharing for brands. I recognize that that may be the inevitable way this policy proceeds. I actually think we would -- my preference would be to focus on lowering -- eliminating the barriers, in fact, going to zero for the generic copay, and I think that's -- you know, the point of this is really sending a signal to beneficiaries that these generics are something that they should be using and figuring out what the best way to send that signal possible and doing it more on the positive side than on the negative side, but, you know, recognize that other policies may pursue.

We also specify -- and I think it's significant -- that the revised cost sharing may need to vary by therapeutic class, and this, of course, does anticipate potential for the higher cost sharing for brands, and if so, we would do that only where there are real generic alternatives, because I think that's -- you know, if we simply raise the copay in the class that's solely brands,

then we're really just raising costs for low-income beneficiaries that we're otherwise trying to protect, and that those decisions -- and that's the third piece of this -- you know, need to be reviewed regularly because available drugs do change. And so what may work today may not work tomorrow, and so the notion of every three years, or at least every three years, is a good direction to go.

To the other issue that Craig raised on the nonpreferred pharmacies, I think, you know, I made points on this at the last meeting. I think the real concern to me is that in all the analysis that CMS has done on geographic access -- and they have found that there are gaps for some plans in geographic access to the preferred pharmacies, I don't think CMS has sort of gone what I would consider the next step with regard to the LIS population, which is are there specific -- they've looked at it broadly as a time and distance kind of standard across the population, and I think one of the concerns I have is that for this low-income population who may be clustered in certain geographic areas with limited availability to pharmacies and individuals who have limited transportation availability, that we may be in a situation where in some

of these communities the only pharmacies available to serve them are the independent pharmacies. In almost all cases where plans have adopted preferred pharmacy networks, they're operating with a particular chain of pharmacies. And so they may be -- and I don't absolutely know this is empirically true, but my impression is that in many of the sort of low-income neighborhoods, it's not the CVS or the Wal-Mart or the Walgreens that's in that neighborhood. It's the smaller independent pharmacy that's been serving that neighborhood for a long time. So I think to look at -- before we would ever consider moving forward, I really want to get some sense of those kinds of issues, and I have serious concerns about sort of the access problems that could arise in that. So I hope we don't, at least in this round, go further in that direction.

DR. CROSSON: Comments on Recommendation 2?

DR. REDBERG: I support the recommendations. Just on the question of access, you know, I think mail order is certainly available to all neighborhoods and is a very convenient way to fill, and I believe preferred pharmacies all mostly have mail-in options. So if we were concerned about access, I would concentrate on the

availability of filling prescriptions by mail.

The other comment I wanted to make -- and I was trying to find it in the chapter, but was just on biosimilars, a little out of our jurisdiction, but it is of concern to me that there's a great delay in approval of biosimilars. There's, I guess maybe today -- and a second one was finally approved, but until now, only one has been approved, and the delay is way longer than a year. I mean, this was an issue when I worked back on this in 2004. We were looking at -- it seems like it's been a very long time in coming. Clearly, lots of specialty drugs are very expensive, are increasingly being approved, and with this long delay at the FDA for approving biosimilars, it's certainly going to have an impact on CMS costs. And so I guess FDA needs more staffing in the biosimilar approval area, but that is of concern. But I'd support the recommendations.

DR. HOADLEY: And I would just add that the FDA still doesn't have standards on interchangeability, which will be an important component in acceptance of some of these biosimilars and how they interact in plan design.

DR. CROSSON: Mary.

DR. NAYLOR: So I support the recommendation as it is, and I think the issues that Greg raised are really very much worthy of further consideration, but I don't feel, especially given Jack's comments, that we have the evidence available right now to really think about -- there is a real robust evidence in the chapter about the value of eliminating or reducing cost sharing as a tool, and we don't have the parallel data about the adjustments in brand. So I would be concerned moving on that now and equally thinking about the issues around the low-income group and the impact of preferred pharmacy and adjustments without knowing what those specific implications might be related to access.

So I support the recommendations as is and think that these other issues are worthy of further consideration.

DR. CROSSON: Seeing no more comments, I think what we'll do here is proceed with the amendment that Craig has rendered.

I do want to point out one thing before we do that, which I think maybe we should have emphasized but didn't, and that is that this recommendation breaks down

into three bullet points, of course. The first bullet point directs the Congress to make changes. The second two provide advice to the Secretary, assuming that the Congress goes ahead and changes the LIS copayment structure.

The language we use in the direction to the Congress is broader and would potentially cover -- could cover, depending on how Congress chooses to act -- the concern you have.

So I think before we vote on the recommendation as a whole, I am going to read the suggested amendment by complete substitution. That reads: Direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars, and maintain or increase cost sharing for brand drugs.

Is that clear to everyone? We don't have the time to reject it. Kathy, would you like me to read it again?

MS. BUTO: No, no. I'm just trying to figure out how you direct the Secretary to maintain or increase. I mean, you're either directing to maintain -- because direct implies you're telling the Secretary that she has to do something, but you're saying essentially keep things the

same or raise them.

DR. BAICKER: It's the same as saying don't lower them.

DR. NAYLOR: Yeah. I was just wondering about the "maintain" because it sounds like that is what will happen. I mean, the Secretary will do what the Secretary wants, but that's what will happen.

DR. SAMITT: Yeah. And I think the purpose here was to include language to offer the option. Since the language is included in the chapter, that opportunity would exist to increase brand drugs, cost sharing, that that be made explicit within the recommendation that this was an option that the Secretary could consider as well, so we can strike "maintain."

MS. BUTO: So maybe the Secretary could consider --

DR. SAMITT: Right.

MS. BUTO: -- something like that.

DR. CROSSON: Okay. Second-order amendment, strike "maintain"?

[No response.]

DR. CROSSON: All right. So let me read it

again.

Somebody -- did I hear a voice?

DR. BAICKER: I just want to make sure I understand the process.

DR. CROSSON: Yes.

DR. BAICKER: You're going to read the amendment, and then are we going to vote on the amendment first, or are we --

DR. CROSSON: Yes.

DR. BAICKER: And then if we vote no on the amendment, then we vote on the original?

DR. CROSSON: That's correct.

DR. BAICKER: Okay.

DR. CROSSON: Sorry. I should have been specific. We're going to vote the amendment first, and then either that gets incorporated into the draft recommendation or it doesn't. And then, either way, we vote the recommendation. Everybody clear?

I'll read it again: Direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars, and increase cost sharing for brand drugs.

Everyone clear on that?

MS. BUTO: I'm sorry, Jay.

DR. CROSSON: That's okay.

MS. BUTO: We're directing the Secretary to increase cost sharing for brand drugs? That's the amendment? Okay.

DR. CROSSON: That's the proposal.

MS. BUTO: That's the whole proposal, or that's the amendment?

DR. CROSSON: This is an amendment by substitution means that we replace the one that's there with this, okay?

MS. BUTO: Got it.

DR. CROSSON: Everybody clear? David. No? Yes?

DR. NERENZ: Clear. I was just going to comment.

DR. CROSSON: Okay, go ahead.

DR. NERENZ: Well, now that it's clear, now it's very strong, and now I'm concerned about it because it allows no exceptions, and it doesn't have any nuance. And it makes a very blunt statement that I think as written that way would probably be interpreted more broadly than we intend or perhaps than the chapter indicated. So now it's

clear, but now it's very powerful.

DR. CROSSON: And here is a parenthetical by the Commission Chairman. This is why we don't do this, except in important circumstances. All right, okay. Because amendments on the fly are often tricky to understand like that.

DR. SAMITT: Well, Jay, let me ask you: How do we memorialize kind of the language in the chapter so that -- so maybe the language needs to be "consider increasing" as opposed to definitively increase, just so that it's a reminder in the recommendation.

DR. CROSSON: But, Craig, that is exactly what the chapter says.

DR. SAMITT: Okay.

DR. CROSSON: Consider increasing. Is that right? That's right. No, wait a minute. It's consider -- let's take a look. Sorry. The word "consider" is in there. I don't think the word "increasing" is in there. Let's look at how we worded it.

MS. BUTO: Jay, is there an objection to creating another bullet that just says "the Secretary should

consider whether to increase the copay," instead of lumping it together with all this direction? I think that takes a little of the --

DR. CROSSON: Right.

DR. SAMITT: I don't want to belabor this. I mean, if you feel that it's sufficiently covered in the chapter, I don't want to wordsmith.

DR. CROSSON: Well, wait, wait, wait. Let's check. what page?

DR. BAICKER: What page are we on?

DR. CROSSON: We're looking here. I know we inserted "consider" in here as we were working this through. Where are we? Here it is.

DR. MILLER: The recommendation would have the Secretary -- page 49. Is that right?

DR. CROSSON: Yeah.

DR. MILLER: Is this the language?

DR. CROSSON: All right. Here is how we worded it in the text, and this was a modification from March: The recommendation would have the Secretary consider moderately increasing financial incentives for LIS enrollees to use lower cost medicines, et cetera, generic

drugs, et cetera. So it can be read whichever way you'd like to read it.

DR. SAMITT: Again, I don't want to belabor it, but certainly the language regarding just reducing copays for generics would sufficiently constitute essentially that language. I certainly don't want to go against the grain. If the balance of the Commission doesn't feel we should have language about both reducing cost sharing for generics and increasing cost sharing for brand, but certainly that would make it more powerful.

DR. CROSSON: Okay.

DR. SAMITT: I'm happy to retract the amendment if that's not the general consensus of the group.

DR. CROSSON: So we have language in the text that can be read in different ways, and that was a modification. I think we have two choices. You can choose to retract the amendment by substitution, or we vote.

DR. MILLER: I think he's retracting, isn't he?

DR. CROSSON: I don't know.

DR. SAMITT: I would rather retract the amendment but modify the language in the report to be a bit more specific about the possibility of either reducing cost

sharing for generic or increasing cost sharing for brand, just to make it explicit that it could be one, the other, or both.

DR. CROSSON: Okay. I'm seeing what is often called a "bobble-head consensus" on the part of the Commission for that solution.

DR. COOMBS: I second the emotion to retract the amendment.

MS. UCCELLO: I just want to make clear here that I think we feel -- Jack, you can correct me if I am wrong, but I think that there is a preference, an empirically based preference for reducing, eliminating, as opposed to increasing. So if we do change the way this is in the chapter, I don't want to go too far the other way and put them on equal standing because that's not where I am.

DR. CROSSON: Right. Yeah. So that's the conundrum as opposed to dealing with the recommendations. If we're dealing with text changes, remember we have in the text the CBO report, which entails both. So that is put into the text, and it says the CBO says basically this is the impact of doing both.

We have inserted, then, language which allows for

interpretation on the part of the Secretary that could be read either way, and I think the general sense that we had there was, again, as Scott pointed out earlier, first of all, Congress has to do something before any of this happens, and then the Secretary is most likely going to use her or his, as the case may be in the future, judgment as to what course to take, and that by creating -- by emphasizing one report and by creating flexibility in our language, we have in fact provided the Secretary adequate flexibility.

So I said, flippantly, we had a bobble-head consensus. I don't believe that's the case because we just heard one objection, and I see another one potentially getting ready to come on to the floor.

DR. MILLER: Well, let me just ask one thing about that. Was your point that under no circumstances, the Secretary could raise it?

MS. UCCELLO: No, no.

DR. MILLER: So then I do think we still have a consensus.

DR. CROSSON: Well, no.

DR. MILLER: I think she just --

MS. UCCELLO: No, I think that --

DR. CROSSON: The question was, do we have a consensus around strengthening the language around raising brand-name copayments? I'm not sure we have that consensus, or do we? Jack?

DR. HOADLEY: My preference would be not to -- I mean, I think the language, as it stands, certainly encompasses the possibility of raising brand copays. In fact, the policy community, I think, has read the 2012 report as if it recommended that, even though it didn't, because there was enough talk about those kinds of options, as there is here, as one of the part of the menu.

But I think -- and Cory put this well. I think what I prefer and what I think the language captures today is that we think the more important case is sending the signal about generics by lowing it or turning it to zero, eliminating it. If a Secretary at some points wants to do -- because of scoring reasons or because of different evidence that might be available at the time this is done, wants to consider brands, there's nothing in our language today that would discourage them from doing that. And I think that's a good place to end up in my mind, and I would

not support the amendment of the current policy, and I would encourage us not to -- I think we have language that's good the way it is.

DR. CROSSON: Right. So, to get back to something, I don't see a Commission consensus to change the language in the text, and of course, this is very difficult because we're not even clear what the language change would be. So I'd come back to the point -- I'm sorry, but if we're going to make this change in this way or not, I don't see any solution here since we can't discuss vague language in the text, but either withdraw the amendment by substitution, or we vote on it.

DR. SAMITT: I would withdraw the amendment.

DR. CROSSON: Okay. The amendment is withdrawn. The recommendation is before you. Seeing no further comments, all Commissioners in favor, please raise your hand?

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Passes unanimously.

Let's move on to Draft Recommendation No. 3. Okay. Comments on Draft Recommendation No. 3? Craig.

DR. SAMITT: Sorry about this. I guess it's my day.

So I certainly comment and am in favor of most of the elements of this recommendation for all the reasons that we've discussed, that each of the subsections of the recommendations need to sort of ride together. We shouldn't be accepting them, each in isolation.

The one that I have questions about, I guess, that I tried to dig deeper in between the meetings and even in the chapter is the recommendation about the classes of clinical concern, and whether in particular we feel that the benefits of this change outweigh the risks of this change. And it wasn't clear to me the degree to which we would achieve savings to the program in removing these two sets of agents from the protected class, as well as the potential risks.

In particular, let's talk about the immunosuppressants, whether we feel that narrowing classes could result in transplant rejection and the costs that

would be incurred in other parts of the Medicare program and whether there would be financial risks to making that change.

So part of it is a question of how comfortable we feel with the clinical review to assure that there wouldn't be negative consequences either to a narrower class of antidepressants or a narrower class of immunosuppressants in a particular plan and the implications to that.

Again, I am certainly in support of tools that will enable plans to manage unsustainable increases in drug costs, but this one of the four gives me pause.

DR. CROSSON: Other comments on Draft Recommendation No. 3? Jack.

DR. HOADLEY: So, again, I support this recommendation, and I take note of Scott's and others' comments that it is important to do all the pieces of this, and so that's part of the spirit of it.

I do have some issues in this case. I have some of the same concerns Craig just talked about with the protected classes or the classes of clinical concern. I do think that choices of drugs in the antidepressant class and the immunosuppressant class can be patient-specific. I'm

not a clinician. I can't really speak as much as others to the clinical side of this.

I'm also somewhat skeptical that given some of the evidence we've seen and that is repeated in this chapter, how much more plan leverage is going to come out of this particular change and these two classes in particular. On the other hand, I'm comforted by the high prevalence of generics in this class -- and this was talked about in the presentation -- and the fact that in reality, plans include on their formularies, all or nearly all generics in any particular class. And so, as the world stands today, there's going to be a broad range of choice in these classes, and most likely, the problems are going to be infrequent.

There is the exceptions process, though. That raises the question of how well that process works. I would suggest that we add in the text that the status of any particular -- and this is really I think in the underlying statute, but we can point to that and reemphasize it, that the status of classes in this regard should be evaluated periodically, especially if new drugs come on the market. So if we have new products in either

of these two classes, that might cause a change in thinking down the line. I think that's in the Secretary's current authority on that, although have to make recommendations and go through notice and comment.

On the second piece of this, I think it was discussed in the clarifying round, we really aren't trying to change what goes on for the non-maintenance changes. It's really a focus on process things that means things that CMS would be inclined to approve don't make it into approval, either when a plan is planning its formulary for the next year or when there is a new drug at midyear and it's trying to make a midyear change to respond to the availability of a new drug, and we're really just trying to streamline that process. And I think that's fully appropriate.

On the exceptions bullet, again, my preference -- I talked about this at the last meeting -- would have been to have said more about some of the things that we've said in our 2014 report about greater transparency and streamlining the process, so that beneficiaries and physicians are not discouraged from seeking exceptions for needed medications, that there is a good discussion of that

language in the text of the report, and you actually made a very nice point of it in the presentation today. And I think that's -- while I would have probably tried to put in the recommendation, I think that's just an important point that needs to be reiterated as this is talked about.

One thought, one of the concerns I've heard is when plans have their request overturned and it may have to do with some of the issues around the right kind of justifications, that that then affects the star rating because one of the star rating factors is the rate of overturn. And maybe that's something in the future we should take a look at, whether that's a particular star rating manager that's having some sort of adverse -- is not meeting the purpose that it's intended to.

And I also appreciate the hope that's expressed in the text that a standardized process will actually help -- and this is I think the wording -- help expedite legitimate exceptions requests, and I think that's something, again, we need to monitor as this process goes on, and I hope we'll continue to look at the workings of the exceptions process.

And finally, on the last point, again, I do think

we want to encourage appropriate tools for managing specialty drugs. That is exactly what we're saying here. We've given some examples for the Secretary to look at, and I think there's some promise in those examples. I think the ideas of two tiers, although it will add complexity to the tier structure and that's the downside, the upside is if it can lower the cost sharing for biosimilars and one of competing products to move market to those products and save everybody money, then that will turn out to be a good thing. We need to think through that and understand that more.

So I think with those caveats noted, I definitely do support this recommendation.

DR. CROSSON: Thank you, Jack.

Further comments on recommendation number three? David, and Scott.

DR. NERENZ: A very minor wordsmithing thing on the last bullet. It's not clear as we've written it who's doing the selecting. Then there are two clear options. Either the Secretary is selecting and our chapter is just listing some examples of the range from which those selections might be made, or one could read this to say we,

the Commission, have done the selecting, and in the chapter there is a definitive limited list and that's what we mean by selected.

I think the intent here is the former and not the latter, and I don't propose that this wording be changed, but just some footnote or something in the text of the chapter might indicate which of these two possible interpretations.

DR. CROSSON: It is the former, and we can do that. And, parenthetically, in response to Craig and Jack, I think the notion of monitoring the classes is something we can do, as well.

Further comments. Scott.

MR. ARMSTRONG: Briefly, it's a little redundant to points I've made before, but I do believe the tools and some of the other component parts of recommendation number three are critical to the success of number one and number two.

I also just generally think it's worth reminding ourselves that through payment policy, we're trying to control a cost that is advancing at a pace that is not appropriate. We're not getting the value from this. On

the other hand, let's remember, investing in the right drugs improves health and saves costs in other parts of our system, and that really affirms the growing importance of having assurance that our beneficiaries are in a relationship with a care delivery system, where their prescriptions and how their prescriptions are managed as a part of their overall care is, in fact, well managed.

I mean, the percentage of inappropriate costs through the prescriptions our beneficiaries are getting is embarrassingly high. The costs of poorly managed drug therapy is incredibly high, not just in terms of dollars, but in terms of poor health.

One of the most important contacts that we have with new Medicare Advantage beneficiaries, for example, is to go through the long lists of prescriptions that our beneficiaries have that don't make any sense when you sit down and actually look at it.

And, so, plan sponsors should recognize that the importance of engaging, whether it is through these kinds of tools or more generally, in a real relationship that better improves the care for these patients is probably the most profound way of improving the overall cost trends for

the use of medications, and we tend to lose sight of that when we're worrying about the mechanics and the complexity of payment policy.

So, it's, I know, something we all agree with and would affirm, but I think it's just worth restating.

DR. CROSSON: Good points, and what you didn't point out is that this sort of management of the total health care dollar more or less exists within the Medicare Advantage program, and I think a lot of the work that we do here at the Commission, and I think we'll continue to do as we look at delivery system and payment reform, is try to understand whether, in fact, that can take place even in the setting of fee-for-service. It's much more difficult, because Parts A, B, and D are all separate with HIPPA regulations and the like. But, nonetheless, I think it has come up before on the Commission as something to explore and I hope that we will be able to do that, as well.

Further comments on recommendation number three.

[No response.]

DR. CROSSON: Seeing none, we will proceed to vote. All Commissioners in favor of recommendation number three, please raise your hands.

[Show of hands.]

DR. CROSSON: All opposed.

[No response.]

DR. CROSSON: Abstentions.

[No response.]

DR. CROSSON: It passes unanimously.

Rachel and Shinobu, thank you very much for this work and your patience during our discussion.

We will now proceed to the public comment period. If you wish to make a public comment, please come to the microphone, get in line so we can see who is going to be making comments or how many.

[Pause.]

DR. CROSSON: Okay. We have one individual at the microphone. I'll just emphasize the fact that although this is an opportunity to provide input to the Commission, it's not necessarily the best or most timely one. The MedPAC staff, both virtually and personally, are available during the period of time when these policies are developed. As well, we receive, both as Chair and Executive Director and Vice Chairman and other Commissioners, receive written information from interest

groups up to the time that we make these determinations. So, there are many other ways of making this input.

Having said that, please state your name and your affiliation, if any. When this light goes out, again, that will be the end of the two-minute period of time that you have for comments.

DR. VOTTO: Okay. I'll make it quick. My name is John Votto. I'm the CEO of Center Special Care in New Britain, Connecticut. It's mainly a long-term acute care hospital that provides all kinds of programs.

I think I understand the presentation of the unified payment system. I understand the statistical work that went into this and, you know, appreciate that. I also see the potential benefits of it. But, I also see a possible wild, wild West of players getting into any player taking any patient. That's my big concern.

I think I only have four points to make and one would be that the quality measures be across the continuum, and I'm not sure that they're established yet that we can go for ventilator outcomes across the spectrum right now. So, we know LTCHs have known it for a long time, but SNFs and, you know, home health care, I don't know how that

would all work. So, that would be one thing, that I think they need to be validated before this is rolled out.

The other thing is the regulations were mentioned and also the COPs were mentioned. I think that those have to be clarified, because, again, that would be how do we decide who's a hospital that can take wound patients and vent patients and those things, and those COPs, I think, need to be established.

You know, I do have a concern about how it affects beneficiaries, Medicare beneficiaries, because of copayments and coinsurance if you change the whole structure of hospital payments, hospital to hospital, those kind of things. So, I'm concerned about that.

And, the last thing is that payments do need to be aligned with the burden of care from the provider, so that if we're going to say that you're going to take vents, for instance, and you're going to be -- you're going to upgrade to this, you know, area, and we're going to pay for that infrastructure, which is not inconsequential, then there should be an understanding that that payment -- and I know high-cost outlier payments were mentioned, but we have to be careful about how we do that, because those can be

tweaked, but they may not be enough.

So, those are my --

DR. CROSSON: Thank you for your comments.

Seeing no one else at the microphone, we are adjourned for lunch and we are due back here at one o'clock.

[Whereupon, at 12:30 p.m., the Commission was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION

[1:07 p.m.]

DR. CROSSON: Okay. I think we can begin now. We're a little bit late, but not too bad.

So, we're going to have a session this afternoon where we kind of review what we've done before in our discussions with Part B, and then, I think, use this discussion as a launching pad for further work that we do into the next term to try to narrow the choices from among a very nice set that Kim and Nancy have put together. I think if we're going to move forward as we want to with recommendations, we're going to want to do the work to understand more deeply and narrow the set of recommendations that we work on into this coming fall.

We do have one recommendation here that we will be voting on today, and Kim, just looking at your body language, it looks like you're going to start.

MS. NEUMAN: Good afternoon. Today, we're going to continue our discussion of Part B drug and oncology payment policy issues that we began last spring and that we discussed most recently at the March meeting.

Today, we'll focus on three broad issues. First,

I'll recap the Part B drug payment policy options that we've been exploring, including an idea to restructure the six percent add-on to ASP as well as broader policy options that could have the potential to increase price competition among Part B drugs or put downward pressure on ASP.

Next, we'll discuss the Part B drug dispensing and supplying fees and Commissioners will vote on a recommendation to reduce these fees.

Finally, Nancy will review four case studies on improving efficiency of oncology services. Recall that the plan is that all of these ideas will get written up in a June report chapter.

Before we begin, I'd like to note that we've made modifications to the mailing materials in a number of places to reflect your discussion in March, some of which we'll highlight as we go through the presentation.

In addition, there was one question from that meeting that I'd like to address now. Kathy, you asked about how new drugs are paid under the ASP payment system when ASP data are not available. For the first six months, when ASP data are not available, a new drug is generally paid 106 percent of the wholesale acquisition cost,

referred to as WAC. If WAC data are not available, the drug is contractor priced if furnished in the physician office or paid 95 percent of AWP if furnished in the outpatient department.

This next slide has background on the ASP payment system. You've seen it before, so I'm not going to go through it now.

So, first, we'll talk about the ASP add-on. As we've discussed, the six percent add-on to ASP may create an incentive for use of higher-priced drugs, although it's hard to know if this is occurring because few studies have looked at this issue.

We modeled a policy option that converts part of the percentage add-on to a fixed fee that generates savings. The option we modeled is 103.5 percent of ASP plus $5 per drug per day. Overall, this approach is estimated to save about 1.3 percent, or about $270 million annually, and that's based on 2014 data, assuming no shifts in utilization in response to the policy.

The policy option has the effect of increasing the add-on for drugs with an ASP per administration of less than $200 and decreasing the add-on for higher-priced

drugs. The net effect of these changes would be to reduce Part B drug revenues for hospitals and specialties that tend to use high-priced drugs and to increase Part B drug revenues for physicians that tend to use lower-priced drugs.

In terms of other implications of the policy option, overall, changes to the add-on may increase the likelihood that a provider would substitute a low-priced drug for a high-priced drug when therapeutic alternatives exist. To the extent that this occurred, it would save more money than we estimated on the earlier slide.

Since these policies reduce the add-on payments for expensive drugs, it's possible that some small practices may have difficulty purchasing expensive drugs at the Medicare payment rate, but this would depend on how drug manufacturers respond to the policy change.

Some Commissioners have asked about how this policy option would affect the trend toward more hospital-based oncology care. It's possible that it could contribute toward that trend, depending on whether oncology practices had difficulty purchasing expensive drugs at the Medicare payment amount.

Next, we'll discuss three options that may increase price competition among Part B drugs or put downward pressure on ASP. The first one relates to ASP inflation growth. Increase in the ASP+6 payment rates for individual drugs are driven by manufacturer pricing decisions. In theory, there's no limit to how much Medicare's ASP+6 payment rate for an individual product can increase over time.

Among the 20 highest expenditure drugs, the median ASP growth has exceeded inflation since 2010. A policy option that could be considered is to limit how much Medicare's ASP+6 payment rate can increase over time. This could be done through a manufacturer rebate or a limit on how much Medicare's payment rate to providers can increase. These two approaches differ in terms of which entity bears financial risk. Under a rebate, the manufacturer would bear financial risk for price increases. Under a limit on provider payment rates, providers would bear the financial risk for payment increases -- or, excuse me, price increases.

Kathy and Bill Gradison, I just want to note, we expanded the mailing materials here to talk more about the

implications of these policy options for beneficiaries and drugs in shortage.

So, next, we have consolidated billing codes. Under the ASP payment system, most single source drugs and referenced biologics receive their own billing code and are paid based on 106 percent of their own ASP. This structure does not promote strong price competition among products with similar health effects.

In other work, the Commission has maintained that Medicare should pay similar rates for similar care. Given that principle, a policy option that could be considered is to place products with similar health effects in the same billing code and pay them the same rate. This would be expected to spur price competition and generate savings for beneficiaries in the Medicare program.

This type of policy could be considered for a couple different areas. One place is biosimilars and the reference product. Under current policy, all biosimilars associated with the same reference product are in one billing code, but the reference product remains in its own billing code. Instead, a potential policy could be to place all these products in a single billing code based on

the FDA's determination that they're biosimilar.

This kind of approach could also be considered more broadly beyond biosimilars and applied to other drugs and biologics with similar health effects. In this case, the Secretary could develop a process to obtain clinical input to identify products with similar health effects that would be appropriate to include in the same billing code.

Another approach that could be considered to spur price competition for Part B drugs is to restructure the competitive acquisition program. Medicare implemented a CAP program from 2006 to 2008. Physicians who chose to enroll in that program obtained drugs from a vendor rather than buying and billing Medicare directly for the drugs. The program faced challenges due to low physician enrollment and the vendor having little leverage to negotiate favorable prices.

Options to restructure the CAP program could be considered. For example, several steps could be taken to encourage physician enrollment. Physicians could be offered the opportunity to share in any savings from the CAP program. At the same time, the ASP add-on percentage could be reduced or eliminated in the traditional buy and

bill system, making it less attractive. And to reduce administrative burden on physicians, the program could be changed to a stock replacement model or a GPO model.

Second, to give the vendor negotiating leverage, the vendor could be permitted to operate a formulary and any savings could be shared with the vendor, too.

Finally, to the extent that the program led to lower prices, the savings could be shared with beneficiaries through lower cost sharing.

Next, we have the issue of the dispensing and supplying fees, an issue you will vote on today. As you'll recall, in 2014, Medicare and beneficiaries spent about $155 million on the Part B dispensing and supplying fees. In 2014, the inhalation drug dispensing fee is $33 per 30-day supply and $66 per 90-day supply of inhalation drugs. The supplying fee is $24 for the first prescription in a 30-day period and $16 for each additional prescription in that 30-day period for three categories of Part B furnished pharmacy drugs.

These dispensing and supplying fee rates were established in 2006 based on limited data. OIG reported that Medicare Part D and Medicaid paid dispensing fees of

less than $5 for these categories of drugs in 2011.

So, this brings us to the draft recommendation, which reads: The Secretary should reduce the Medicare Part B dispensing and supplying fees to rates similar to other payers.

In terms of implications, this draft recommendation would reduce Medicare program spending by between $50 million and $250 million over one year and by less than $1 billion over five years. The draft recommendation would reduce total Medicare revenues to these suppliers by less than five percent. And we do not expect an adverse impact on beneficiary access or providers' willingness or ability to serve Medicare beneficiaries.

So, now, I'll turn it over to Nancy to talk about oncology services.

MS. RAY: So, now, we are going to turn to the four case studies of approaches used by Medicare and other payers and providers that have attempted to improve the value of oncology drug spending. These case studies will be included in the June report chapter.

We focus on oncology drugs, chemotherapy, and

supportive drugs because Medicare spending is substantial, roughly $11 billion in 2014. Our preliminary bundling analysis included in our June 2015 report found that oncology drugs accounted for nearly half of a total six-month episode spending.

The case studies we are discussing today is a continuation of our June 2015 report chapter that began to explore approaches for bundling oncology services.

The first two case studies are relatively narrow approaches that affect the drug price and drug selection. Outcomes-based risk sharing agreements are made between payers and product manufacturers and oncology clinical pathways are used by some commercial payers and providers. The broader case studies attempt to redesign the delivery of care by affecting the use of drugs as well as other services, an oncology medical home implemented by CMS and an oncology episode of care approach implemented by a commercial payer. These are the same four case studies we discussed during the March meeting, so I'm going to describe them pretty quickly, but I'm happy to answer any questions at the end of the presentation.

So, regarding outcomes-based risk sharing

agreements, from the payers' perspective, these agreements are intended to improve the value of drug spending by linking the price of a drug to its effectiveness. In your briefing paper, we summarized an arrangement in the United Kingdom between the National Health Service and the product developer for Velcade, bortezomib, a product used to treat multiple myeloma, administered in the office or hospital outpatient setting. Under the agreement, the product developer refunds the full cost of the product to the payer for patients who have less than a partial response. The response is based on a biomarker for disease progression.

Outcomes-based risk sharing agreements have also been implemented for non-oncology drugs. Because these agreements are usually proprietary, we were not able to find current information online about the level of rebate or product replaced under this agreement.

Our next case study is oncology clinical pathways, and their goal is to reduce prescribing variability, maintain or improve quality of care, and reduce costs of care. Pathways are detailed evidence-based treatment protocols that identify specific treatment options based on maximizing survival benefit, minimizing

toxicity risk, and then cost. Pathways are more specific than guidelines, but often based on guidelines. Some providers have linked financial incentives to the use of pathways. For example, payment could be adjusted based on pathway adherence.

Rita, in response to your comment, the draft chapter summarizes some of the issues raised by researchers and stakeholders about the processes used to develop clinical guidelines and pathways.

Moving to the two broader approaches, the first is CMS's oncology medical home. Its goal was to improve health outcomes and through improvements in access and coordination of care, reduce admissions and ED visits and total cost of care. The oncology medical home builds on the concept of patient-centered care under which a designated provider is responsible for complying with several requirements, such as integrated care and enhanced access.

CMS provided a grant to test the Community Oncology Medical Home, COME Home. The demo ran between 2012 and 2015. Seven practices participated. Practices had enhanced capabilities, including same-day appointments

and extended and weekend hours. We are still awaiting for CMS's evaluation of the program that compares the outcomes of participants to a control group to see what type of effect the program had on outcomes and spending.

Herb, in response to your question, Medicare's local coverage determinations apply during the demo.

The last case study is an episode of care approach implemented by United Healthcare. Its goal was to reduce potential financial incentives to prescribe one drug versus another. The pilot paid participating practices ASP+0 percent and repurposed the ASP add-on as an episode fee. Practices were eligible for shared savings that was linked to improving the survival rate or decreasing cost.

Under the three-year pilot, total spending decreased, and this was linked to decreases in hospitalizations and radiology. However, drug spending increased. The larger scope of the episode means if a more expensive drug or longer chemotherapy regimen is appropriate, oncologists have the flexibility to do so without jeopardizing overall savings.

The upcoming CMMI oncology care model will test an episode of care approach for participating practices.

So, this concludes our presentation. You will be voting on the draft recommendation on dispensing and supply fees that Kim will put back up on the screen. This slide lists the other topics we discussed today, which will be included in the June report chapter.

Please let us know if there are any additional work on these topics that you would like us to pursue.

DR. CROSSON: Okay. I'm going to ask for clarifying questions. I also want to talk a little bit about how we're going to do this.

First of all, time is a little tight.

Secondly, we've got the recommendation, and I'm going to suggest we take that first, because while we're doing that, you can think about the next piece, because I think what I'd like to do is take a clue from the Millennial generation here and we're going to do this like Facebook. We've got eight ideas up there on the slide, and in the discussion, of course, period, we don't have time to analyze all the pros and cons of this. It's going to take us a good part of the next term to do that. But, what I would like to get is an indication of, "I like this one," and for ones that are not on your immediate "like" list,

what would you suggest -- what information or analysis would you suggest we need in order to move up some other on onto your "like" list, okay.

So, let's have the slide on the recommendation first. So, you have the draft recommendation before you. I won't read that. We have presented it at the March meeting, as well. Any comments or questions from Commissioners on the draft recommendation.

MR. ARMSTRONG: So, you're not going to entertain any amendments to this?

[Laughter.]

DR. CROSSON: Oh, yeah, sure. Go ahead.

MR. ARMSTRONG: Actually, I just rescinded my proposed amendment.

[Laughter.]

DR. CROSSON: I'm sorry, I'm getting ahead of myself. I think that -- let me just ask, are there any clarifying questions on this recommendation? Alice.

DR. COOMBS: What's on the laundry list up here, bottom line? Has ASCO done any work surveying their membership with the medical homes in terms of any data that they may have prematurely, the oncology, professional --

DR. CROSSON: Alice, excuse me. I serve to confuse you here. We're taking the recommendation first, and then we're going to go back to the list. Sorry.

Clarifying questions on the recommendation?

[No response.]

DR. CROSSON: Comments on the recommendation?

[No response.]

DR. CROSSON: We will now take the recommendation. All in favor of the recommendation, please raise your land.

[Show of hands.]

DR. CROSSON: All Commissioners opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: The recommendation passes unanimously.

Okay. Now, clarifying questions on the range of choices that are on that slide.

I'm sorry. If looks could kill. Alice, sorry.

MS. RAY: Can you repeat your question?

[Laughter.]

DR. COOMBS: It's okay. I'm sure ASCO has done something in this area, but I'm wondering about the literature. You did a great job identifying those four cases. Has there been a preponderance of literature on the medical homes in terms of just comparing? I have some preliminary data from an oncologist, but I'm wondering if there's been some published data on just cost savings that exist with any pilots or anything.

MS. RAY: There's been an initial evaluation of the COME HOME model, the CMS's model, but in that evaluation, they're not comparing costs or outcomes to a control group. It was just of the study participants.

We do cite other literature that does discuss some outcomes with other oncology medical homes, but I think that there's a lot of interest in learning about what the effect is of the CMS model.

DR. COOMBS: Is there going to be a Round 2?

DR. CROSSON: Yes.

Clarifying questions on this? That is everything except for the recommendation.

[No response.]

DR. CROSSON: Seeing none, do we have comments?

Alice.

DR. COOMBS: Thank you so much.

For the laundry list and going down the laundry list, can I do that really quickly?

DR. CROSSON: Yeah.

DR. COOMBS: Okay. So in terms of the things that I rank are the low-hanging fruit is the consolidated billing codes I think is someplace that we can go, easy enough to do, although I know that there's some struggles and challenges within -- because it sounds like to me the RUC codes and the family of codes and putting them all together and saying these two or these three or four go together versus the other. So it's going to take a little bit of deliberation on that.

The clinical pathways, I think no one is in question about that. I think the adherence to them is pretty good amongst the community.

Medical homes, I think is unquestionable. The episode of care, I'd be interested to see, because in the United Healthcare model, I think that was problematic in terms of looking at the individual cost, overall cost versus cost due to drugs.

The CAP limit on ASP growth, I think that's where the money is right there because we're looking at things we can do in terms of prioritizing how we can stop the actual growth of the cost of drugs, and I think that does us justice in terms of feedback to the manufacturers as well as the plans.

The things that I'm concerned about are many. Small providers within oncology practices with the CAP program before accessing the shelf life for a lot of the chemotherapeutic agents and being able to -- and be able to get the drugs in a timely fashion to treat patients, and so some oncologists had expressed the concern that patients come in, come into their offices to receive an agent, and the agent is not there. And so it necessitates a patient coming back again, and these protocols and clinical pathways are time-based, so that, you know, you might have the nadir of your white count at a certain point so that it's really important to have a timely -- that's strict adherence to being able to get the chemotherapeutic agents on time, so I think that's important.

And then the question of is this going to force somewhat of a repeat of what happened with the

cardiologist. I am told that the newly trained oncologists that come out of training, they may go into a group practice, and then shortly afterwards, someone comes along with 100K increase on their salary from a hospital base, and they say, "Goodbye." And they leave the solo practices. The unintended consequences of the hospital-based care in oncology via physicians is more expensive. I really think so, and so that it could be problematic of doing the very thing that we want to do, which is to keep patients in the community setting and oncology practices.

So I think I have a couple more, but in respect for the rest of the Commissioners, I'll yield my time.

DR. CROSSON: Hey, I kind of like this formality thing.

Let's see. I saw Craig. Let's come up this way. Let's go to Jack and then come this way.

DR. HOADLEY: So, I mean, I think this is -- first of all, I think we've got a really good chapter here for this year's round, and I think one of the advantages that we've accomplished, both last year and will accomplish with this is to continue to identify a range of options, which really helps people in the policy community as well

as ourselves sort of work through relative merits and disadvantages of different approaches. So I think the general approach we're taking here is very positive.

In sort of your sense of yes or no on the options, I definitely want to see us continue to look at the adjustments to the 106 percent of ASP. I think in addition to this 103.5 plus $5, we could potentially look at other variants, like I think was mentioned sort of a lower percentage without an add-on or some kind of a lesser of, to sort of balance out what happens on the less expensive drugs and the more expensive drugs. I don't know. We could go crazy just sort of inventing other variants. We have to be careful, obviously, there.

I really do think the limit on ASP growth has got a lot of potential, and personally, I like the approach that tries to help -- well, I think we've got to work out on the impact on what it does to coinsurance versus sort of who bears the cost, and sort of we've laid out that contrast and I think continuing to think that through. I won't go any further on that.

I think the consolidated billing codes, I like. I guess my question there continues to be -- it makes a lot

of sense for biosimilars. I think it's more unclear how it will play out for other classes of drugs, both the politics that we've seen with some of the other approaches to least costly alternative and so forth, of trying to define what are the competing products and sort of the ability for CMS to find enough clinical consensus to establish that these really do work together, and there's always going to be pushback from both patient groups, provider groups, manufacturers on that point. And then it doesn't really address the sort of single drug in class kind of situation.

So I think it's at least a good tool for biosimilars in the point we've already made, I guess, in our comments, putting the biosimilars together with original product, and I think it's worth looking at another context. But I think there are definitely practice problems.

I continue to be skeptical about the camp restructuring. I mean, I'm willing to continue to look at it as an option to see how it could be made to work, but I just have trouble getting there right now.

And I think the other four, I think they're great topics to continue to look at. I don't right now have sort

of reactions of one versus another. I mean, I just have random questions -- not random, but particular questions, like on clinical pathways, how does it end up generating savings. But I think all of these are worth continuing to consider, and I think in general, I feel like I'm going to need more information if I was trying to pick among them.

And maybe in the end, this isn't a question of picking one out of four as much as are there models out there. So those are some reactions.

DR. CROSSON: Thank you. Coming up, Bill.

DR. HALL: Thank you. Are we doing Facebook now? Is that okay? I want to have a big shout-out for the oncology medical homes.

Just briefly, geriatric oncology is a relatively new field, and it's turning up some very interesting information. One is that as the care of cancer patients becomes more complex and particularly for older adults where the decision is often do/don't do, modify/not modify, the oncologist becomes the de facto, the primary care provider for these people, and that's a good thing. And it's an area where what Mary calls other providers really excel.

If an older individual has to go back to a primary care physician because of a rash, not knowing whether it has something to do with the cancer chemotherapy or maybe a new manifestation of disease, it results in two or three redundant visits. So at least that model has the potential for actually reforming the way that we provide cancer care for older patients. So I think it really needs or deserves a really good luck. So if we could nudge whoever is trying to analyze this data to see what's happening, I think that would be a giant step forward.

DR. BAICKER: Of the potential items on the list, the one that probably makes me the most uncomfortable is the limit on ASP growth. It strikes me as potentially quite arbitrary, disconnected from murky conditions and circumstances that would normally, we think -- we would like competitive pricing to vary based on those market circumstances. There are all sorts of reasons to think we're not getting competitive prices now, and I'm very much in favor of trying the items on the menu that move us towards competitive prices. I worry that this moves us away from it in a way that's arbitrary with all sorts of consequences under many different circumstances that some

might be good, some might be very bad, and with a rule like this, this mix is quite uncertain. So I'm just voting thumbs down, like the economist I am.

DR. CROSSON: Craig.

DR. SAMITT: So the two on the list that I would single out that I'm interested in learning more about would be clinical pathways and oncology medical homes as well. Clinical pathways, just because we've had very good success with clinical pathways within our organization, and I think there are added advantages to clinical pathways, especially if the development of the pathways is continuous and even somewhat automated, given the complexity of oncology care, that to have a vehicle to kind of stay on top of true best practice and clinical oncology is conducive to what we would want for beneficiaries.

The one concern I have about clinical pathways, the chapter talks about sort of the proprietary nature of some of these pathways with certain organizations, and I would like to understand how do we get past that proprietary nature because that seems to be something that should be used more broadly.

Then what I like about medical homes is just the

notion that it rises above, yet again, this notion of just thinking of care as episodes, that it is truly a population health focus, and maybe an episode is really not the right choice for the beneficiary. There are other, more palliative approaches or caring approaches.

And certainly, the cost of oncology care goes beyond just the drug costs of any particular episode. There are other considerations -- avoiding hospitalizations, rehospitalizations, and the like.

So those would be the two I would be most interested in learning more about and hearing about.

DR. CROSSON: Over this way. Rita.

DR. REDBERG: So I like the consolidated billing codes because the idea that we're sort of looking at the outcomes and paying for sort of beneficial outcomes is one that we've used before, and I see that as aligned with it.

The risk-sharing agreement, I have concerns about. I don't know. You mentioned outcome-based, but certainly in the example that we saw on Slide 14 where the patient response is based on a biomarker -- a biomarker, so surrogate outcome is very unclearly, if at all correlated to actual clinical, meaningful outcomes. So I wouldn't

favor risk-sharing agreements if they're based on meaningless surrogates.

And this clinical pathways, as we have talked about before, a lot of the oncology studies are also based -- and approvals of drugs are based on surrogate outcomes that have not been correlated to survival, which is really what we're looking for. So I would have concerns about using the clinical pathways for that reason.

Thank you for adding the detail to the chapter about the quality of evidence in the clinical pathways, but it looks like, uniformly, it didn't come out well. They all were rated as low quality, low rigor of development, didn't meet the standards the IOM set forth for clinical practice guidelines.

And the other issue in the clinical pathways is that I think what seems to me limited in the data for oncology is actual -- we get a lot of new drugs, and so we tend to use them in succession as opposed to figuring out actual rational course of one compared to another, and also the alternative of no treatment because clearly there are patients that would have been better off without any of the chemotherapies than the ones that they actually got,

because they're all toxic. And if they're not extending life, then we have reduced quality of life without improving outcomes, and so an outcomes-based pathway perhaps would be good, but currently, I don't think that's the way they're focused. And when I say outcomes, I mean survival benefit.

DR. CROSSON: Thank you, Rita. Mary? Kathy? David.

DR. NAYLOR: Mary, Kathy. Okay.

DR. REDBERG: Just one last thing, we also talked before about the bundled, but we didn't really get a lot into it in this chapter, unless I missed it.

MR. RAY: Right. That --

DR. REDBERG: Well, not the UnitedHealthcare.

MS. RAY: Right. In the June 2015 report, we talked a little bit more about bundling and the issues that would have to be considered in developing an oncology bundle.

DR. MILLER: And that is still on the list. If you want to say "I don't like it" or "I do like it," just -- it is still up there.

DR. REDBERG: It seemed worthy of further

discussion.

DR. CROSSON: Mary.

DR. NAYLOR: So I want to give two thumbs up to an approach which is more comprehensive, whether it's called the oncology medical home or the oncology geriatric something. I was on the IOM, now National Academy of Medicine, delivering high-value cancer care, and much of our attention was on the fact that new diagnosis of cancer are occurring much more frequently, in fact, predominantly now in the Medicare population, but in the context of people who have heart failure and diabetes and depression. And so to think about where you're going to get the value from high-value care coordination, long term, focus on palliative care, and all of that, I think is really central to getting to high-value payment.

DR. CROSSON: Kathy.

MS. BUTO: So, on the first one, 103.5 plus $5, I think somebody else mentioned this, maybe Jack, lesser of 106 percent of ASP or that, because I think we point out there is some real low-cost drugs that would actually increase in cost, and there's no reason for that. So I think we ought to think about that as we refine the policy.

On the ASP limit on growth, that's growth in the price, and I guess one unintended consequence I think is going to be higher launch prices, which I think has also been an area of concern, so I would point that out.

And also, that of the two options that were laid out, one was a rebate approach, and the other was limit on Medicare payments, which I think we're very much used to through hospital payments and other things, even the SGR, that that's an approach that would benefit the beneficiary more directly, although I noted in the chapter that you all came up with a way or some possible ways to have that benefit under rebate go to the beneficiary as well. But I think it's a little, maybe slightly tortured, and so we might want to think about that as we develop this option further.

On consolidated billing codes, I'm very much opposed to this, and the reason is that I generally like the options that look at limiting overall drug payments or payment levels without trying to, in some sense, bias a clinical decision towards a lower cost drug. So I am nervous about that and something like this, and I think Jack didn't quite say this, but that would be my biggest

concern about the therapeutically equivalent, where the patients -- this is just a drug. It's not like a whole DRG.

I think you pointed out in your paper where there are a number of different services that can be traded off. It's a drug, and if the patient needs that one and it happens to fall above the median price or whatever the rate is set for that bundle or that category, I think we are going to see therapeutic clinical decisions driven by that because otherwise a physician has to bear the cost of the higher, more expensive drug.

So I know there's been a little research outside the U.S. on what happens when that happens, and one thing I would ask is that you all take a look at the literature on reference pricing and its impact on both clinical decisions and ultimately costs and whether it really saves money.

And I guess, thirdly, incremental innovation, which there's a little -- again, I think it's in Germany or somewhere else that they've shown that there's less inclination to invest in that category once it's put into a reference grouping.

So, again, I think the U.S. is a whole different

deal because we're such a big market, but there have been some glimmerings that this reference pricing does have an impact, and I think we just want to be understanding what those impacts are.

On restructuring CAP, I would just say that CMS has been successful in DME competitive bidding now for seven or eight years. It's a different deal, but I think there are lessons to be learned from how -- what obstacles they had to overcome to do that kind of competitive bidding. Competition and the ability to attract in different vendors is critical to making that an effective approach, and of course, the way it was structured because of the legislation and otherwise made that difficult. So I think looking at it fresh and then looking at some of the private sector approaches would also help us. So rather than starting only with the CMS sort of failure, if you will, I would look at where it's been successful and what we might suggest in that area.

And then oncology medical homes and episodes of care, I am particularly interested in because I think ultimately that it's the episodes-of-care approach, the more bundled, if you will, approach that goes across the

care that's involved in a service is really where we're going to see tradeoffs made at the level of practice and care management rather than our trying to figure out how to correctly price individual products.

DR. CROSSON: Thank you. David.

DR. NERENZ: A couple of loose-end issues about the chapter, and both of them relate to the first bullet about the 103.5 percent.

One is I don't know we're quite as clear as we could be about what the policy intent of that plus 6 percent was or is, and there are at least three options, and they're all in front of us. I'm not quite sure what the blend really is.

One of the headings in the report talks about profit margin, and we never say that that actually was an explicit intent of the plus 6, but at least it's in there in the chapter. You asked the question: Is it actually effectively a profit margin? So that kind of raises a question of: Well, is it supposed to be one?

Then in one of the letters that came to us, there's the concept of buffer, the idea that it serves as a buffer at the individual provider/hospital level because

the actual acquisition price isn't always the same as the standard national price, so there's a buffer concept.

Then there's also some mention of drug handling costs that are different from the separate administration fee, and there's some talk about difficult handling and hazardous and this and that.

So it seems like there are at least three distinct underlying rationales for this, and I don't know that the chapter is clear about is the policy intent to cover all three, is it one of the three, all the way back to the origin in Congress, is it none of the three. Just anything we can say about that I think would be useful, because then it kind of tees up where do you go with it, because if you're trying to solve this problem, you do it or don't do it this way.

Then the second related thing is kind of an obvious point, that if part of the problem with plus 6 is that there's an incentive to prescriber higher-priced drugs, the incentive goes down a little bit when you go to 3.5, but it does not go away, and it certainly doesn't get turned around.

So when we talk about that as an example option

and we talk about possible consequences, we might be able to say more about do we actually expect behavior to change, and if so, why. Is that change big enough to actually change the underlying incentive and motivation? Or do we think behavior really won't change because the incentive is still in the same direction, but it will, in fact, change the payment?

So, again, I'm just looking for a little clarity about do we or don't we think that this incentive for higher-priced drugs is going to actually change behavior -- I'm sorry, I should say would the change of this type change behavior.

DR. CROSSON: David, I would just like to underscore the first point you made, because, you know, personally, as I have thought about that and talked about it, I've thought about it in all those three ways. And I think, you know, if we're going to proceed with this direction, which I think -- and I hear a fair amount of support for it, I think in addition to trying to understand what the policy thinking was, it would also be helpful -- and here we go, more work. It would be helpful to try to figure out, if we can, empirically what the justification

is with those three ideas in mind. In other words, you know, how much variation -- I realize I'm saying things that we may not be able to do, but how much variation in acquisition price is there really and what does that look like. What is the cost for handling? And is it uniform across drugs, or is it concentrated in only a small number of drugs? And then I forgot the third one, David. The buffering, the handling, and the -- well, yeah, I mean, so -- I don't know there's any empirical analysis one can do on what the right profit ought to be. But I think at least with those two, if we could kind of understand that a little bit more, and I realize that some of this information is likely proprietary and not easily accessible. But I would just ask you to think about that.

DR. HOADLEY: Yeah, on that last point, I mean, I think, you know, we have gotten some empirical data that you've included in here that gives us some sense of the spread and, you know, what the acquisition prices relate and sort of how much of that 6 percent may be eaten up. So I think that's a really good effort, and maybe I don't know if there's more we need to do on that.

But I think on the other side, you know, one of

the things that we haven't mentioned, in this conversation at least, is one of the other changes that was made back in whatever legislation it was that created this whole ASP system was to build in more administration fees because in the old days it was viewed that the AWP-based price was, you know, one of the rationales, at least post hoc, was that it helped to cover the administration of the drug, and there was no separate administration fee. So now there is, and maybe one of the questions is to look at those admin fees, and are they sort of calibrated correctly? And I don't even remember now how much they vary by specific drugs and so forth because, clearly, there should be products within this array of products where there's a lot more. And is it only relating to the actual administration, or is it also covering the cost of storage? You know, because one of the versions of that rationale is it's at least that 6 percent some people would say was supposed to cover, you know, the cost of going out and purchasing it, the more administrative cost, and/or maybe the storage, and sort of where does the administration fee relate to those things. So I think that's actually a really good notion of where to get a little more

understanding.

The other thing I would just mention based on what Kathy said, I mean, I think one of the issues around the coding, the common coding, is what's the manufacturer's price response, because certainly some of the experience overseas has been that when reference prices are set, the manufacturer response is to change their price, either come down to the reference product's price or at least to move in that direction. And so, you know, you have to think about what are the price response to these kinds of things, and, again, relating to how the particular rules of a reference pricing or a common coding system are set up. So I think that's part of it.

And I think there is some research -- there's something that should be available soon I've heard about -- that will draw some illustrations from what's going on overseas on some of these issues that may be useful to us, so we can talk offline about that.

DR. MILLER: Can I say just a couple of things? And, by the way, on that very last point that you made, yes, we would be interested, if you're aware of something, just on the off chance that we missed it.

So David asked this question about do we think this was all about profit, is it the distribution or the buffer, whatever language was used, or was it to cover other costs? And then everybody way saying, yeah, we should definitely understanding those things better. So I'm guessing that the two of you are having a heart attack right about now. Is that correct?

[Laughter.]

DR. MILLER: And so I just want to -- yeah, so we have two ways to proceed. I can sort of externalize what some of the issues are or Nancy and I can agree that Kim will do this and we'll just walk away.

[Laughter.]

DR. MILLER: I'm for the latter, Nancy. Go and get a drink and -- okay. So the thing is you are correct that we did present some information on acquisition costs, and it was kind of a difficult analysis to process, and there are reasons for that, which is it's proprietary data, and we have to be very careful about the level that we can use it at. And that's going to bear very directly on profit and the buffering issues. And so getting the line of sight that you may in theory want will be hard.

And then on the pricing points, like the additional costs that occur in the delivery chain, my sense, you know, the discounts that occur, prompt pay and that type of thing, that stuff I also am under the impression can be hard to get your hands around it.

So the only thing I want to say is we're not saying, you know, absolutely not, we're not doing it, but we are trying to set your expectations a little bit differently. Okay?

DR. NERENZ: And just to be --

DR. MILLER: I was surprised you guys let all those comments go by without --

DR. NERENZ: And just to be clear, the intent of the question was not to induce a heart attack or even extended work. I just thought if the legislative and regulatory history of the plus 6 is known, okay, then -- then you could just say it's not known or it's not clear. Either way, I just saying a statement. Either it's known and here it is, or it's not known and it's not known.

MS. NEUMAN: And I thought what your question was not just what did they think about then in terms of creating it, but what do we think it should be about and

how does that bear on this policy option. And so we can't answer the first question. We have some -- we had a writeup in last year's, which we could include this year, that goes through all the theories. But no one agrees on what it was for originally. But that doesn't mean your second piece can't be thought about, which is what should it be for?

DR. MILLER: And that's the way I took your question, and no problem asking it, because those were all completely rational thoughts. I just want you to understand that our ability to penetrate may be some --

DR. HOADLEY: Yeah, and I totally get the data issues, and I think part of my point was that what you've already done actually goes a fair distance towards answering the distribution and cost question. And I don't -- and when I was thinking about the administration, it isn't so much some of those financial considerations, but it's more the internal to the physician practice or whatever in terms of -- and I realize that still may be hard to do, but I don't know if there's been any look at that since the law first went into effect.

DR. MILLER: I don't remember how far back your

memories go, but we did some of that way, way back, and it was very difficult trying to extract that out, because, again, there's not -- like the hospitals, you have a cost report --

DR. HOADLEY: Right.

DR. MILLER: -- you can start to disaggregate, and then the physician office world, we don't have a lot of that.

DR. HOADLEY: But it may be just a matter of looking back at what was done and seeing if that gives us any clues or whether anybody -- the same way some of the group practice groups or whatever have sometimes done internal surveys, whether there's anything that can be gleaned on that, obviously stakeholders have a stake, so there's that issue.

DR. COOMBS: I might be in the minority, but I'm wondering why there's a problem with the limit on ASP growth. I mean, you might rationalize that it's innovation, but I'm trying to think of the beneficiary, the providers, and from that standpoint, from the beneficiary and the provider standpoint.

DR. CROSSON: Do you want to take this outside?

No. I'm sorry.

[Laughter.]

DR. BAICKER: Debate rules, if you're referenced, you're allowed to jump back in? She was very careful not to use my name.

[Laughter.]

DR. BAICKER: So it strikes me as an artificial price control that may or may not bear on the market conditions that are underlying it. We don't say the price of computers can go up by 2 percent a year. I don't care what new capabilities it has. I don't care who enters the market. I don't care how expensive it is to produce it. Two percent a year, that's the answer. And the odds that that's the right answer strike me as pretty low.

DR. COOMBS: I actually like that rationale, but we don't apply that rationale to other industries around this table. So I'm just thinking about -- well, no, I'm just thinking about --

DR. BAICKER: You mean within health care.

DR. COOMBS: Yeah.

DR. BAICKER: Well, yeah, but we're busy trying to introduce more competition and market pricing into other

things. We're saying, gee, fee-for-service isn't working so well because we have to pick these numbers for the prices to go up and we're guessing about a lot of things; and, gee, if it was only more like a competitive market where people were going where the highest value was and how can we introduce better pricing and pricing that matches value into those other sectors. So I'm in favor of introducing that same logic elsewhere rather than saying we have something here that is intended to be based on market signals, let's just not.

DR. COOMBS: Okay. This is not a cat fight, but I just wanted to bring that up.

[Laughter.]

DR. BAICKER: Nor did I think it was.

[Laughter.]

DR. HOADLEY: And there is some evidence -- I mean, two points. One is we do this in Medicaid, so Medicaid's rebate system does build in this same kind of factor, so it's not like we haven't looked at that before. And, obviously, people can argue whether it's working well there.

Part of the issue is that there's evidence --

there's been a couple of studies in certain classes of drugs where the trend is upward, and when a new product comes in, the old products price themselves up to that new higher price. And so, I mean, there's a lot of sense that the market isn't working, and the question is: Is this a method that would tame the market's failures? Or is there another method that would address the market failures better? And, you know, that's the notion -- some of these common coding things, if we really had a sense that politically we could throw these things into one category when there are competing products. But there are some issues. I mean, when we tried to do that with least costly alternative, you know, it ended up in court and got kicked out.

And so I think that's exactly the tradeoff that this menu of options is getting us at, but I wouldn't want to take this one off the table prematurely.

DR. BAICKER: And I completely agree that we are not in any way at perfect competition in these markets, and I think you're both raising that important point. And so the solutions to that that seem most appealing to me are more along the lines of bundled payment and value-based

pricing or reimbursement rather than just picking a number. But I'm very much in agreement that we don't -- we're nowhere near competitive equilibrium in these markets now.

DR. CROSSON: Thank you very much, Kim and Nancy. More to come.

[Pause.]

DR. CROSSON: Okay. Our next topic is using encounter data for risk adjustment in Medicare Advantage. It's a topic we have had as a discussion item before. We're going to get a little bit more in-depth in that. Andy Johnson and Dan Zabinski, and who is starting, Andy?

DR. JOHNSON: Yes, thanks, Jay.

Good afternoon. In this session, Dan and I are going to discuss the risk adjustment model used to pay MA plans. In particular, we're going to focus on issues to consider if the risk adjustment model was modified to take into account MA plan cost information rather than provider costs from fee-for-service Medicare.

We are going to trade off presenting three topics. I will begin with an overview of how payments to MA plans are risk adjusted and how fee-for-service Medicare cost data is used to develop the current risk adjustment

model. Then Dan will discuss theoretical issues to consider if the risk adjustment model was modified to be based on MA plan costs from encounter data. Finally, I will discuss the state of the MA plan cost information in encounter data and some practical issues related to using the MA encounter data for risk adjustment.

Now to start with an overview of MA risk adjustment. Medicare pays a monthly payment to MA plans for each enrollee. These payments are the product of two factors: a base rate that is plan and locality specific, and a beneficiary-specific risk score. The base rate represents the average spending for the fee-for-service beneficiaries in a given locality. The risk score adjusts the base rate by increasing payment for beneficiaries with expected medical expenditures that are higher than average, and vice versa. A risk score is calculated for each beneficiary based on his or her demographic characteristics and whether he or she has certain medical conditions. The CMS-HCC risk adjustment model groups medical conditions into hierarchical condition categories, or HCCs, which are identified by diagnosis codes.

The first step in risk adjustment is calibrating

the CMS-HCC model. Through model calibration, CMS estimates the expected medical cost associated with a beneficiary having a particular demographic characteristic or HCC. Each expected medical cost is then divided by the average fee-for-service spending amount, generating a coefficient that is proportional to average fee-for-service spending. The middle column of this table shows the expected medical cost for a few example demographic characteristics and HCCs. In the right column, the expected medical costs have been divided by average fee-for-service Medicare spending of $9,050 to generate a proportional coefficient for each characteristic and HCC.

The second step in risk adjustment is calculating a risk score for each MA enrollee. CMS identifies the relevant medical conditions or HCCs for each enrollee and then adds together the relevant coefficients. The risk score for a beneficiary with average expected medical costs is 1.0. In this table you can see that the risk score for an 85-year-old male with congestive heart failure is 1.077. This risk score represents expected medical costs that are 7.7 percent higher than the average fee-for-service beneficiary.

To calculate the payment rate for this beneficiary, CMS multiplies the risk score by a local base rate. If this beneficiary were enrolled with an MA plan in a county with a monthly base rate of $1,000, the Medicare payment to the plan would be $1,077, which is the product of the risk score and the base rate. Because the risk adjustment model that is used to pay MA plans is currently based on fee-for-service cost information, $1,077 is also the monthly amount that this MA enrollee would have expected to cost if he was enrolled in fee-for-service Medicare.

This chart shows the flow of risk-adjusted payments with the vertical arrows and the two sources of medical cost data that could be used to calibrate the risk adjustment model with the horizontal arrows. Risk scores, shown in yellow, adjust the capitated payments that Medicare pays to MA plans. In the current risk adjustment model, risk scores are calibrated using fee-for-service Medicare payments to providers, shown in green, and, therefore, reflect treatment costs in fee-for-service Medicare.

However, CMS has been collecting encounter data

which includes information about MA plans' payments to providers, shown in blue. A risk adjustment model could be calibrated on this data and would reflect MA plans' costs, which is our term for the aggregate of a plan's payments to providers. CMS is working toward calibrating risk scores on MA plan payments to providers using the encounter data.

Now Dan is going to discuss some theoretical issues to consider if such a risk adjustment model were implemented.

DR. ZABINSKI: An important point from what Andy just talked about is that CMS currently uses data from fee-for-service beneficiaries to calibrate the CMS-HCC model and then uses that model to determine risk scores for MA enrollees. And this difference between the population the CMS-HCC model is calibrated on and the population that it's applied to has resulted in two incentives for the MA plans.

First, the plans have an incentive to encourage more intensive coding of conditions than what you have in fee-for-service Medicare because all MA payments depend on the conditions that are coded while fee-for-service payments for most services don't. And research, such as an analysis by Kronick and Welch, indicates that plans have

responded to this incentive, and this leads to higher MA risk scores and payments. In response, CMS applies a uniform downward adjustment to all MA payments.

Second, Newhouse and colleagues made the comparison of the cost of treating conditions in a large MA plan to the cost in fee-for-service Medicare, and they found that some conditions -- such as diabetes and cancer -- were less costly in the MA plan while other conditions -- such as major organ transplant -- were more costly in the MA plan. They identified factors that explain these differences in costs between MA and fee-for-service Medicare, and it's plausible that these factors also apply to most other plans. Therefore, differences between MA and fee-for-service Medicare in the cost of treating conditions may be widespread. And to the extent there are widespread differences in the costs between these two sectors, there's an incentive for the MA plans to avoid beneficiaries who have conditions that are more costly to the plan than to fee-for-service Medicare and to attract beneficiaries who have conditions that are less costly to the plan.

Now, earlier, Andy discussed risk adjustment that is calibrated using encounter data from MA plans rather

than fee-for-service mc. And now we're going to discuss the pros and cons of using encounter-based risk adjustment in place of the current fee-for-service-based model. Doing this would end the need to adjust MA payments for the more intensive coding in MA because there would no longer be a difference in the coding intensity between the population used to calibrate the model and the population that the model is applied to. But plans still have an incentive to code intensively because MA payments still depend on the conditions that are coded.

Also, the incentive for MA plans to avoid beneficiaries who have conditions that are more costly in MA than in fee-for-service Medicare would be eliminated because the coefficients on the conditions in the CMS-HCC model would now reflect the cost of treatment in MA, not fee-for-service. However, plans would have an incentive then to compare their costs to the costs of the average plan because the CMS-HCC coefficients would then reflect average costs. So for a given plan, it may then be beneficial to avoid a new set of conditions.

A final issue concerning using encounter-based risk adjustment is that it is inconsistent with MA payments

that are financially neutral with fee-for-service Medicare. In the past, the Commission has supported financial neutrality, where payments for MA enrollees equal 100 percent of local fee-for-service spending after adjusting for risk. This has the benefit of encouraging care to be provided in the sector that is more efficient, MA or fee-for-service Medicare. For me, it's easiest to explain financially neutral MA payments with the formula that's in the second primary bullet. In a given county, you need a base payment amount that equals what the national average fee-for-service beneficiary would cost in that county. And for each beneficiary who enrolls in MA, you multiply that base amount by a risk score from a model that is based on fee-for-service data. If either or both of these two parts of this formula are not used, financially neutral payments will not occur. Therefore, if an MA enrollees' risk scores are from a model based on encounter data rather than fee-for-service data, MA payments will not be financially neutral with fee-for-service Medicare.

Now Andy will discuss our evaluation of the encounter data that we have.

DR. JOHNSON: So far, our evaluation has focused

on assessing the feasibility of using MA encounter data to calibrate a risk adjustment model. We evaluated 2013 MA encounter data and found that information about beneficiaries' conditions, or HCCs, are generally of good quality. However, there are several issues to address regarding plan payments to providers, as recorded in the encounter data.

First, it is important to note that only medical costs are included in the encounter data. Information about plans' administrative costs and profits are not included. Therefore, a risk adjustment model using encounter data would be based only on payments to providers, and all other costs would be reimbursed proportionally.

A potentially more serious issue results from the fact that many MA plans do not pay providers on a service-by-service basis. For example, group model HMOs generally pay a capitated rate to a medical group or independent practice association, and staff model HMOs generally employ physicians on salary. In either of these arrangements, plans do not make individual payments for services or encounters, making it difficult to determine the payment

for a specific encounter.

In the MA encounter data, CMS does not require encounters provided under a capitated arrangement to have a payment amount. A payment amount of 0 dollars is recorded for these encounters. To get a sense of how common this was, we compared an estimate of the aggregate amount MA plans paid to providers in 2013 with the aggregate payments to providers recorded in the encounter data, and we found that the amount in the encounter data was about 30 percent less. In a separate analysis, we confirmed our expectation that encounters paid under capitation, and, therefore, without a payment amount recorded, were concentrated among certain plan types.

Before MA encounter payment data can be used to calibrate a risk adjustment model, a method needs to be developed to address the capitated encounters without payment amounts. From a practical perspective, we identified three broad approaches.

The first method would not use MA encounter payment information at all, but would use prices from fee-for-service Medicare fee schedules and payment systems to estimate the cost of each MA encounter. A risk adjustment

model incorporating fee-for-service Medicare prices, or some other standardized pricing mechanism, would reflect MA utilization patterns, but the cost structure of MA plans would be lost. This method would be difficult to implement as every encounter would need to be assessed under fee-for-service payment policies.

A second method would calibrate a model using only MA enrollees with complete payment information in the encounter data. This method would incorporate both MA utilization patterns and plan cost structure, but only for plans with fee-for-service provider arrangements. Beneficiaries receiving services from providers paid under capitation would be excluded, and plans that are pure group or staff model HMOs would be excluded entirely.

Finally, CMS could help plans develop a method for allocating MA capitated payments to MA enrollees receiving those services. Calibrating a risk adjustment model only requires knowledge of each enrollee's annual medical expenditures. Therefore, a plan's MA capitated payments would only need to be allocated to an MA enrollee and would not need to be allocated to individual services or encounters. Developing and implementing such an

allocation method consistently across plans would have significant challenges and would require additional time and effort for plans with capitated provider arrangements. However, this method would also offer the most comprehensive representation of both MA utilization patterns and cost structure.

In summary, using MA encounter data to calibrate a risk adjustment model would have the following implications: It would generally address the impact of differences in MA and fee-for-service coding intensity on Medicare spending. MA plans would still have incentive to code more intensely, but doing so would only draw Medicare payments away from other plans, creating competition among plans based on coding. Although Medicare's budget would be insulated, the incentive may produce inefficiency if plans expend effort on coding that does not result in a corresponding benefit to MA enrollees.

Second, an MA-calibrated model would generate payment for a medical condition that is proportional to average MA plan costs and thus would create competition among plans to be among the most efficient for their enrollees and the conditions they cover. This is in

contrast to the current model under which plans compete with fee-for-service Medicare and can expect to generate sufficient revenue by focusing on conditions that they can cover more efficiently.

A third issue is that with an MA-calibrated model, financial neutrality is no longer possible. In other words, it would mean that Medicare expenditures for a particular beneficiary would be different if the beneficiary enrolls in MA or receives care through fee-for-service Medicare. This situation may generate need for additional policies. For example, under a premium support program, beneficiaries would select MA or fee-for-service Medicare based on cost signals. These cost signals would differ by sector, potentially introducing incentives to beneficiaries and plans that have unknown consequences.

The final issue presented today is that there are several data and implementation challenges that would need to be addressed before an MA-calibrated risk adjustment model can be produced. These include developing a method to address encounters paid under capitation, as well as a process for validating encounter payment information before using the data as the basis for risk adjustment.

Now I'll mention our plan for continuing to assess the MA encounter data.

For risk adjustment, our plan is to assess the feasibility of allocating MA plan capitated payments to MA enrollees and then consider calibrating a risk adjustment model with the complete set of MA plan cost information. We would like your input on this direction, and we plan to report back to you with our progress during the next meeting cycle.

In the second set of work, we are continuing to assess utilization patterns in MA and differences with fee-for-service Medicare. We also plan present on those findings during the next meeting cycle.

That concludes our presentation, and we look forward to your discussion. Thanks.

DR. CHRISTIANSON: Thanks, Andy and Dan. This was a really interesting chapter to me, but humiliating, all the stuff you brought up that I hadn't thought of about using MA encounter data.

[Laughter.]

DR. CHRISTIANSON: We'll do a first round of just clarification questions, and I think the second round will

be more along the lines of what direction (should this go at this point. We'll start here and go down.

MR. ARMSTRONG: So, first of all, unlike Mark, I've been giving a lot of thought to the July retreat agenda.

[Laughter.]

MR. ARMSTRONG: And I think we just landed on the topic.

DR. REDBERG: Oh, it's just because you're not going to be there.

MR. ARMSTRONG: I think you just landed on the topic. Excuse me.

I guess my first question is -- I mean, this is really complicated, but what's the problem that we're trying to solve with this? Is it the accuracy of the risk adjustment methodology? Or is it sort of the problems we run into with trying to balance fee-for-service with Medicare Advantage payment -- or neutralize?

DR. JOHNSON: I think it depends on who you ask. I think some people have presented it as a way forward on addressing the coding intensity adjustment, and others have looked at it more towards the balancing of MA reimbursement

with plans' costs. So I think that is probably one of the most important issues for you to discuss today and that we would appreciate feedback on about what parts of moving to MA encounter-based risk adjustment would be -- you know, what would be the rationale and what would be the most important reasons?

MR. ARMSTRONG: So maybe a quickly follow-up. So we know that we are seeing higher risk scores in the Medicare Advantage plans relative to the same population in the same marketplace. But have we ever done a study as to which one is more accurate? Is Medicare Advantage higher intensity but actually more accurate? Or are we concerned that it's overcoding and less accurate?

DR. JOHNSON: I don't think we have done a study, but the two -- the differences in language I think are used by different people at different times. And I don't know that, you know, there's necessarily something negative going on with Medicare Advantage coding. I tend to look at it just as a fact that right now the only available data or source of data for diagnostic information and costs for the same set of beneficiaries is fee-for-service; and, secondly, that there are coding differences given the

different incentives in the two sectors. So as a result of those two, an adjustment is necessary. But I do take your point about the type of language used to describe them, yeah.

MS. BUTO: Just a follow-up to that, Andy. Can you be more specific about where in fee-for-service the coding accuracy is not where it might otherwise be? Because I know that inpatient hospital coding is king, right, in terms of getting the right DRG payment? It's one of the big pots of money. Where exactly -- because I think you contrasted and said the MA plans have a greater incentive to code and I guess reflect intensity. But I'm just wondering where are we not seeing that on fee-for-service?

DR. JOHNSON: You're definitely right on the inpatient hospital as also having similar incentives to code completely inaccurately. I think that the number of diagnoses that go into the risk adjustment model, whether or not they are the sole source, 80 percent of them come from physician claims and outpatient. So, there is -- to the extent that there is an effect from the inpatient diagnostic information, that's only a small set of the

total diagnoses going into the HCCs.

MR. ZABINSKI: And, I'll add to that. There's been a number of studies done on sort of consistency of coding chronic conditions over time in MA versus fee-for-service, including by MedPAC, and, you know, it's clear that the consistency of coding the chronic conditions is steadier in MA than fee-for-service. In other words, you have somebody who's got, for example, diabetes. It doesn't go away. They always have it. But, on fee-for-service claims, appear in one year but not the next year. Well, MA, it's pretty consistent, and I think primarily, as Andy, I think, was alluding to, is that that's because the physician and the OPD, which are two big factors in determining the conditions, there's no incentive in the fee-for-service side to actually code conditions because every payment is on the basis of what's done, not what the conditions that the beneficiaries have.

DR. CROSSON: We're going down this way. Mary.

DR. NAYLOR: So, my question really relates to principle, because after that, I wouldn't have a clue. But, as you're thinking about, you know, the value of severing a principle of financial neutrality in order to

get to risk adjustment for MA, with that principle of financial neutrality driven, undergirded by the opportunity to get to a more high-value Medicare program overall, I'm wondering, you know, if you've assessed what's the potential loss from severing that principle to the potential gain from a better system of risk adjustment, if that makes any sense.

MR. ZABINSKI: Okay. I think Andy wants me to handle that one. Okay.

[Laughter.]

MR. ZABINSKI: I'm looking at him. He's looking at me.

Well, I'm not sure if this is going to be helpful, but I'll try. Okay. You know, you have the financial neutrality, and the idea there is that it causes incentives to go to the more efficient sector, or not incentives, necessarily, it encourages the more efficient sector. And, you know, you need fee-for-service-based risk adjustment to do that.

Now, what -- you know, the problem with the fee-for-service -- this is speaking largely from my own viewpoint -- is that you have these coding incentive

differences between the two sectors, and you've got the MA being higher intensity coding. So, the payments end up being higher than what you would expect. And when you get down to it, that actually defeats financial neutrality right there.

So, there's this -- you've got to weigh -- those are the two trade-offs, you know, getting to the more efficient sector or sort of paying what the beneficiary is actually expected to cost.

DR. NAYLOR: [Off microphone.] Thank you.

DR. CROSSON: Okay. Bill.

MR. GRADISON: Perhaps this is in this paper or a prior one, but do you have any data with regard to the risk adjustment for beneficiaries who have left MA to come to fee-for-service, not necessarily come back to fee-for-service, but there is a certain amount of movement in that direction now and then, and I would just be interested in any data that you might have that would compare the risk adjustment that had been assigned by the MA plan to the people who left it to come to fee-for-service versus how they would be rated once they come back to fee-for-service.

MR. ZABINSKI: Well, I've done some work, and

others, as well, in terms of looking at that population in terms of what they actually cost. They tend to be real high-cost people with real severe conditions. As far as coding of conditions, I've never done anything and I'm not really aware of any -- you know, I'm looking over at Carlos, if he's aware of any --

DR. MILLER: I would say there were actually a couple parts to this question. Just to nail down the first part that he answered, it sounded like the first part of your question, and you tell me if this is right, is if someone leaves a managed care plan and returns to fee-for-service, what kind of a -- in a risk profile, what kind of patient is that? They tend to be, Dan, the more sick, more expensive patients, and he did some work on this, I don't know, four years ago, something like that. We could pull that back up and put it in front of you. There are not huge percentages of people who leave the plan on that basis, but when they do, they look like they are sicker. And, Dan, my recollection is you've found that, and to the extent other people have looked at it in the literature, it's pretty consistent, what's found there.

MR. GRADISON: Well, that is a different question

than --

DR. MILLER: Oh, then I --

MR. GRADISON: -- the question of how they were rated, how they were --

DR. MILLER: Well, then I was going to go to the coding part, because there was sort of a leave part of your question and then a coding part. And, Scott and Carlos should be -- don't be shaking your head. You did do something on this.

[Laughter.]

DR. MILLER: And, also, the whole shaking and nodding is after I ask something, okay. That's the plan.

[Laughter.]

DR. MILLER: What I thought you guys did recently -- and Carlos covers his face. All right, they're being less than constructive.

[Laughter.]

DR. MILLER: So, what they were saying is that what you find, when somebody enters the managed care plan, they tend to look like they are more healthy, or their codes are lower, right. Then as they stay in managed care, their code goes up. And, of course, this is the other

side, and I want to say this very gently to the managed care folks, but this is always this phenomenon of, like, well, we're not coding more. We're just coding more accurately. But, it also can look like you join managed care and you become sicker, and we don't think that's what's going on. You join managed care, and as they very clearly pointed out, there is a real strong incentive to code that diabetic every time they show up, whereas in fee-for-service, since it's the office visit, not so much.

And, so, the phenomenon is you enter, in a sense, looking more healthy, less codes, and then over time, that code and your risk profile goes up over a series of years. Now I get a nod? Okay. Thank you.

So, that's sort of the pieces of your question. So, they kind of enter, you know, lower than average, and then creep up above average over time.

MR. GRADISON: But, that's not really the question. The question is --

[Laughter.]

MR. GRADISON: When they -- that particular --

DR. MILLER: It was a good answer.

[Laughter.]

MR. GRADISON: That was a good answer, a good answer to a different question.

[Laughter.]

MR. GRADISON: But, when this particular small group moves from MA to fee-for-service, how were they at that most recent year coded when they were in the MA plan and then how did they become coded in fee-for-service once they made the move?

This has nothing to do with -- when you say, as some folks here have said, going back to fee-for-service. They may never have been in fee-for-service, so I'm not phrasing it that way.

DR. JOHNSON: I don't know of any research that has looked at that, but it's --

DR. MILLER: Right --

DR. CROSSON: Can we have that ten minutes back?

[Laughter.]

DR. MILLER: But, by inference, if it goes up when they enter MA, you would almost expect it to come down when they exit.

DR. JOHNSON: You would expect that, yeah.

DR. CROSSON: David.

DR. NERENZ: A quick check. Are we separating round one and round two here?

[Laughter.]

DR. NERENZ: I don't think so, but I --

DR. CROSSON: Yeah. Clarifying questions.

DR. HOADLEY: So, one small question on the coding thing. Has there been any sense of that pattern of less coding in fee-for-service changing as more use of electronic health records, where you would think there was the potential for the diagnoses just to be in the system and then to be kicked out on the claim?

DR. JOHNSON: There is some. I don't know that we have done a comprehensive look, like an overtime look to see if the rate is going up. We have not done that. But, there are elements in discussion of pathways in which that seems to be happening in fee-for-service.

DR. HOADLEY: So, at some point, one could imagine that the differential that we're sort of thinking about, how the coding, could be reduced, go away, something. I mean, that's too much to say empirically.

DR. JOHNSON: Right.

DR. HOADLEY: My other question, on the Newhouse

study that you talked about, the statement in the chapter was that the cost of treating specific conditions differs widely between, and I guess they looked at one MA plan versus fee-for-service. Any sense of the -- can you characterize in any better way the magnitude of that difference, and then how much it's just in a few conditions versus lots and lots of conditions?

MR. ZABINSKI: Oh, the differences were in most conditions --

DR. HOADLEY: Okay.

MR. ZABINSKI: -- and the differences were wide in some of them.

DR. HOADLEY: Okay.

MR. ZABINSKI: How to say -- and, some were higher in MA, some were lower in MA. I mean, you've got to think -- realize, everything's done in relatives here --

DR. HOADLEY: Sure.

MR. ZABINSKI: -- so, everything's sort of like a fraction or decimal. And, so, it's sort of -- that's a key thing to understand. So, yeah. But, there were really wide differences between --

DR. HOADLEY: Okay. That's helpful. And, I

guess one of the interesting questions, and maybe this is something more in round two, in the work plan, is the extent that we can see, you know, was that one plan typical and how much variation. Are there some kinds of plans where you wouldn't see those wide differences? I mean, one could imagine integrated systems having a much wider difference than systems that are more sort of internally fee-for-service.

MR. ZABINSKI: Well, you know, they sort of talked about, in the paper, sort of three factors that they identify for creating these differences, and I sort of thought about it, and, like, it seems like they should be applicable to most, if not all, plans. So, my guess is might be pretty widespread.

DR. CROSSON: Next, Cori.

MS. UCCELLO: So, also on the Newhouse study, it's both price and utilization that varies between them that's causing those. But, is there anything that's -- and those vary by condition. It seems like some conditions could be more price is dominating the difference, and in others, it's utilization. But, are there any patterns at all on which overall seems to be more important, or is it

just really all over the place?

MR. ZABINSKI: I mean, can you --

MS. UCCELLO: Meaning, you know, at the end of the day, is price or utilization more important?

MR. ZABINSKI: From the paper, I couldn't glean anything in that respect, no.

DR. CROSSON: So, just on that. So, in the paper, there's no -- which I haven't read yet -- there's no differentiation between so-called discretionary procedures and non-discretionary?

MR. ZABINSKI: No. No.

DR. CROSSON: Bill.

DR. HALL: Is there any proprietary data that you could mine on this subject? It seems to me that any insurance company with a vested interest in MA might want to understand the differences when they see a MedPAC report that says we're taking a look at this whole situation. Is there any possibility of getting access to any of that?

DR. MILLER: Look at what, the price utilization difference or some other --

DR. HALL: Yeah. Yeah. Doing exactly what we're doing, but from the perspective of the insurance company.

DR. MILLER: Umm, well, I mean, we're going to pursue this using the encounter data, which will be a pretty good data source but for the problem of the capitation stuff that Andrew walked through at the end, which, in theory, could preclude the need to do this -- to go to another insurer.

That distinction that Cori was just talking about, whether we could get more information about price and utilization, might be something that we could get more precision on if we went out to an insurance company. I would have some reservations about how generalizable that is. You know, the prices are negotiated between that particular payer in that particular part of the country, depending on what their spread is and all the rest of it, and whether it would tell you what you would expect to find in all the rest of the industry, which is not a way -- you know, it's not, hell, no, it's just I would have to think about the value.

DR. JOHNSON: I think the other way that we've looked at that is that leads to sort of the three broad approaches that we presented, and that instead of looking at one specific plan, we can use MA utilization information

and tack onto it fee-for-service spending, which has its own pros and cons. We could look at just the plans for which we have complete information, the encounter data, which also has its own pros and cons. Or, we can try and sort of fill in or allocate the capitated spending. So, I think that seems like a more -- that's our plan, I guess, for heading forward rather than a specific plan, so --

DR. CROSSON: Kate.

DR. BAICKER: So, just -- I want to be sure I'm clear on the use of financial neutrality as you're using it now, that that's different from budget neutrality in that you could, for whatever rearrangement of the schedule you did for people -- for the risk adjustors, you could then scale it such that it was budget neutral between MA and fee-for-service writ large. But for any individual person, the way you're using financial neutrality is the Medicare program is paying the same for that person regardless of whether he or she is in an MA plan or a fee-for-service plan. And then the problem you're potentially trying to solve is that generates differential incentive to enroll people in MA because some people can be treated more cost effectively in MA and some people are more expensive in MA,

and so the fact that the risk adjustors are done off of fee-for-service creates differential incentives across people, but it's not an issue of program budget neutrality.

DR. JOHNSON: That's correct.

DR. BAICKER: Okay. Good.

DR. MILLER: [Off microphone.] I just want to say, she did that in two minutes -- when we did that internally. That was that conversation we had. Good job.

DR. CROSSON: Craig.

DR. SAMITT: So, just a small clarification. On Slide 11, when you talk about the third category of a method for addressing the capitated encounter gap, would you have each plan independently determine how to allocate their capitated payments to their various clinicians, or would there be a standard methodology by which all plans would do that?

DR. JOHNSON: Ideally, it would be a standard methodology across plans. There are several complicating factors to address and it's unclear just how feasible that is or what sorts of -- the magnitude of those issues as they are able to be sorted out or not.

DR. SAMITT: All right. I'll come back to that

in round two.

DR. JOHNSON: Okay.

DR. CHRISTIANSON: Another quick question. On Slide 10, at the top, you talk about the HCC data is good quality. Could you remind us of the metrics that you use to decide whether data is good quality or not?

DR. JOHNSON: We took a look at the risk score file as it is identified through the RAPS data, which is the submission process that's been going on for several years, and looked at HCCs as identified in the encounter data and did a comparison, and they tended to be -- have a decent amount of overlap and, I guess more importantly, the total number of payments identified based on those HCCs or the risk scores themselves in some were very similar.

DR. CHRISTIANSON: So, it's completeness that you're using as --

DR. JOHNSON: Correct.

DR. CHRISTIANSON: -- relative to the other data sets.

DR. JOHNSON: That's correct.

DR. CHRISTIANSON: Okay.

DR. CROSSON: [Off microphone.] Clarifying

questions.

MS. BUTO: Just a quick question. Does this -- how does this complicate that comparison that we were doing a while ago within certain market areas, looking at which is more considered a better value for the beneficiary -- a better value, period, whether it's MA, fee-for-service, or potentially ACOs? I mean, how does this complicate that?

Let's take the hypothetical of a MA plan that has a high risk score using MA data, somehow. So, it actually costs the program more, but may still be an efficient and high value provider of care vis-a-vis a more unconnected, uncoordinated fee-for-service system. I just wonder how you -- does that make the comparison just that much more complicated?

MR. ZABINSKI: I think it does, yes. It adds an additional -- I think what you're getting at, it adds an additional, at least one layer of, you know, another variable to consider when thinking about which sector is more efficient. So, yes, it does.

DR. JOHNSON: And the other area we've discussed that with respect to is with premium support, where in those given markets you're looking at whether the average

of MA plans is more or less efficient relative to fee-for-service Medicare, but that may depend for an individual beneficiary who now has a different risk score or an expected set of program payments, whether they enroll in fee-for-service or MA. It definitely complicates the incentives and how the budget works out in the end.

DR. CROSSON: Okay. I think we're ready to go to general discussion. So, I think what would be most helpful here is to try to provide guidance to the staff in two areas. Are there some, you know, fatal flaws or poison pills that have been developed that you heard in the presentation that would suggest this is a really big problem with proceeding, and then if that's so, what could be done, if anything, to overcome that.

And then maybe the second part is, assuming that's not the case, and we're getting -- this is going to be a technical discussion, I think, for those who think that way -- you know, what advice would you give to the staff so that when we come back to this the next time, the choices are honed as well as they can be, something like that.

Craig.

DR. SAMITT: So, I actually would have rather spent the whole time talking about your very last bullet, which was utilization patterns, because, frankly, I think that's where the meat of the opportunity will be in the encounter data, more than risk adjustment. So, I'm looking forward to the next presentation.

But, that being said, I actually am in favor of the direction here. I think that looking at encounter data provides progress for us, frankly, because of all the reasons that we've described that the current HCC-based risk adjustment model has inaccuracies, whether it is that we under-predict payments for the very ill or that we over-predict payments for the well, or that there's concern about driving higher intensities of coding that don't necessarily match the clinical condition.

Although, I must say, as one of the MA guys in the room, in the defense of MA, coding is viewed in our world very much as a documentation resource to identify those patients that have the highest needs for which we need to allocate supplemental resources and care coordination. So, there's a wealth of additional services that MA plans provide that are based upon sort of the more

accurate coding representations. So, yes, a side effect is that it affects risk adjustment, but I think the primary purpose is to assure that we have the resources necessary to support the needs of those members.

So, given my comments that I think I'm in favor of the progress we've made, I'm not a whole lot more confident about the encounter data, given all of the gaps that you described. I'd love to learn more about the three, you know, potential scenarios to address them, but I have to admit, I don't like any of them. None of them sound very good. So, using fee-for-service Medicare information feels as if -- it feels like we're confounding the separate risk adjustment methodology we're trying to create.

In terms of excluding MA plans that actually subcapitate their provider groups, I think that's a terrible idea, because, frankly, I would imagine that you would see the most efficient care and the best outcomes in those groups that do receive capitation from MA plans. So, I think we'd see that in the utilization data. So, I don't think that's good.

And, then, as someone who in the past has tried

to allocate capitation payments to various specialties and providers and determining a methodology to do that, it's a crazy methodology to try to even start to think about, and more power to you if you can come up with a methodology, but I think many folks have tried that unsuccessfully, to figure out what the right methodology would be.

So, I take a step back and I jump on Scott's recommendation. Maybe this is a good topic for us to discuss in July, because I'd be in favor of stepping back and saying, is there a better way to think about risk adjustment? How do we use HCC? How do we use encounter data? I think we would all agree that we don't really have a clinically relevant and clinically accurate risk adjustment methodology. What are we missing, and is there some other approach?

Maybe we can use encounter data to make this better, but I feel like we need a more inclusive, transparent risk adjustment development methodology with experts from the field. I think there are a lot of people that I talk to around the country that are trying to get their arms around what more accurate risk adjustment would look like. It feels to me like we should be thinking more

broadly and at a higher level about how we accomplish what we're trying to accomplish with risk adjustment.

Finally, you know, I'm trying to figure out how I feel about this notion of financial neutrality and whether we really care about linking creating financial neutrality, especially as it relates to our discussions about premium support. You know, everyone's going to be incented to deliver the highest quality outcomes at the lowest cost, and so everyone is going to need to care about the cost of services. And so I don't know why we would need to assure financial neutrality, if beneficiaries will select the highest value alternative, whether it's MA or fee-for-service. So maybe I'm missing something, but I'm not sure why we would have to link neutrality in this particular case.

DR. CROSSON: Kate.

DR. BAICKER: So there's a lot to chew on here that I think is really interesting, and I am trying to think through along the lines Craig was saying about which way of doing the adjustment promotes what we're trying to do. And I think what we're trying to do is the beneficiaries we want to most move over into MA are the

ones where the efficiency of the resource use is going to change the most. There is where there is the most return to getting people to move over.

So one small implication of that is that even though it seems it may be impractical -- and I'm very much open to persuasion on that front, but applying the fee-for-service prices rather than the MA prices seems like it would further that because you want strong incentives for the MA plans to negotiate lower prices. You don't want to take that back from them in the adjustment, but it may be impractical. Conceptually, it seems like that makes sense to me, and conceptually, you want to maintain the incentive for returns to the plan of better managing care in reducing resource use conditional on achieving high-quality, good outcomes for people.

So, in some ways, the problem that seems the most important to solve is the coding intensity one, and the question is how do you solve the incentive to the return to coding more without undermining the return to manage resources better. And that's the part that I'm having trouble thinking through right now, and I don't know if there's some hybrid of these options where you take the

average -- you know, you use the coding from the encounter data, but then somehow use average utilization. I'm having trouble thinking about how to take the coding intensity out while not undermining the incentive to use resources better. So that's not a suggestion that's actionable in any way, except for the hard -- except for the impractical one about the pricing.

But that's the goal I'd be trying to achieve in thinking about which parts of the encounter data to use in combination with the fee-for-service data. Maybe Dave will figure it out by the time it gets to him.

DR. CROSSON: David, you had a point over here before.

DR. NERENZ: I was going to follow on Craig's point, but now I find I can follow on both, and I would just do a slightly different pathway but get to the same point.

When we talk about the risk adjustment, we appropriately talk a lot about incentives. We don't want to create bad incentives. We want to provide good incentives.

But another way of just using words to talk about

risk adjustment is protection, and now we don't think about what plans actively do. We think about what they can't control, and that's also one of the strongest rationales for risk adjustment. You want to protect plans or provider against variations that they cannot control, and if we assume that plans, for example, don't have a lot of control about who comes in, that's why you do this kind of risk adjustment. Okay.

Now, when we look at the description in the text about the study, page 12 and 13, I think it is, when you talked about why District of Columbia this MA plan have lower cost, the things in there were things that were under their control, that they did better negotiating of networks or they did better care coordination or did something.

Now, here's now where it's going to tie back in. I don't think you want to adjust that away. I think you want to reward that. So I think that's why I was nodding when you said -- I'm using different words, but I think it's the same point. This difference is not something that is outside the plan's control. The difference is within, and in a good way within. So that leads me to say maybe the way to do this is to go ahead and use the fee-for-

service data to set sort of the expected cost or the sort of uncontrolled cost or the unmanaged cost, and then you bring that in. And if the MA plan or plans, plural, can do a better job managing those conditions, good. Good for them. You don't want to adjust away that action, or you don't want to discourage it.

So take it to extreme. Let's say that that happens, and now plans can act. And so now what happens is the people who can be treated very efficiently end up more than average in MA plans, and those who can't be treated efficiently end up more than average in fee-for-service. Why is that bad? That's probably a really good thing, and if a net result of that on a large scale is that the MA plans are now all of a sudden making a lot of money, well, now you go back and you deal with the base rate. You don't necessarily need to deal with the HCC calibrations. That's really about the -- among plan adjustment.

Anyway, I was feeling I was in agreement with both places, but slightly different paths to get there.

DR. BAICKER: And just to close the circle on that, the productive part of moving the patients from one plan to another is the change in real resource use. If

it's just a shell game about differential coding and it's a race on coding, but there's no change in actual health care resources used, there's no gain. And that's what's underlying this financial neutrality tension in some ways, is the whole purpose of this exercise is that there's a difference in resource, in real resource use between MA and fee-for-service. If they were the same, we wouldn't be worried about all of these incentives, and so that's another avenue in thinking about the premium support question that you raised.

I don't think this difference is problematic necessarily for premium support, introducing this gap, because the marginal incentives are still going to be the same. You're changing the per-person dollar amount for any given person, but for that person, there's still the incremental gain to going to the plan that is offering the highest value care at the lowest cost. So I think it's all about finding the patients who would benefit most from being in an alternative plan and setting up the incentives to reward that.

DR. MILLER: Can I ask one thing? And I'm having a bad say, so I'm afraid to ask this, but the other thing

in your comments -- and I did follow your summation there, but when you went through your first round and we were talking about these methods and Craig was -- I don't think any of them was unhappy with all three of them -- you're point on the first one was, "Well, you know if you use fee-for-service prices, in a sense, you are tracking the utilization, which is what you want to track, and not necessarily including the variation in price and negotiations, and maybe that's a good thing because they still will have all the motivations to do that."

And that's at least a thought that occurred to us when we were talking among ourselves, and I wanted to just nail down: You did say that and you think that. Did I catch that?

DR. BAICKER: That feels like a trap.

[Laughter.]

DR. MILLER: Well, then you got off into some more complex conversation, and I wanted to make sure that I didn't lose things.

DR. BAICKER: Yes. I think we're on the same page.

DR. MILLER: Okay.

DR. SAMITT: And I would jump in and say that of the three, that would also likely be my favored alternative if we could understand more fully what the implications would be of using that approach. I think the other two have far greater flaws than the first one.

DR. CROSSON: Cori.

MS. UCCELLO: Thank you. So Kate and Dave, I think said much more coherently what was going through my head when I read this, so thank you for, I think, putting forward what I think I thought.

So just to add kind of one more thought, this idea on -- which may or may not actually be relevant at this point, but the admin cost issue, we shouldn't be risk-adjusting admin costs that aren't claims variable. So, to the extent that that stuff is taken out, I think is a good thing.

And I think I might come up with stuff later, and I'll get back to you.

DR. CROSSON: Alice.

MS. UCCELLO: And if you wanted me to be a guest at July, I'd be happy to come.

DR. COOMBS: So I had a question about the

capitating encounters with zero payment and data. I am curious about what that group looks like that 30 percent looks like, relative to the 70 percent, because if you can find some internal comparison, then that gives you a little bit more confidence in the populations being similar, whether it's -- you get some information, proprietary information, just some trends or something that you can actually compare even with a pilot, with utilization in terms of services, because that group is important. That capitated group is really important for extrapolation.

And I think the reason why we're looking at this is that we wanted to have some kind of true comparison for efficiency and pricing and cost and all of that.

DR. JOHNSON: I think that's right. We do have the utilization information for those encounters that are capitated. It's just the dollar amount that was paid to the provider.

So if we wanted to go forward with a method that incorporated to the greatest extent possible, both the utilization and cost structure of the MA environment, we would want -- one method would be to try and allocate capitated dollars to a beneficiary to incorporate those

differences. But we could do some other comparisons on the utilization front.

DR. COOMBS: I mean, not just a concern, that they kind of look similar in terms of some of the factors and indices, and maybe some, even, quality benchmarks of some gross things like admission rates and things like that. I don't know if you can pull that, but I would imagine that you can pull that information out of those two groups because the comparison probably is going to be powerful in terms of telling you what you're looking at and then being able to extract right to the next level, whether or not you correlate this with fee-for-service.

DR. CROSSON: Jack and then Jon.

DR. HOADLEY: So, like Cori, I was going to try to say something about some of these issues that I think, in the end, Craig and Kate and Dave kind of covered. I guess my other question -- so I won't say more about that. My other question on your menu up here, when you talked on your last bullet about utilization patterns, were you proposing that narrowly in the context of risk adjustment-related or really much in the broader context of just fundamentally looking at utilization pattern differences

between the two sectors?

DR. JOHNSON: That's a much more broad context.

DR. HOADLEY: Okay.

DR. JOHNSON: Sort of a separate body of work started earlier.

DR. HOADLEY: Got it. That's good. That's where I was hoping you were going, and I think this is also where I think it's going to become important to look within the MA sector and trying to understand because, I mean, I think one of the things that I found challenging in many of the discussions we have is that we lump MA as if it's one undifferentiated group. Obviously, there's a correlation with some of the data issues in terms of group and staff and more integrated HMOs that tend to be the capitated payment models and the salary payment models and so forth.

But particularly if you're looking at the utilization side only, without the dollars, you don't have that issue, and so I think trying to understand, give us some insight into whether there really is a big difference, as I think many of us suspect there is, across these sectors. And then at some point down the road, what are the implications of that for payment policies and anything

else, I think that's going to be potentially very powerful.

DR. CROSSON: And you have made that point several times, Jack, and I think it's a good one.

Did you have something on this?

DR. BAICKER: So I feel like I've rambled my way into something potentially actionable on this, but getting closer.

So I realize the problem I'm struggling to reconcile is that if you do the risk adjustment just within the MA plans, as you've highlighted, then you really limit the incentive for more intensive coding, but you dull the incentive to get the people where you have the greatest resource improvement. Whereas, if you use the fee-for-service, there's this coding intensity problem, but you've got great incentives to pick off the people with the greatest resource use.

The problem, my wish that we could separate out the coding intensity from the resource use, you can't, and that's the whole crux of the problem, which it took me till now to realize. Sorry.

But then that -- so there's a tradeoff there, and the question is, what's the magnitude of the tradeoffs?

And so then my potentially answerable question, not today, but going forward is, what's the within-MA across plan variation in cost per people, per person, with that MA risk adjustment, MA encounter database risk adjustment, versus the between MA and fee-for-service difference in the resource use, using a common set of risk adjustors? Now, that may require either looking at movers between the two sectors, which there is a critical mass of along the new house lines, or some imputation about what they would have looked like in the counter factual, which is going to be a little fraught, but holding risk adjustment methodology constant, how big a gain is there in the people who move versus doing just the encounter-based risk adjustment, how much variation is there across plans, because it could be that there's this tradeoff. But the real return is within MA competition. If the difference there is much bigger, then if you're doing the coding intensity to expenses on the aggregate in MA, if the real return is that within MA, they're still competing to get people into the most efficient plans and that the dollar amount, the dollar-valuated benefit of that is the big piece, then you can say, "Okay. So I'm letting go of this emphasis on

selection between MA and fee-for-service," versus if the within-MA-sector spread is relatively small, then you say, "Well, I'm not sure I want to let go of the strong selection pressure between the two things.

That's a thing.

[Laughter.]

DR. MILLER: I think I'd probably want to follow up because I did understand you were setting up the kind of within variation or within variation and seeing what -- right. Where I lost you was in the second half of the comment, whereas what it told me when I found it, but that's just me, and it's late in the day.

And I can ask: Did you follow what she was doing there at the end?

DR. JOHNSON: I have a question, so --

DR. MILLER: Oh. Well, we'll find out.

DR. ZABINSKI: I'm fine.

DR. JOHNSON: Dan's got it.

DR. MILLER: [Speaking off microphone]

DR. JOHNSON: Just to clarify for everyone else at the table, if we were able to identify what risk scores would be under fee-for-service calibrated model and MA

calibrated model and then look at who actually switched from fee-for-service to MA are the people who were the more efficient and would have the resource gains. Is that what you're talking about? Okay.

DR. CROSSON: Jon.

DR. CHRISTIANSON: So I think I'm with Craig and what I think Jack was saying too in terms of where I would like to see you focus, and that is I think one of the things we really hope to get out of the encounter data is a better understanding as Commissioners about -- for similar patients in two different kinds of delivery systems. I know within MA, it's multiple kinds of delivery systems. What kind of services do they get? How is treatment different? I think that's still for me where I'd like to see the emphasis going forward.

And given all the limitations that you point out in the data, as you go about doing that, I would like to have you inform us about, well, here's the difference that, given what we know about the data, we think you can take to the bank, but here's a difference given what we know about the data that just seems kind of -- it's there. We're not quite sure what to make of it because of some data issues.

It's to help us sort of be wise about reaching conclusions about whether something has gone on differently in MA plans and different kinds of MA plans and not just here's a difference, MA, fee-for-service. Okay?

DR. CROSSON: Okay. We're running a little short of time here, so let's try to be efficient. Scott.

MR. ARMSTRONG: Okay. So, very briefly, actually first, I would reiterate a point I made earlier. I really think a full day of the July retreat on this topic would be worthwhile. In case you wondered, I already checked. I'm not available.

[Laughter.]

MR. ARMSTRONG: I also just think we should embrace, I mean, we should celebrate over-coding. This is to Craig's point, and that is relative to fee-for-service. I think, actually, my experience is it's far more accurate, and it's for the purpose well beyond just payment. It's for the purpose of having well-documented information that improves the quality of clinical information or clinical decisions.

So I hope as we move this forward -- and I think we should -- that we find a way. I don't know, out of this

dialogue over here, really how to respond, but I would just encourage the group to keep trying to find some path through it all because we're just so stuck in this fee-for-service, MA comparison, and I understand how it becomes a lever we don't want to get rid of around setting payment policy that sort of controls cost, but I just think there are better levers. And my real hope is with this encounter data that we can discover what they are, and I will be cheering you on.

DR. CROSSON: Okay. Kathy.

MS. BUTO: Okay. So I'm wondering whether, as you continue your work, you can look at maybe those opportunities where we think that MA is being underpaid to risk adjustment is insufficient to adequately compensate for the kind of care that is being given and in some sense is appropriate, and to think about whether if we can never come up with the perfect, you know, MA risk adjuster system and we don't want to give up the comparison to fee-for-service because it gives us extra dollars to provide in payment to MA plans, that is there a way to then look at those cases and use MA risk adjuster information, encounter data to make adjustments, maybe selectively, to the fee-

for-service data? So is there some hybrid that you could come up with?

And then the other comment I would make is, as we look at APMs and MIPS, is there some way -- which I know is not your bailiwick per se, but it just strikes me that one other thing we have an opportunity to do is to try to get better encounter data on the fee-for-service side. And as the requirements are being developed under MACRA, there may be some ways that that could be built into it so that, going forward, the data will be of higher quality coming from fee-for-service. Because it seems to me we need that in the alternative payment models, anyway, as better encounter data.

MR. GRADISON: First, a disclaimer or a confession. I'm really troubled of finding an article of faith really that I strongly believe in being undermined in this discussion, which is the notion that we know how to have payments that are roughly equivalent for the two different systems. A lot of us had to swear on a Bible practically that we believed in that, and now I'm finding out not only that we don't know how to do it really, but that we don't do it.

But, more specifically, I want to quickly hit on two points. One, it's just my phraseology but I want to make sure to make this point of something that has been mentioned before. There's an across-the-board adjustment to correct for what is considered overcoding of 5 or 5.5 percent, whatever it is, applied uniformly. My question in that connection is: Does that create problems of fairness? Not just fairness in the theoretical broad sense, but in the ability to finance necessary care. Does that affect care that that is done on a uniform basis rather than on some system which might be more tailored to the individual MA plan? That is just for the future.

And the second thing -- and this may seem off point, but it's been bothering me for a long time, so let me say it as clearly as I can -- from a policy point of view, should we care whether an MA plan pays its providers by volume-based fee-for-service or by capitation? I think that might be something worth giving a little thought to.

DR. ZABINSKI: Just a question on your first question, just to clarify that. You're asking about, you know, does this uniform adjustment create some degree of unfairness? Are you talking about unfairness across plans

that some will code more intensively than others, so if you hit them all by the same amount, one will --

MR. GRADISON: Yes.

DR. ZABINSKI: Okay. I just wanted to be sure.

DR. CROSSON: Okay. Thank you very much. I think that has produced some valuable information for you, and we'll eagerly await the next iteration.

[Pause.]

DR. CROSSON: Okay. We'll wait a second for the crowd to clear out.

[Pause.]

DR. CROSSON: Kim, you are getting double duty today at least, huh? So we're going to come back to our evaluation of the evolution of the hospice benefit and its impact on Medicare costs. And Kim is going to take us through this.

MS. NEUMAN: So today we are going to talk about hospice and Medicare spending. Over the years, when the Commission has talked about hospice, a question that often comes up is: What is hospice's effect on overall Medicare spending? Most recently, at the January meeting Kathy asked this question.

As we've discussed previously, hospice's net effect on Medicare spending is a reflection of a couple of dynamics. Hospice reduces spending on acute-care services like inpatient hospital stays in the last days of life. At the same time, Medicare spends money on hospice services -- paying hospice providers a daily rate for each day a beneficiary is enrolled. Whether hospice results in net savings or net costs depends on how the amount Medicare saves on avoided acute care compares to the amount Medicare pays hospice providers.

So today we're going to discuss this issue of hospice's effect on Medicare spending in more detail, as I will update you on findings from a contractor report that MedPAC commissioned on this topic. In addition, we did some further analysis of a finding from the contractor report that may have policy implications.

Before we discuss the findings from the contractor report, I have some background on hospice for you.

As you know, hospice is a holistic model of care that provides palliative and supportive services to terminally ill beneficiaries who choose to enroll. To be

eligible, a beneficiary must have a life expectancy of six months or less if the disease runs its normal course.

At the start of each hospice benefit period, a physician must certify that the beneficiary's life expectancy meets this criteria. There is no limit on how long a beneficiary can be in hospice as long as he or she continues to meet this criteria.

A second requirement of the hospice benefit is that the beneficiary agree to forgo conventional care for the terminal condition and related conditions.

Hospice offers a number of positive benefits to patients.

First, hospice offers terminally ill patients a choice of what type of care best fits with their preferences. It's up to the patient and family whether they want to enroll in hospice or remain with conventional end-of-life care.

Second, hospice focuses on patient quality of life, with an emphasis on patient comfort, less invasive care, and psychosocial supports.

Third, hospice helps make it possible for patients to die at home or in another place of their

choosing according to their preferences.

Awareness of hospice and what it has to offer patients has increased. Over the last 15 years, we've seen substantial growth in the share of decedents that enroll in hospice before the end of life.

Besides the positive effect of hospice on patient care, there was a presumption when the hospice benefit was enacted that it would also be less expensive than conventional end-of-life care.

There have been a number of changes in hospice care over the years that may have implications for its effect on Medicare spending.

There's been greater awareness of hospice as an option for patients with non-cancer diagnoses, and this population is more likely to have long hospice stays. Also, MedPAC and others have expressed concern that some providers have been entering the hospice field in recent years and may be pursuing revenue generation strategies.

So now moving to the issue of hospice's effect on Medicare spending, the evidence in the literature on this question has been mixed.

Some studies show modest effects of hospice on

Medicare spending, either small net costs or savings associated with hospice, or savings only for certain subgroups, for example, those with cancer.

On the other hand, a few studies have found hospice is associated with substantial savings for a wide range of patients. To investigate this further, MedPAC contracted with Christopher Hogan of Direct Research LLC to review the literature and conduct further analysis.

The contractor report examined the effect of hospice on Medicare spending in three ways.

First, the contractor examined national trends; then the contractor reviewed and replicated the literature; and, finally, the contractor report developed a new market-level approach to assessing the effect of hospice on overall Medicare expenditures.

So first the national trends. The report found that over a period from 2002 to 2012, use of hospice increased and Medicare spending on the last year of life also increased. During this period, the share of elderly fee-for-service beneficiaries who used hospice grew from 26 percent to 47 percent.

Over this same time period, controlling for

changes in age, gender, and death rates among the Medicare population, the share of Medicare fee-for-service spending for elderly beneficiaries in their last year of life increased about 1.1 percentage points.

While an analysis of these national trends is not a strong test of hospice's impact, nothing in the national trends suggests that hospice reduced Medicare costs for beneficiaries in the last year of life.

It is also important to note that the study found roughly one-third of hospice spending occurs prior to the last year of life. So, in other words, out of the $15 billion Medicare spends on hospice in a year, about $5 billion of that spending is for care furnished prior to the last year of life.

Next the study reviewed and replicated the literature on hospice's effect on Medicare costs. There were two types of studies that the contractor looked at: fixed period studies and enrollment/pseudo-enrollment studies.

So in the fixed period studies, what the researcher does is compare spending for decedents who did and did not enroll in hospice over a fixed period,

typically the last 6 or 12 months of life. And these studies in the literature have found small costs or small savings for hospice users compared to other decedents, depending on the time period studied and the patient's diagnosis.

So the contractor replicated this methodology on current Medicare claims data and found that overall hospice was not associated with an aggregate reduction in Medicare spending, but by diagnosis, hospice was associated with significant savings for cancer decedents and significant costs for non-cancer decedents.

Then the contractor took a look at a few studies that use an enrollment and pseudo-enrollment approach. Here the researchers look only at the period of hospice enrollment and compare it to a pseudo-enrollment period that the researcher creates for decedents that did not enroll in hospice. Using this approach, the contractor report, like the literature, found a substantial reduction in spending associated with hospice for a wide range of patients.

So the contractor then took a look at the two methodologies to figure out why they were giving

contradictory results, and this graph helps illustrate the explanation.

So if you look at the right bar, we have hospice decedents' spending in the last year of life. And that spending is broken into spending before hospice enrollment (the orange part) and spending after hospice enrollment (the blue part).

For decedents who do not enroll in hospice, the folks on the left, researchers can try to create a hospice pseudo-enrollment period to compare with spending of hospice enrollees post-enrollment. But what the contractor report finds is that the creation of this pseudo-enrollment period may be problematic.

Beneficiaries often enroll in hospice after a high-expenditure hospitalization or post-acute-care episode where the beneficiary decides conventional care no longer offers them benefits. With the best of intentions, researchers can try to identify beneficiaries in the non-hospice population who are similar to hospice enrollees through a random or propensity-matching approach and assign these beneficiaries a pseudo-enrollment date. But what's very difficult to match on between hospice and non-hospice

beneficiaries is the timing of that high-expenditure event that leads the beneficiary to decide now is the time to enroll in hospice. And you can kind of see this in the chart.

So if you look at the blue bars, which reflect spending in the enrollment or pseudo-enrollment period, it appears hospice decedents have lower spending than non-hospice decedents. But when you look at the orange bar, which is spending in the pre-enrollment or pre-pseudo-enrollment period, hospice enrollees actually have higher spending than non-hospice enrollees. And over the entire last year of life, the full bar, hospice enrollees on average have higher spending than non-hospice enrollees.

So the contractor then sought to go at this question in a completely different way, using a market-level analysis rather than a person-level analysis. He examined the relationship between hospice use in a market and decedents' costs in the market.

The idea is if hospice reduces aggregate Medicare expenditures, then greater hospice market penetration would be expected to be associated with lower end-of-life costs.

So what the analysis found was that higher

hospice penetration in a market was actually associated with modestly higher costs per decedent; higher costs were due to hospice use among non-cancer decedents and were mostly attributable to patients with very long stays.

So based on the three sets of analyses, the report concluded that overall hospice does not appear to result in a reduction in aggregate Medicare spending relative to conventional end-of-life care.

Hospice may be associated with lower spending for cancer patients, but higher spending for non-cancer patients and for patients with very long stays.

These results are not dissimilar from other studies that came out around the same time. Two studies from 2015 showed higher aggregate costs associated with hospice for certain populations -- the nursing home population and patients with Alzheimer's disease and related dementias.

Now, when the hospice benefit was enacted, there was a presumption that it would result in lower spending for patients at the end of life. As hospice has matured and gained greater acceptance among beneficiaries with a wider range of conditions, the greatest benefit of hospice

appears to be its effect on patient care, not costs.

For some populations, hospice appears to cost the program more than conventional end-of-life care, and this stems from long hospice stays among a subset of enrollees. Some of this is likely the byproduct of the unpredictability of life expectancy. But also we've noted over the years that some providers appeared to have pursued revenue generation strategies, enrolling some patients for very long stays who may not meet the eligibility criteria.

The contractor report found that roughly one-third of hospice spending is for care prior to the last year of life.

Hospice is covered for beneficiaries with a life expectancy of six months of less if the disease runs its normal course. We would expect to see some patients with hospice care prior to the last year of life because life expectancy is unpredictable.

But as we noted, we've also been concerned about unusual patterns of care among some providers. When we've looked at long stays in hospice, we've seen these stays being more prevalent among certain providers.

So similar to that work, today we have for you an

analysis of the share of hospice payments for care prior to the last year of life by beneficiary and provider characteristics and by individual provider.

So here's what we found. In 2013, about 35 percent of hospice payments were for care prior to the last year of life. This varied by level of hospice care. About 38 percent of hospice payments for routine home care (the default level of hospice care) were prior to the last year of life. A much lower share of payments for general inpatient care and continuous home care -- high acuity levels of care -- were for care prior to the last year of life.

There was also variation by beneficiary and provider characteristics. About 16 percent of hospice payments for beneficiaries with cancer were prior to the last year of life, compared to 40 percent for non-cancer patients.

About 29 percent of payments to nonprofit hospices was for care prior to the last year of life, compared to 40 percent of for-profits.

Hospice providers that began participating in Medicare before 2000 had a smaller share of their payments

for care prior to the last year of life than newer providers.

So we also looked at individual providers and their share of payments for care furnished prior to the last year of life, and we found variation across providers. The chart gives you data on the share of routine home care payments for care prior to the last year of life.

And what the last line in the chart shows is that the top 20 percent of hospice providers received 46 percent or more of their routine home care payments for care prior to the last year of life.

Medicare paid these 20 percent of hospices about $2.3 billion for routine home care in 2013, of which $1.2 billion (52 percent) was for care prior to the last year of life.

So that concludes the presentation. I'd be happy to answer any questions. Also, it would be helpful to get your feedback on directions for future work.

For example, one implication of this work might be to use it to help focus program integrity efforts. For example, medical review efforts could focus on providers with a high share of their payments for care prior to the

last year of life.

We could also think about these issues from the perspective of payment policy and explore whether a payment adjuster linked to the share of a providers' payments outside the last year of life would be beneficial.

DR. CROSSON: Okay, Kim. Thank you very much. That's an excellent presentation, and what I'd like to do is ask for clarifying questions. Then when we're done with that, I'm going to ask who would like to start the discussion. So you may want to think about that. Wait, I got lost. Who was raising their hand to start the discussion? Bill -- two Bills. Double Bill, okay.

Now, clarifying questions?

DR. REDBERG: Thanks for a great presentation and chapter. On Slide 2, can any physician certify prognosis or do you have to have had some existing relationship to that patient?

MS. NEUMAN: So when a patient first elects hospice, their attending physician, if they have one, and the hospice physician both must certify. And then as the patient goes into continued benefit periods, it's just the hospice physician that certifies.

DR. REDBERG: My other clarifying question: It's a very interesting finding that one-third of payments are prior to the last year of life, because even allowing for six months, you can't be exact, that's a lot longer. And you noted that a lot of those were for non-cancer diagnoses, which I assume was heart failure. Is that correct? And can you be more specific about what kinds of services were in those hospice services that were driving up costs?

MS. NEUMAN: So I think we've got a breakdown in the paper by some very broad diagnosis categories. So, you know, for heart conditions and circulatory conditions, which is a broad category, about 39 percent of payments were outside or prior to the last year of life. Neurological is a little higher at 44 percent. But you can see COPD, debility, they're all in that range.

In terms of what services they were getting, it's an interesting question. We haven't looked to see if the services -- the amount of visits somebody gets when they're getting hospice care prior to the last year of life is, you know, less or more or the same amount as people who are closer to the end of their life. We know in general that

people who have shorter stays have a higher visit intensity than people who have longer stays, but we've never caught it in this way with where are you relative to the end of your life. So we could look at that.

DR. MILLER: And just to be clear, what they have is the summary.

MS. NEUMAN: This is in the summary -- it is Table 3 on page 12.

DR. MILLER: In the middle, right [off microphone].

DR. CROSSON: Clarifying questions?

DR. NAYLOR: So I thought in that same table, one of the most interesting findings was that 39 percent of beneficiaries who received hospice greater than one year were under 65, and I'm wondering if you might help us to understand a little bit more the characteristics of that population. I'm assuming some are in nursing homes and some -- but just to try to get a sense of who they are.

MS. NEUMAN: Yeah, I don't know that I can give you an answer right now on the characteristics of the under-65 hospice population, but that is something we could look at.

DR. NAYLOR: Thank you.

DR. CROSSON: Coming down this way, Bill, did I see --

MR. GRADISON: Later.

DR. CROSSON: Later? Okay. Jack.

DR. HOADLEY: This is partly a follow-up to Rita's question on the certification by the physician. The hospice physician who is doing that certification, is that an employee of the hospice? Is this, like -- I mean, what kind of fiduciary relationships do they have with the hospice organization typically?

MS. NEUMAN: It would be an employee of the hospice, yes.

DR. HOADLEY: And I wonder if there are some issues there that are worth trying to think about. I'm not sure quite where to go with that, but --

DR. CROSSON: Clarifying questions. Sue -- oh, Bill, Sue, Craig, and Jon.

DR. HALL: Just a technical question. The contractor calibrated costs of hospice versus non-hospice care in real and pseudo situations, how do they do that?

MS. NEUMAN: So, what --

DR. HALL: How do you -- okay. Just -- I'll stop my question there. Go ahead.

MS. NEUMAN: So, you can look at the hospice population and you can see what the length of time they enrolled prior to death, and you can have a distribution of lengths of time in hospice, and then you can create that same distribution among non-hospice enrollees, you know, cut off their service use at the same time period so that the distribution of length of time in the hospice enrollment population is the same in the non-hospice. And, so, you can compare them over similar time periods, similar lengths of time prior to death.

DR. HALL: Okay. And, in that scenario, they found that at least in some of the instances, it costs more to be in hospice than to be in non -- or to be in conventional care?

MS. NEUMAN: So, overall, a couple of the different approaches used in the study found that hospice -- that the overall costs were higher for hospice enrollees than non-hospice enrollees, and that's in the aggregate, right. That's total spending, not on a per beneficiary basis. And, what's driving that is long hospice stays.

DR. HALL: Right.

MS. NEUMAN: So, hospice is costing somewhere between $4,500 to $6,000 a month, and so if you have someone in hospice for a long time, those costs can outweigh the savings at the end of life when they're not hospitalized. And, so, that is what's driving the fact that in the aggregate, you don't see a reduction in spending.

DR. HALL: Yeah. I'd like to come back to that in round two.

DR. CROSSON: Sue.

MS. THOMPSON: Within the definition of hospice, in the opening definition, you're including palliative care. So, palliative care services as well as hospice services are in that dollar spend around hospice?

MS. NEUMAN: I was using the term palliative care to mean services that are intended to palliate the symptoms rather than -- I know what you're meaning. There's another use of palliative care, which is non-hospice providers who provide these services to a range of patients. And, so, I didn't mean that. I'm sorry if it was confusing.

MS. THOMPSON: Well, I'm curious, because with

the advent of and the more broad utilization of palliative care, as we identify folks with chronic disease, particularly folks not necessarily with cancer, to enter into a palliative care coordination relationship, I think we not only see a lengthening of life, but also an improvement of quality, and I'm wondering how that's driving not only the spend, but the, perhaps, longevity of life. That's my question. Does that make sense?

MS. NEUMAN: No. So, you want to understand the effects of non-hospice palliative care on spending --

MS. THOMPSON: On the overall spend.

MS. NEUMAN: -- and quality.

MS. THOMPSON: Mm-hmm.

MS. NEUMAN: Okay.

MS. THOMPSON: Mm-hmm. Yes. Thank you.

DR. CROSSON: Craig.

DR. SAMITT: So, my question is about the one-third/two-thirds and whether -- and how we know whether that's the right percentage or not for the decedent's last year of life or the year prior to the last year of life. So, are we looking at a benchmark? Is there an international benchmark? Is there something that can tell

us what the right percentage would be?

MS. NEUMAN: So, no, right. We don't know what the appropriate number is. I think that when we see variation across providers and it cutting in certain directions, you wonder if there's a portion of it, not all of it, but a portion of it that might not be driven by the unpredictability of life expectancy but other things.

DR. CROSSON: Historical trend?

MS. NEUMAN: Historical trend? So, the contractor report found that in 2002, it was about 25 percent, and by 2012, it was in the one-third range.

DR. SAMITT: This is a follow-up question. Have we looked at differential -- you alluded to it a second ago -- differences between systems. Have you looked at differential utilization of hospice in last year of life in provider-sponsored health plans or other different system types to see if there's differences in the numbers?

MS. NEUMAN: So, we know -- we know, in general, that Medicare Advantage enrollees are more likely to use hospice at the end of life than fee-for-service beneficiaries. But, we haven't gone down into finer detail than that. We could look at that.

DR. CROSSON: Okay. So, we're now going to try to help the staff think about policy options based on this point in the analytical framework that has been developed, and so we're going to start with Bill Gradison and then Bill Hall and then others.

MR. GRADISON: I asked to start because I was there at the beginning and was one of the strong advocates for it. Many of you have heard this story, but some may not have.

There were people who believed that it would be costly, so your statement that it was assumed to save money depended on who you talked to. I argued that it would save money.

At one point, representatives of the Office of Management and Budget came up to my office and they spread out a bunch of spreadsheets and were arguing that it would be more costly. Where they lost me, and the meeting went totally downhill after this, is when they referred in their numbers to use the term -- when they used the term units of production, which, I think, most of us in the room would say might more appropriately been patient or beneficiary or something of the sort. But, that was -- but, I do want to

stress the point that it was not totally -- there was not total agreement. But, that's historical.

I think that our assumption, the assumption of some of us that it would save money may have been correct. I mean, these data are for relatively recent years, and in those -- and I think the main difference, as I think about it, and you may have some thoughts on this now or later, had to do with the mix of the decedents that were -- in general, but also of those who signed up for hospice. It started very slowly. Patients didn't know much about it. Doctors were reluctant to tell families that somebody only had -- had less than six months to live. There were a lot of factors going on.

But, the big growth was in cancer, and the cancer diagnoses then were more predictable, let's say, than some other condition -- than the diagnoses of some other conditions might be today. And, even now, I think one of the things that many of us have pointed out is that the stays in hospice for cancer patients are too short because they wait until the last four to six days or something like that to come into it.

So, my point is that the mix of conditions that

cause people to die may have changed some over the years in ways that have affected hospice. I can't demonstrate that for sure, but I think it's worth taking a look at.

I'll give you kind of a classic case, because this is a condition that wasn't even known when the legislation was passed, called AIDS. And when AIDS came along, it was kind of a one-way trip. It is, thank God, it is not the case today, and many of these folks may continue -- may or may not continue under hospice. But, the stays weren't very long in those days for people who had AIDS. And, the conditions were shifting.

I suppose there were folks who knew more about health care than I did in those days that used the term Alzheimer's. I do not remember hearing it bandied about. I heard a lot about senility in those days. Again, that has become a more --

So, anyway, anything that would be available to show the mix of the -- of conditions of the people in hospice at a few points of time over the years might be informative about this, because the mix of patients, the mix of conditions has several implications in terms of cost, which is what we're talking about here, and in

particular has an impact on the long stays -- or may have influence on the long stays. These long stays may be in conditions where it's harder to be sure, but also where there may be more of an incentive to sign up people, where after the fact, at least, six months may not have been the correct number to use.

So, that's my specific suggestion, is take a look at the conditions. And the other thing that I would welcome, not today, but in terms of our next go-around, is your thoughts on whether CBO has gone far enough in the change in the payment for the long stay versus the short stay. So, I mean, my reaction is they probably have not done enough to bring about the kind of meaningful change that we recommended ourselves here in the past. That's a value judgment. But, I think it -- and it's maybe too early to get data on it, but I think it's something we should be monitoring, because if there is anything to that hypothesis, we may want to have another word to say about that in some future report. Thank you.

DR. MILLER: All right. So, we did -- CMS did finally get around to implementing some of our recommendations here, and I think, and we try to pay very

close attention to the language that we put in the comment letter, I think, basically to agree with you, Bill, that we think it was a step in the right direction and we will be closely monitoring it. No, it wasn't quite probably what we would have done if Kim were in charge of the world.

The other thing I wanted to gently take back a little bit in your comment is we did go through -- and we haven't -- I don't know if the last time we did it, but we have gone through some of the growth in lengths of stay, and you're absolutely correct that changes in the mixes of conditions that have gone into hospice have driven some of that change.

But, the other thing that we found is that there's been a great influx of different types of for-profit provider, and what we show there is consistent differences in the lengths of stay between for-profit providers and not-for-profit providers by any condition. And, so, there's more phenomenon than just the change in the conditions. There's also the change in the providers who are actually entering this particular field.

MR. GRADISON: I totally agree with what you just said and would point out that at the time this legislation

was passed, there were no for-profit providers at all. The first big one, in Connecticut, of course, was a not-for-profit, and we hadn't even thought about this. So, that is a major change and I'm glad you brought it up and I'm sorry I didn't.

DR. CROSSON: Bill Hall.

DR. HALL: I have really been very interested in the work you've been doing on hospice, and it's been excellent work. Each report has been very insightful and enlightening, to me, at least.

Hospice, the whole trend in hospice care has been, I think, one of the greatest innovations in medicine in the last 50 years, compared to the way that providers, me and others, handled people with terminal illnesses. This is a precious concept. It may have some flaws and some improvements, but I don't think that we should approach this entirely from a cost basis, I guess is what I'm -- I know that's not news.

We just finished looking at perhaps another example of where we do comparisons, the MA and fee-for-service scenario that we just talked about, where we took reasonably comparable groups of patients and we say, if we

look at them in one scenario or the other, what are the cost implications. And we even said, what happens if they switch back and forth. And, the integrity of that type of analysis is that, by and large, we're looking at the same group of people, and reasonable people would make the same kind of decisions. It's really a question of administration and how we structure services.

You can't really take that and put it into the hospice world. I mean, nothing teaches us humility as a physician more quickly than trying to sort of guesstimate when a patient is going to die. Believe me, anyone who thinks they are good at that just hasn't done very much of it -- not dying part, but the analysis part.

So, honestly, I think the real challenge here is not that hospice might be a bad thing. I know we don't -- but, if I were to read this report as someone who never came onto it before, I would say, well, hospice isn't really very good, you know. I mean, the patients cost us more and ultimately the result in the same is the end, right. They both die. And, if you take that to its logical conclusion, it's absolutely frightening. No one is going to do that.

But, I would say, let's assume for the moment that the hospice is a good thing and then we can say, where are the -- where can we make constructive changes? This is what I really want to get to. And the constructive changes would be, I would concentrate very, very much, as you've already mentioned, on the profit versus nonprofit sector here, and also the whole question of who decides? We say there's a physician who's hired. That's true, but it's true, but, then -- let me just say that I have been told that in some parts of the country, the certification is actually filed well -- without actually seeing the patient. I can tell you that. And maybe they're going to see them next week or something like that. It's not a precise science, either.

So, I think we should spend a lot of time on looking at the profit/nonprofit part of this and be very, very careful about saying that hospice is an unreasonably expensive way to practice medicine. I know we're not saying that, but one could reach that conclusion.

DR. CROSSON: Let me just make a bit of a comment here. So, I think -- I mean, I'm going to oversimplify a lot, but my sense of this is sort of like this. The

hospice movement and then the hospice benefit had something in mind. Here, we go back to what did people have in mind, and it was something like we wanted to provide an alternative higher quality of life option for people who had roughly six months to live. And, as a side effect of that, there was an expectation that since there would be less intensive treatment, then the Medicare program would save money, in addition.

And now, we're sort of observing the fact that the application of the hospice benefit has morphed over time, and you've talked about the reasons for that. But, it's morphed in a couple of ways that are uncomfortable. One is the fact that individuals with cancer, who, among other diagnoses, have maybe a more predictable lifespan -- not always, but maybe -- are accessing the benefit late, a lot later than what we might have thought they should be, and whether that ends up with more expense for Medicare or not, that late accessing of the benefit. One effect of it is a lower quality of life for these individuals.

And then on the other side, we have the introduction of new diagnoses that were not probably contemplated at the time, whether they are actually new or

they just have new names, like debility and neurologic disorders and Alzheimer's. Those seem to be increasing in use and generate higher costs and end up, then, changing the total cost for the Medicare program of caring for those individuals, at least in that cohort, or in the total cohort.

So, Kim has proposed here, has given us a nice analysis of this, and our job is to try to figure out what priorities we would recommend for policy changes that might address one or the other or both of these problems. And, she suggested a couple, but I'd like to see us hone in on that notion. What sort of can we do about this, if anything, to get it back to where it was intended to be in the first place. Okay.

DR. HALL: You said it much better than I did, but that's exactly right.

DR. CROSSON: So, let's start with Rita.

DR. REDBERG: So, to try to pick up on that, because I think there are a lot of important issues and certainly a lot of potential benefits, and I agree a lot of it isn't realized when hospice care comes so late, but particularly looking at the slide, Slide 8, and the high

cost just before entering hospice, you know, I think we perhaps need to do something to kind of encourage a more informed decision making.

I actually think it relates somewhat to the last discussion we were having on oncology care and bundled payments, because what I see is a lot of hospices who are not really aware when they're offered chemotherapy in a very poor progress metastatic cancer situation that's going to be very toxic what their actual -- you know, they think of it, this could save my life, when the truth is a lot, unfortunately, less optimistic than that and the chances -- perhaps they would get a few weeks of progression-free survival or some biomarker would change, but the chance of it saving their life is just very low and the toxicity is significant. And, those are the people that, you know, you said they've exhausted everything else, so they go into hospice.

But, I think if we had better informed discussions and patient decision making before offering all of that, a lot of patients would not choose to get that very expensive and very toxic chemotherapy and would go into hospice sooner. And, so, if we can think about, you

know, I don't know if it's bundled payment or informed decision making or -- but some way to sort of encourage the informed discussion sooner, before all of the things happen that are very high cost and not really benefitting patients where they then go into hospice, but they had the choice and they at least could make an informed choice sooner, that would accomplish a lot of our goals of improving care and would probably decrease program costs.

DR. CROSSON: Right.

Mary.

DR. NAYLOR: So, first of all, I think this is a really important report in helping to target and understand how a benefit evolves and is used, and I think that the framework used of a market analysis and trends and kind of replicating studies, that multiple approach, multiple methodological approach is really quite wonderful.

I guess a couple of things, I would comment, one is I think there are real challenges with the data here. It has nothing to do with direct research. It has to do with, in many ways, we are dealing with very limited data and very old data. So watching what's happened -- you talked about 26 to 47 percent growth since 2002 to 2012,

but the data on some of these big studies are a decade earlier than that, so we just have to make sure we frame it.

I think what could be most compelling here to help make the case about what we're seeing in terms of use of hospice dollars in the last year of life that may have no implications for what the benefit was intended to accomplish is to really look -- is to take that information and augment it with "Well, what if we look at what happens to people who get the benefit as it was designed?" kind of stratify a group that gets four to six months or something like, or to Jay's point, the group that gets it in the last 10 days, but maybe acknowledge simplifications and stratifications, to make the case, maybe, that if we do it right, we get the intended benefit, which is better quality of care, better outcomes, and better use of Medicare dollars.

I think there's some evidence. Zeke Emanuel and his team had a paper in New England Journal just a couple of weeks or months ago showing that the U.S. and Netherlands are doing the best in cancer patients, 65 and older, and making sure that they don't die in the hospital.

So there's some evidence that we're making progress, and I think what we need to do is to say how is it that this kind of work can illuminate, well, if you don't put your dollars where it really was intended or we don't get people early enough into the benefit to have the benefit achieve what it's intended, that that really does affect how program dollars are used.

So one way to think about it is a stratification, so just a thought.

DR. CROSSON: Kathy.

MS. BUTO: So I do have a question. I know that's how it was intended, and it was originally intended really to serve as an alternative for cancer patients, but I do have a question about these other conditions and whether if they've been sort of exposed to clinical analysis to see whether, in fact, clinicians would agree that they in fact are good candidates for hospice. And it could be that they are good candidates, but it's not a 6-month thing, that really if they're willing to forego standard medical care and go into hospice, it's not such a bad thing, but maybe there needs to be carved out a different and maybe lower routine home care benefit for

those categories. In other words, think about it not just as how do we get back to cancer, but maybe do we need to modify anything to accommodate these other categories.

And then I liked your suggestion in the paper that maybe if we look at that and say, "You know what? No. There are a number of people in these categories who really are just living with a heart condition or a circulatory condition. They don't really require hospice. They don't require ongoing medical care except for monitoring, and that there is some overuse or overuse by that population," the suggestion you made in the paper that maybe one option could be to look at some kind of value-based adjustor after the fact, to look at those hospices that tend to, in a sense, go after that population.

So I like that option, but I'd first ask the question of, are these all really inappropriate, or really, should we be looking at ways to hone in on those individuals and those categories who really could use the hospice benefit instead of standard medical care?

DR. CROSSON: Herb.

MR. KUHN: So lot of good information, Kim. Thank you for this.

On the directions for future research, I saw something recently that indicated that when hospice is recognized as conventional end-of-life care, only then will we see savings in the program.

Right now, according to the information I saw is that a third die within two days of admissions. The median length of stay is 18 days, and so the savings opportunities are getting people to enter the hospice program at the right time instead of doing through all this additional care and then coming in very late in the program. And I think that's the opportunity.

So having said that, I think some of the research should look at that option, and one of the things I'd like to see, maybe look at the future, is Medicare payments for advanced care planning, or is there a rise, or is there movement for additional palliative care consultations in acute care hospitals? What's going on with that benefit, and are those consultations occurring at the right time where people are looking at advanced care planning or palliative care early on in the process to manage that?

The second thing I'd look at is the MA experience with hospice. What's their experience? This came up a

little while ago, but their experience with live discharges, length of stay, savings. Scott made a very impassioned point that the MA plans collect all this great data. They know their patients very well. Is that translating into something, better care or better opportunities for advanced care planning with that population? Is there something we can learn there?

The fourth thing I'd look at, particularly dealing with these long lengths of stay, is what kind of quality improvement programs do these programs have, or do we only see mostly the QI in the not-for-profit and less so in the for-profit ones? As I read the research and listened to your presentation, I think what we see hospice falling into is a chronic disease management program. People might be entering the program for the proper diagnosis, but it's morphing into a chronic disease management program. And if they had good QI programs through a COP, through the Medicare program, I think they would be considered for discharge at the right time, and we would be manage this population I think a little bit better, so that's something to look at.

And then the final thing I'd look at is a core

measure set, have core measures for hospitals, for others out there, but end of life, performance, quality metric domains, different things like that. I think if we had a set of core measures, the tide could lift all boats in this area, and we could then improve some opportunities there. So those would be the areas I would recommend for additional research.

DR. CROSSON: Okay. Further comments? Jack.

DR. HOADLEY: So it seems like there's two different tracks that we've been talking about. One is sort of this whole notion of getting the right people to hospice care at the right time, and a lot of that is about patient education, provider education, informed decision-making, and that sort of thing. And that makes a lot of sense, and that includes this notion of sort of maybe just understanding better the right model outside the cancer situation, and I've seen data in the past on the patterns. Most people understand the patterns are just different, and you can't really predict. So that's fine, as long as we understand it and figure out sort of the right pattern.

But it seems like the other track is the issues that are more specifically addressed in this research,

which is what certainly appears to be some bad performance from the hospice industry and parts of the hospice industry and whether -- you mentioned targeting for integrity kinds of issues, maybe looking at this question of whether there is a better model of physician certification in terms of whatever might be -- one might call conflict of interest or just where are the -- is that -- the way it's being done now, it feels like it doesn't really do the job that it was intended to do, at least doesn't do it very well.

And then looking specifically at the for-profit side, I don't know that we've ever looked specifically at payment differentials and for-profit and not-for-profit, but it just feels like that's such a big dimension of this problem that we should potentially take that on more directly. We kind of look at the differential impact and we try not to do policies often that sort of target on that, but it feels like that's just such a big part of an issue here. I think we should probably think about what's the right way to take that on and try to be more explicit about that.

DR. CROSSON: Alice.

DR. COOMBS: So, recently, I had two patients

with end-stage congestive heart failure who actually was referred to hospice, but it's very interesting. I don't think that you can say that if someone gets the hospice, three days later and passes away, the family is very content with the whole process that that was too late. And certainly, looking at these patients, they were doing pretty good, reasonably well in terms of their home existence, and they came into the hospital for an acute event.

But what I've noticed is recently the MOLST --we have a MOLST form. It's the Medical Order for Life-Sustaining Treatment, and in states where you have -- it's either MOLST or a POLST or whatever -- you actually may change that second bar because when the patient comes in, those expensive interventions may be altered because that's what you're really talking about. You're way up here. You're not talking about certification of any kind of providers. You're way up here. You're saying discuss with the patient prior for those interventions, and when that episode happens, then you can actually make a different decision in terms of going to hospice at that time.

So I think that there probably is some

correlation with -- and I don't think all states have it. I was just looking to see. I think it's between 40 and 43 or so states that actually have state regulatory mandates that when someone comes in with one of those forms, you have to honor their wishes, and if you change it, you need to go through the process of the full documentation.

So not just that, but primary care doctors will feel compelled to speak with patients who -- especially the ones with -- I mean, most of the time, they're talking with the oncology patients, but the ones I see in the ICU with end-stage CHF or end-stage COPD, they don't have the conversation because they could think, they could talk, and they can eat, so people think, "Okay, everything is okay."

But there's nothing more beautiful than being in the presence of a family that really expects appreciation, on matter what time they pass away, and you say to them, when the good Lord says come fourth, you don't come fifth, and they're very pleased with the fact that this was a good death. And I think that's what we're talking about, so the patients are comfortable and they're in the right environment.

Whether or not for-profit and non-profit is

different in terms of how they process that piece, it might be interesting to look at the length of time. I think we have some information on that, but I think that's probably an issue that I have, and I think that with the congestive heart failure, you might see more of it if you don't have the discussion. And in several cases, the patients have actually gone home with PleurX catheters because the end-stage failure is so bad that you can't even diurese the fluid off, and every couple of days, they take the fluid, and it just prolongs things where you actually have a nurse going. And at some point, the family says, "Okay. I think this is the time." And so I think that looking at time alone can be a very complex thing, but I would look at state regulatory underpinnings, how that happens, and does that influence what happens with patients in the long run.

DR. CROSSON: Thank you. Comments? Craig.

DR. SAMITT: So I am struggling with this a little bit. I recognize that there are problems here that this analysis has pointed out, but I'm somewhat reluctant to pursue the standard policy recommendations that we would pursue because I'd be afraid we'd get them wrong because there will be certain hospice stays prior to the end-of-

life year that certainly may be appropriate.

So I'm curious to see whether there are any ways that we can address this issue through greater accountability by the referring clinicians who would want to be attentive to the clinical circumstances and maximizing the quality, maximizing the quality at the end of life, attentive to the efficiencies as well.

So, in essence, I can't recall how the hospice, the costs of hospice are included kind of in the ACO dimension. I can't remember where we stand in terms of the carving in of hospice into the MA benefit and creating greater alignment which was disconnected. So it feels to me that hospice remains somewhat fragmented, whether it's from MA or Part D or ACO, and creating that greater alignment and accountability at the referring provider level would help resolve some of the concerns that we're seeing here.

DR. CROSSON: Can somebody MA-wise remind me? I remember we talked about this the last time we did the MA. Did we make a recommendation for hospice to be subsumed?

DR. MILLER: We did, and it hasn't been taken up as of yet. Correct?

MS. NEUMAN: And then just to answer your question on ACOs, hospices' cost do count in the ACO mod.

DR. CROSSON: Okay. Bill, last.

MR. GRADISON: I just want to stress the sensitivity of cultural, religious, and frankly, to some extent, racial attitudes towards hospice. Certain groups are more likely to agree to participate than others, and we have to be sensitive to the choices that they make. That's one point.

The second point is that the remarkable progress being made through the development of new pharmaceuticals may very well have an impact on the way people think about this in the future. In other words, maybe it isn't a death sentence if you have a particular kind of cancer. We were talking about oncology drugs earlier. I am not talking about the clinical side, but the cultural, the attitudinal side of this in terms of where should grandma be and what are her chances of being around for a couple more years. So I think that both those factors, the developments, the remarkable developments that are taking place with regard to treatment through use of pharmaceuticals, and some really pretty fundamental attitudes -- cultural, I refer to

them -- needs to be factored into our thinking about this.

DR. CROSSON: Okay. The real last comment. Scott?

MR. ARMSTRONG: Just briefly wanted to add and reinforce a couple of comments people made about how hospice is one label for services that are provided in the context of an overall system that our patients are cared for within. I had some of my staff look into our own experience with this, just to try to understand whether our experience was similar to or really inconsistent with the data that you are reporting, because it seemed very unlike what our own experience was. And I would just assure you that for patients in hospice in the last 50 days of their life cost us tens of thousands of dollars less than patients who are not formally entered into that program, that when we look at the average length of stay, there's less than 10 percent of our patients who are in hospice for more than 200 days. And some of the other things that you found that are really disturbing are just so different, and I think it would be interesting for us to try to discover, well, what is different.

There are systems where a hospice is working the

way it was envisioned way back when it was first started. How is that happening, and how might that also inform some of the policy considerations that we have pursued?

DR. CROSSON: Absolutely.

Kim, thank you so much.

[Pause.]

DR. CROSSON: Okay. Our last presentation and discussion today is on measuring low-value care. We have talked around this issue. Now we're going to talk about this issue. Ariel, you're up.

MR. WINTER: Thank you. Good afternoon.

I want to begin by thanking Aaron Schwartz and Michael McWilliams of Harvard Medical School, who helped us with our analysis.

There has been increased interest in recent years in measuring and reducing the use of low-value services, including interest from Commissioners. And here is the outline for today's presentation.

I'll be offering a definition of low-value care. I will then discuss the development of claims-based measures of low-value care by a team of researchers. We applied their measures to Medicare claims data from 2012

and 2013, and I'll describe the results of our analysis, and then conclude with some potential policy directions.

Researchers define low-value care as services with little or no clinical benefit, or care in which the risk of harm from a service outweighs its potential benefit.

Low-value care is a concern for two reasons:

First, it has the potential to harm patients: both directly, by exposing them to the risks of injury from the service itself, for example, exposing patients to radiation from imaging; and indirectly, when the initial service leads to a cascade of additional tests and procedures that contain risks but provide little or no benefit; and it may also displace higher-value care.

And, second, it increases health care spending.

So I'll say a few words about our motivation for exploring this issue.

First, there is a growing literature that examines the use and growth of low-value care. In addition, practitioners are making efforts to identify and reduce low-value services through the Choosing Wisely campaign, an initiative of the American Board of Internal

Medicine Foundation.

Thus far, over 70 medical specialty societies have identified more than 400 tests and procedures that are often overused. As part of our recommendation in June 2012 on redesigning the Medicare benefit, the Commission supported value-based insurance design, in which the Secretary could alter cost sharing based on evidence of the value of services.

Under this approach, cost sharing would encourage beneficiaries to use high-value services and discourage the use of low-value services. Therefore, CMS would need information on how to define and measure low-value care.

In addition, some Commissioners, including Rita, have said that when we measure quality, it's important to look at overuse as well as underuse.

A group of researchers that included two physicians developed 31 claims-based measures of low-value care and published their findings in JAMA Internal Medicine in 2014 and 2015.

Nineteen of their measures are based on Choosing Wisely guidelines; other measures are based on the U.S. Preventive Services Task Force recommendations, the medical

literature, and other sources.

They developed two versions of each measure: a broader one with higher sensitivity and a narrower one with higher specificity.

Increasing the sensitivity of a measure captures more potentially inappropriate use, but also is more likely to misclassify some appropriate use as inappropriate.

Increasing a measure's specificity means that it is less likely to misclassify appropriate use as inappropriate, but is more likely to miss some instances of inappropriate use.

To explain this concept, we'll look at a specific measure, and the full list of measures is in your paper.

The first measure on the slide detects inappropriate imaging for patients with nonspecific low back pain. The broader version of this measure includes all patients who received imaging for low back pain and, therefore, captures more inappropriate use, but also some appropriate use.

The narrower version of this measure excludes patients with certain diagnoses, such as cancer and trauma, and is limited to imaging provided within the first six

weeks of the diagnosis of low back pain.

Although the narrower version identifies fewer cases of inappropriate imaging, it is less likely to misclassify appropriate use as inappropriate, and the same principle applies to the other measures on this slide.

Last year, we contracted with the authors of the JAMA Internal Medicine articles to obtain their measures and the algorithms to calculate them. We applied their initial set of 26 measures to 2012 data, and spending estimates were based on standardized prices from 2009. These prices adjust for regional differences in Medicare payment rates.

We presented these results to you last April and also published them in our 2015 data book and our 2016 March report. For the analysis we're presenting today, we applied the 26 measures from the original work plus the 5 new measures to 2012 and 2013 data. We also updated the standardized prices from the base year of 2009 to 2012.

So here are the aggregate results from our analysis of all 31 measures for 2013; the results for 2012 were similar so we are not presenting them separately.

Based on the broader versions of the measures, 38

percent of beneficiaries received at least one low-value service. A single beneficiary can receive more than one service, which explains why there were 74 low-value services per 100 beneficiaries. Medicare spending for these services was about $7.1 billion.

Based on the narrower versions of each measure, 23 percent of beneficiaries received at least one low-value service, and there were 35 low-value services per 100 beneficiaries. And total Medicare spending for these services was about $2.6 billion.

We grouped the measures into six larger clinical categories, using categories created by the authors of the JAMA Internal Medicine articles. This table shows which categories accounted for most of the volume and spending, and it is divided by the broad and narrow versions of each measure.

Under the broader version (in the first column), imaging and cancer screening accounted for most of the volume of low-value care, but cardiovascular tests and procedures and other surgical procedures made up most of the spending.

Under the narrower version of the measures (in

the second column), imaging and diagnostic and preventive testing accounted for most of the volume, but other surgical procedures and imaging comprised the majority of the spending.

This indicates that if you wanted to reduce spending on low-value care, you probably want to focus on cardiovascular tests and procedures, other surgical procedures, and imaging services.

Here are results for some of the individual measures, and results for all the measures are in your paper.

The first row on the slide shows back imaging for patients with nonspecific low back pain. Based on the broader version of measure, the number of cases per 100 patients in 2013 was 11.9 and spending was $236 million. Based on the narrower version, the number of cases per 100 patients was 3.4 and spending was $68 million.

The second measure is PSA screening for men age 75 and older. The number of cases per 100 patients ranged from 9.2 under the broader version to 5.2 under the narrower version.

The third measure on the slide is colon cancer

screening for older adults; the number of cases per 100 ranged from 8.4 to 0.4.

These results show that the volume of low-value care that we detected can vary substantially based on the measures' clinical specificity.

In addition, the measures on this slide account for a relatively high share of low-value care; there are other measures -- not shown here -- that account for very small shares.

Our results probably understate the volume and spending on low-value care, and thus they represent a conservative estimate of the actual amount of low-value services, and this is for the following reasons:

First, there are a limited number of measures of low-value care that can be calculated with claims data. This analysis used 31 measures, while the Choosing Wisely campaign has identified over 400 tests and procedures that are often overused.

It can be challenging to identify low-value care with claims data because claims may not have enough clinical detail to distinguish appropriate use from inappropriate use.

In addition, our spending estimates probably understate actual spending on low-value care because they don't include downstream services that may result from the initial low-value service.

For example, a PSA test with an abnormal result can start a chain of events that leads to prostate biopsies and prostate cancer treatments.

A recent study estimated Medicare spending on PSA tests and downstream diagnostic services related to the test. For men age 75 or older, average annual spending for the PSA tests and follow-up diagnostic services was $145 million.

PSA tests accounted for only 28 percent of the $145 million. Half of the cost was related to biopsies, and about one-fifth was related to pathology.

This research raises the question of whether changes in payment policy and delivery systems can influence the use of low-value care.

In one of the articles we referenced earlier, Schwartz and colleagues compared changes in the use of low-value care between beneficiaries in Pioneer ACOs and a control group of other beneficiaries.

The study used the same 31 measures that were in our analysis, and it excluded Medicare Shared Savings Program ACOs.

The authors found that Pioneer ACOs had a greater reduction in volume and spending for low-value care relative to the control group. These results suggest that changing financial incentives at the organizational level can discourage overuse.

I would like to conclude by laying out some potential policy directions for addressing low-value care.

First, you could think about payment and delivery system reform, such as ACOs.

Second, quality measurement could incorporate measures of low-value care, although it would be difficult to apply these indicators to groups with a small number of beneficiaries.

A third issue to consider is CMS' coverage policy.

And, finally, you could think about encouraging greater beneficiary engagement through changes in cost sharing or use of shared decisionmaking.

In shared decisionmaking, providers communicate

with patients about the outcomes and uncertainties of tests and treatment options, and patients discuss with providers their values and the importance they place on risks and benefits.

This concludes my presentation. I'd be happy to take any questions.

DR. CROSSON: Thank you, Ariel. Very clear.

Let's start with clarifying questions. Clarifying questions for Ariel?

MR. GRADISON: On Slide 12, it's kind of a subjective question, but these percentages, while important and in the proper direction, are relatively small. Do you think that the definitions that are used in measuring this are specific, that these numbers are meaningful? And, of course, a follow-up question is: Can you get data from larger managed care plans that might shed additional light on this?

MR. WINTER: So one thing to keep in mind in terms of the numbers is that the analysis was comparing three years of data before the Pioneer ACO contract went into effect with only one year of post data, after it went into effect. And so the authors suggest that the changes

could be greater over time as the Pioneer ACO becomes more -- implements, you know, its changes to how care is delivered.

On the second question, you're asking about the specificity of the measures and how that might affect the changes we're seeing. That can certainly play a role, and if you had a bigger set of measures or if your measures were more broadly defined, you might see bigger changes. But it's hard to predict how that might go.

Then the third question was about looking at managed care organizations, and I'm going to infer that you're maybe about asking using encounter data for Medicare Advantage plans, and that's something that we can think about doing. We certainly would want to talk to the measure developers and explore the encounter data, particularly how complete the data is. That's something we can think about for the future.

MR. GRADISON: Thanks. The reason I raise that obviously is that issue here, in part at least, is trying to influence the decisions that are made by practitioners, and there may be a little bit more leverage in the organized plans.

DR. CROSSON: Bill, I'll just make one point, probably the same one that Scott's about to make. I can tell you from my own experience in my former life, with my former organization, I had data like this, and the differences were vastly greater than what we see here.

MR. GRADISON: Thank you.

MR. ARMSTRONG: Actually, I had a clarifying question.

[Laughter.]

DR. CROSSON: [off microphone] violation.

MR. ARMSTRONG: I think it's a great piece, and the analysis that has been done around this I think is really interesting and very important. You talk about the estimated cost, and I presume you're really looking at the cost of the services that were low value, given the definitions. But is there any estimate that's been done of like the broader harm or the subsequent procedures or subsequent costs, which could be quite a bit more than that? I just don't know if we have any feel for that at all.

MR. WINTER: This earlier question, that's something we talked about last year as well when we

presented the data from 2012. I don't have -- the short answer is no, I'm not aware of an estimate of the broader downstream effects, but -- and it's difficult to link downstream services using claims data to an initial service. And it's something that I've talked about with the contractors from Harvard Medical School, and they agreed it's very difficult to do, but -- which is why I looked at the literature in particular with regards to PSA tests and brought to you the study which looked at the costs of both the PSA tests and the downstream diagnostic services, which was a larger number than we were finding for this side group of men over age 75.

Then there's another study which we cite in the report, but I didn't mention in the presentation, which found that -- which looked at the total lifetime costs of prostate cancer screening and treatment and found that the diagnostic part of that cost is only about between 2 and 8 percent -- I'm sorry between 4 and 8 percent of the total lifetime costs. So the treatment costs are a much bigger part of the total costs.

DR. CROSSON: Other clarifying questions?

DR. HOADLEY: You measure these various things.

I'm thinking like the imaging, for example. If one beneficiary has multiple cases of imaging that's rated as inappropriate, do you count all of those? Or are you counting whether a particular imaging occurs for that person as one as opposed to if it happened three times you count it as three?

MR. WINTER: I don't remember how their algorithm works in that regard, so I'll look into it and get back to you. They can certainly have multiple different kinds of low-value services, but if they have three imaging studies from low back pain --

DR. HOADLEY: Repeating a month later --

MR. WINTER: Yeah, I don't know, and it might vary by service also, so I'll look into that.

DR. HOADLEY: Okay.

DR. SAMITT: So I think this is a clarifying question, but it may morph into Round 2. How effectively do you feel Choosing Wisely recommendations are a proxy for low-value care?

MR. WINTER: So, I mean, these are determined -- developed by the specialty societies, so it's based on their judgment. They're supposed to be evidence-based, and

each one of them cites a literature that backs up their recommendation. But, you know, there is sometimes disagreement among different specialty societies. For example, for PSA tests you have groups like the Academy of Family Medicine saying it should not be done -- PSA tests should not be done routinely, and you have the American Urological Association saying they should be done but only with shared decisionmaking.

So there is a range of recommendations even for the same test, and we've talked about where the Preventive Services Task Force came out, which most recently said that -- they recommended against PSA tests for men of any age. So there's clearly some differences, and not being a clinician, it's hard for me to say, you know, how many of them are -- to what extent they are valid. But just to -- I'm sorry. I should have said earlier that the team of researchers that we've relied on for these measures, they reviewed, you know, each of the Choosing Wisely recommendations and picked the ones that they thought were most valid and most relevant for the Medicare population and could be detected with claims data.

DR. CROSSON: Craig, there's a point there that

you have, and it was my observation, you know, in looking at at least the first iteration of the Choosing Wisely, the choice of the Choosing Wisely issues, that they seemed to lack the presence of the most highly remunerative issues almost by specialty. And, I have to admit, I haven't seen the most recent ones, but I think there's a point there.

DR. SAMITT: And, I think this is where I was going, and this may move into round two, but in my new role, I've become very much steeped in the whole world of evidence-based medicine and the use of evidence-based medicine to really help make policy decisions about what's high value and what's low value.

And, so, I wonder to what degree Choosing Wisely syncs up with the true evidence about high value/low value, and I'd be curious to know, and I'm not sure if we've ever done this, when we look at large managed care plans or large national plans and we look at coverage determinations and their view of high value/low value, how does that sync up and match policies that sit with CMS?

And, I don't know if there's ever been a comparison to really identify where the greatest distinctions are. And, I would imagine a lot of what's in

Choosing Wisely is included. You know, those 400 things, I would imagine, are common to both CMS and large plans. But, my guess in all reality is it's more like 2,000 things that are considered low value, not 400, that would identify that this opportunity in low value is far bigger than we're possibly talking about here if we studied it correctly.

DR. CROSSON: Hey, Rita, would you like to begin the discussion?

[Laughter.]

DR. REDBERG: Sure. I have just a few things to say.

[Laughter.]

DR. REDBERG: But, I did want to, just to clarify, and maybe you already knew, but in Choosing Wisely, which ABIM Foundation says was a start, which is true, certainly, there was no requirement for an evidence review and there was no requirement that they look at more commonly used procedures. And, certainly, one of the criticisms has been that it was some of those procedures were already not done or not done very much anyway.

But, getting -- and, so, I agree. Actually, my first point, it was a great presentation and chapter and I

think there is a lot in here for us to look at, because to eliminate things that are harming our beneficiaries and cost a lot of money seems like a no-brainer to me. And, I agree, it's a small fraction here of what is actually being done in terms of low-value care.

Even, for example, if you look at the cancer screening list -- well, first of all, for whatever reasons, I mean, I'm sure they took things that were easily attainable for administrative data, but mammography is not on here and mammography is not recommended for women over 75. Colorectal cancer screening, you know, the other issue is the frequency of colonoscopy. It's only supposed to happen every ten years, but we know that Medicare pays for it more frequently than that.

And then the whole PSA testing. So, here, the recommendation, the broad one was over 75, but, you know, in 2012, the test was updated that to a Grade D for PSA testing full stop. So, that's huge. And, you're right, that's only a few percent of the actual cost of PSA testing, and so it's true that there's a wide range of recommendations. I have to say, you know, because so much of the PSA testing leads to a lot of treatment, and the

Urologic Association, of course, has been most positive about it, but that is also -- I mean, financially, they are very busy with a lot of the downstream.

There was a New York Times article a few years ago on PSA testing that just gave the numbers, and I'm just going to -- I brought it up. I mean, this would be sort of the informed discussion, I think, if they wanted to go ahead with the informed discussion. It says, imagine you're one of 100 men in a room. Seventeen of you will be diagnosed with prostate cancer and three will die from it, but no one knows which one. So, then someone comes -- a doctor comes in and has 17 pills, one of which will save the life of one man with prostate cancer. So, you know, there, you're at one in 100.

But, then it says, after handing out the pills, the same doctor in the white coat randomly shoots one of the men dead and then shoots ten more in the groin, leaving them impotent or incontinent, because that's what we do with the treatment for prostate cancer. Well, you know, knowing that, then do you want to go ahead and have the PSA, and that would be the informed discussion. I guarantee you, that's not happening.

[Laughter.]

DR. REDBERG: So, you know, and actually, the doctor who discovered PSA in 1970, Richard Ablin, has written a book called The Great Prostate Hoax: How Big Medicine Hijacked the PSA Test and Caused a Public Health Disaster. But, yet, Medicare is still paying for PSA. I mean, we're obligated. Medicare has to pay for tests for its Grade A and B. But, why do we have to pay for Grade D? We don't, obviously, have to, but, you know, there's no tradition of take back, clawback, or -- and I would suggest that it doesn't make a lot of sense to me that Medicare would pay for a Grade D cancer screening that we know is leading to tremendous harm.

That's not to say if men want to get PSA screening, they can certainly get it, but why should Medicare pay for it when the recommendation from the task force is not to do it and we know -- and we know that payment policy does influence medical testing.

And, I was just -- in the mailing materials, there was a commentary from Gail Wilensky on understanding responses to reductions in CMS payment, but she notes that part of the Affordable Care Act was that CMS is supposed to

reduce amounts paid by Medicare for overvalued services. So, I think there's already the regulatory authority to do that. And, she particularly notes that CMS should consider using this strategy for other potentially overvalued services -- her commentary is on nerve conduction studies -- particularly those that have a high cost, such as the use of proton beam therapy, which is a very expensive intervention with little clinical evidence supporting its use. And we know that proton beam therapy is used for prostate cancer.

So, you know, those millions that you showed us are just a small fraction of the actual spending on prostate cancer therapy, and that there are a lot more harms and hundreds of millions, if not billions, of dollars being spent. So, I think there's a lot of opportunity there.

It also occurs to me it's an opportunity in these overvalued services to introduce, again, that concept of reference pricing, so that if you have a lot of different therapies, say, for prostate cancer, you pay the same amount for all of them, because they differ very much in price, but they all would have the same sort of outcomes.

That's another opportunity to sort of drive higher-value care.

And, again, looking at that, because one of the higher spends were in cardiac care, it said, for PCI for stable coronary disease. Well, we know a lot of the PCI for stable coronary disease is done in patients who are not on medical therapy, which is equally effective for stable coronary disease. So, again, the concept of reference pricing, where we pay for treatment of stable coronary disease, but the same amount. It would take away the incentive that there is in the current fee-for-service system where procedures are reimbursed much higher than medical therapy.

And, so, I think that there's a lot of opportunity for really a win-win in terms of improving care and decreasing cost and decreasing harms, because these procedures that have -- and imaging. I mean, all of this, really, it's only touching the surface. The imaging tests, you know, the back pain, they lead to billions of dollars of back pain procedures of unclear benefit.

So, again, I think that we should -- seem to have the authority, and that is a very fruitful area, because we

can improve care for our beneficiaries.

DR. CROSSON: So, thank you, Rita.

Let me -- could you put up -- yeah, you've got it, Slide 13. So, I want to have a little bit more discussion about relative weighting of these policy directions. I have to admit, when I first looked at the list, I said, yes, because it seems like they're all fruitful and I couldn't rule one or the other out at the moment. But, I wanted to get a sense of where the Commission is.

Kathy, and then Mary and Scott.

MS. BUTO: So, I want to add one to the list. First of all, Medicare coverage policy is a good one to have up there, but it's a tough one to actually use on a procedure by procedure, technology by technology basis. You can use it, but when you're trying to differentiate which imaging can be used for what things and so on and so forth, it's cumbersome. It takes a while.

What I wanted to add up there is prior authorization, which we never bring it. It also, on the same issue with the consolidating coding approach on drugs, one of the things I forgot to mention is if you're

concerned that individuals are using high-cost drugs inappropriately, a good tool is to have some kind of, you know, prior authorization or something that is more sensitive to what their clinical need is, and if they don't need it, then you've got an avenue to go down.

But, I think that's a tool that is not available right now in fee-for-service, and particularly for a number of these where you might approve imaging for certain patients and not other patients, or it's okay to start with a non-coverage decision for a whole category, but it's also true that you might want to have shades of some kind of coverage policy that allows for oversight, but not a total ban on coverage for this thing.

So, I just wanted to add that to the list, because I just don't think payment -- we can use payment exclusively to drive to the appropriate treatment. I mean, payment has its place, but there are other things and we ought to have some way to look out for what's being provided on a, you know, more of an ongoing basis. It is a cost, but we're already spending a lot of money in this area.

DR. CROSSON: Mary, Rita, and Scott.

DR. NAYLOR: So, I think this is a terrific report and highlights a tremendous opportunity if we can get our arms around it. Even if you stick with the 31 and the narrower definition, you're still talking 2.6 billion. And then if you can grow it to 2,000, that's extraordinary. But, I think it's a critically important signal to start somewhere, and this makes a great deal of sense given the body of work.

In terms of -- I should acknowledge that I am on the American ABIM Foundation, and just to clarify that Choosing Wisely was always intended as a campaign to stimulate conversations between physicians, other health professionals, and patients about this, not to come up with the 31 of these measures.

That being said, I think what we can learn from the Pioneer, the Schwartz work and the evaluation about how they were successful in getting to probably the behavioral changes as well as what incentives they used would be very helpful. The Robert Wood Johnson Foundation is funding multiple demonstrations of efforts to do this, get to pay for high-value care, somewhat stimulated through Choosing Wisely. So, I'm happy to help connect you with that.

I do think all of these apply, but I would say, you know, and I know we go to beneficiary engagement early, but it's really tough. I mean, I think it's -- you know, if I were to build, it would be a sequence of trying to get the providers to change their behavior through whatever coverage or value-based outcomes that suggest that this was worth the investment. But, getting beneficiaries to go from health literacy to informed decision making and shared decision making, to me, is a tool in the toolbox, but it's not where I would direct a lot of energy first. I would go really directed toward those who are ordering these tests or services.

DR. CROSSON: Rita.

DR. REDBERG: Thank you. I actually didn't have my hand up, but there was something I wanted to mention in terms of quality measurement. I do think Medicare coverage policy, as I mentioned, is an effective means, and certainly not covering low-value tests, even cancer screening, would be very important.

In terms of quality measurement, I would say CMS did just introduce a quality measure related to PSA testing and then has dropped it.

DR. CROSSON: Right.

DR. REDBERG: So, that is of concern, I would say.

DR. CROSSON: Yeah. If I remember correctly, it was pretty extreme. No -- what was it, no PSA testing at all, or no PSA testing --

DR. REDBERG: I have to look it up. I wouldn't want to --

MR. WINTER: I can address that, if you want, Jay.

DR. CROSSON: Go ahead.

MR. WINTER: So, the proposed measure -- they were developing this with Mathematica and there were supposed to be electronic clinical quality measures for eligible professionals, so for PQRS or the HR incentive program. And, so, the measure -- it would have measured the share of all adult men who received a PSA screening test, and there were exclusions for patients with a history of prostate cancer or a prior elevated PSA test result and a couple of other exclusions. And, they temporarily, as you were saying, they temporarily suspended development of the measure -- these were their words -- after they

received many comments opposing limits on PSA screening. And, they said, they'll continue to solicit input from stakeholders.

DR. REDBERG: I would say that didn't sound extreme to me. I mean, they had their appropriate exclusions. I mean, you could put in a few percent, but I can imagine where the comments came from.

DR. CROSSON: Fair enough. Scott.

MR. ARMSTRONG: Yeah, just very briefly. I think I would focus on the first and the fourth bullets. I think I'd argue a little with Mary and say I think our tendency has been really to live in the first bullet around payment reform and there's been all this around MA and ACOs and bundles and so forth, and that I actually think probably through as much as anything the way you've designed the benefit through cost sharing or whatever, but also creating some expectation that -- I mean, your metaphorical situation, it's, like, that's all about being informed about what is the likelihood that this will help you or hurt you, that we understate the impact that that can have. It doesn't happen well if you don't have a delivery system that's capable of it.

But, I think one and four are really the two areas I would focus on, with four too often not getting the amount of attention here that I think it deserves.

DR. CROSSON: Bill Hall.

DR. HALL: Just one observation. I agree with the one and four choices. If I take a hundred patients that I've counseled on this, on any of these topics here, PSA testing, X-rays for low-back pain, et cetera, 99 out of 100 will say one response to me, after my pitch. They'll say, well, does Medicare pay for it? And, that just erases the last ten minutes of my life.

DR. CROSSON: Herb.

MR. KUHN: So, let me make first an observation on something Kathy raised, because I thought it was pretty important, the prior authorization issue. Just -- it's used in Medicare sparingly, but mostly in the program integrity area. And right now, CMS has, or they finished comments on an initiative they were looking at doing a hundred percent prior authorization, I think, on home health in five states. And, what I think concerned a lot of folks is that you have the CJR Initiative that began on April 1, and so here you've got a 90-day bundle for hips

and knees and one of the primary things you're trying to do is discharge those folks, hopefully, into home health, the lowest-cost setting. But now, all of the sudden, you've got a pre-auth that might cost you days back up in the hospital waiting for that pre-authorization. So, pre-authorization is a good tool, I think, in the program integrity area, but as we get more into these bundled payments and other things out there, it could get complicated, and just to put that on the table as we move it out there.

Also, it's an incredibly resource intensive thing, and whether CMS has the bandwidth to manage something like that. So, I think if you think about that one in the future, do think about CMS resource allocation and the complexity of an organization that really has never used this tool before in this way. It would be brand new to them, since mostly it's been in the program integrity.

MS. BUTO: [Off microphone.] -- contractor.

MR. KUHN: Yeah. The contractors would ultimately have to do it. Kathy is right.

So, having said that, I agree with Scott. I think one and four are the real opportunities, you know,

particularly, as I just mentioned, on the CJR Initiative, people are going to be trying to get rid of frivolous activities and try to really focus on the value that's out there. And, so, I think the payment and delivery system reform holds real opportunity.

And, then I was curious about, ultimately, the work of comparative effectiveness and the work of Cori, and are there any learnings from there that ultimately can migrate into some of this work to help us.

DR. SAMITT: See, I'm more inclined with you, Jay, to think that all four categories have potential merit, and I think we should at least keep talking about them and evaluate the levers that we could pull in all four because I'm concerned that the strength, for example, of the payment alignment isn't sufficient to sort of countervail the intentions to still generate volume that may be unnecessary, and that sort of having a belt-and-suspenders approach to really aligning interests around high-value care makes sense. And so I think multiple categories, including Medicare coverage policies, should not be discounted as we evaluate ways to do this.

The one that's missing, though, on here -- and

maybe we just assume that delivery systems would do this because of the other four levers -- are things like decision support and really requiring delivery systems to integrate decision support. I think one of the reasons why we're not seeing some of the Choosing Wisely recommendations more broadly implemented is that there isn't a sort of a point-of-service reminder for clinicians that this is a Choosing Wisely issue that really should be rethought, and so I don't know to what degree CMS would ever think about either requirements for decision support or even evaluating some methodologies to prompt clinicians at the point of delivery regarding Choosing Wisely guidelines.

There's some organizations out there that are developing methodologies to do exactly that. I think that having the tool to complement the incentive is much more effective than just the incentive alone.

MR. WINTER: Can I Just address something that you just said, Craig? In terms of clinical decision support, there was recent legislation that mandated that imaging providers consult with clinical decision support software about the imaging order in order to get paid for

it, and CMS has begun the process of identifying -- certifying clinical decision support software for that purpose, so that will go into effect in the next couple of years for imaging.

DR. HOADLEY: So I guess as I look at this list, I can sort of feel like I can articulate the limitations of each of these tools. I mean, some of them have been said. Coverage policy is bulky. It's hard to do. A lot of individual measures, quality measurement, there's just always a question of how much it really changes behavior. So it may not be a helpful comment.

I mean, I think on the beneficiary engagement, the thing I worry about is it becomes a matter of just increasing cost sharing for a set of services that we think are undesirable. If it's put in partnership with some lowerings of cost sharings elsewhere that are burdensome and don't seem to be related to decisions, whether to do care like some of the hospital stuff, make more sense. Obviously, it's got the aspect of being blunted by the Medigap coverage as well.

I think with each of these, we're really got to think through if we really want to see an impact on the use

of these services. I don't know if we've got the right solutions on this list at all, but I don't, fortunately, have anything to add to it.

And prior authorization, which was added, you can talk about those issues there too with -- again, the item by item, I think Herb made some of these points, as well as the potential, is it like on the drug area where you have to then think about exceptions and how do beneficiaries that really need it sort of get to it, and so you have potential access here.

MS. BUTO: Just to follow up on something that Jack was saying, I'm wondering -- and I think it was Herb who mentioned to Cory -- if something that we might think about I this context would be a process for CMS to get advice on an ongoing basis, the way they do with the Preventive Services Task force; in other words, instead of putting it on them to come up with the list and then go through a coverage process, if there was a more kind of systematic way for an evidence-based group, whether it's PCORI or otherwise, to identify low-value services for the Medicare population that then gives CMS a little bit of cover in proceeding to either go forward with a limited

coverage or whatever it is, I think that would be helpful, so, as you flesh this out, if you could think about those bodies or entities.

And I think we've mentioned like the Coverage and Evidence Development workgroup and so on, but there may be others as well that we can tap into.

DR. CROSSON: Cori.

MS. UCCELLO: So I don't have an opinion on these four, but I do have a comment on what categories of low services. On Slide 9, you broke things up into categories that account for the volume, most volume, and those that are most -- the spending. And I don't think we necessarily want to focus solely on those that account for the most spending because those high-volume, low-value services still have the potential for those screenings and imagings themselves to cause harm, and they will also have potential high cost downstream. So I don't think we want to kind of eliminate those from consideration as this moves forward.

DR. CROSSON: On that point Ariel, has anybody done that sort of categorization, taking a look at both the low volume and the high cost and then looking at the downstream cost? I mean, it seems like that would be

important but a lot of work.

MR. WINTER: Yeah. I'm not aware that anyone has done that, and these categories were the categories created by the folks from the Harvard that we contracted with, and when they do the analysis, they came up with a similar set of categories that were high volume and high spending, but they did not look at what the downstream costs were of these high-volume categories.

DR. CROSSON: Great input for Ariel and the staff. Thank you very much. We will be hearing more about this in the future.

Now we have the second opportunity today for input from the public. If there are any individuals in the audience who would like to make a comment, now is the time to come to the microphone, so we can see how many people we have or if we have any.

[No response.]

DR. CROSSON: Seeing none, we are adjourned, then, until 8:30 tomorrow morning. Thank you.

[Whereupon, at 5:05 p.m., the meeting was recessed, to reconvene at 8:30 a.m., Friday, April 8, 2016.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, NW
Washington, D.C. 20004

Friday, April 8, 2016
8:27 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
SCOTT ARMSTRONG, MBA, FACHE
KATHERINE BAICKER, PhD
KATHY BUTO, MPA
ALICE COOMBS, MD
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
HERB B. KUHN
MARY NAYLOR, PhD, FAAN, RN
DAVID NERENZ, PhD
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
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AGENDA PAGE

P R O C E E D I N G S

[8:27 a.m.]

DR. CROSSON: Welcome to our last session of this Commission year. I'll just take this brief opportunity in public to thank once again the five Commissioners who will be leaving us and who have contributed so greatly to the success of this Commission.

This morning, we are going to take up again the issue of access to care services, particularly emergency care services, in rural areas. We've got a presentation from Jeff Stensland and Zach Gaumer, and it looks like, Jeff, you are going to start out.

DR. STENSLAND: As Jay said, we're going to revisit our October discussion of ways to improve efficiency and preserve access to emergency care in small rural communities. We expect that your mailing materials on this topic will be revised based on your discussions today and then become a chapter in our June report. And the idea is not to have formal recommendations at this point, but to get policymakers and those in the hospital industry to start talking about alternative models for efficiently preserving access in some sparsely populated

rural communities.

Before I start, I want to thank Anna Harty for her excellent work on this project.

Since the start of the prospective payment system in 1983, Medicare has made special payments to certain rural hospitals with the objective of preserving access to care.

However, the current models are all inpatient centric. They pay higher inpatient rates for small rural PPS hospitals and cost-based payments to critical access hospitals for inpatient and outpatient services.

There are two main problems with these models:

First, as inpatient volumes decline, these models become increasingly inefficient. Costs per unit increase, and the literature points to concerns about the quality of care when clinicians have few inpatient cases to gain experience with.

Second, the models are not always successful in preserving access, and some hospitals have been closing.

I will briefly review these two problems and then discuss some alternatives.

There are four key Medicare programs that are

intended to preserve access in rural areas by increasing inpatient payment rates to rural hospitals.

The sole community hospital program increases payments by about $900 million per year to over 300 hospitals, primarily by increasing their inpatient rates.

The Medicare-dependent hospital program increases inpatient rates by over $100 million to 150 hospitals that have high Medicare shares in rural areas.

In addition, the MDH and SCH hospitals can also qualify for a low-volume add-on if they have fewer than 1,600 Medicare discharges, and most of them do.

Finally, the majority of rural hospitals right now are critical access hospitals, and they receive cost-based reimbursement for inpatient and outpatient services.

And the takeaway point from this slide is that existing special payments to rural providers all require that they provide inpatient care.

The inpatient focus of the existing models in the foundation of their limitations. As hospitals have lower volume, their unit costs go up. Lower volume, as I said, also raises questions about the quality of care. There is a fairly consistent literature on the concerns regarding

the relationship between volume and outcomes. With higher unit costs and questions about quality, there is a concern that low volumes may lead to low value.

Second, most rural hospitals are critical access hospitals that receive cost-based reimbursement, and there are three issues with cost-based reimbursement I would like to highlight.

First, hospitals with higher profits on their non-Medicare business tend to have higher costs, and we discussed this and showed some quantitative information in your mailing materials.

Therefore, cost-based reimbursement can direct higher payments to CAHs that are better off financially. In contrast, if a critical access hospital is struggling financially and tries to reduce its cost structure to stay afloat, Medicare payments decline due to the reduced costs. So higher payments for the better-off hospitals, lower payments for the worse-off hospitals.

Second, it encourages non-emergency services such as MRI services and post-acute care. These services have higher shares of Medicare and private patients which can generate cost-based reimbursement or high private rates.

In contrast, emergency services tend to have more uninsured individuals which makes them less profitable under a cost-based system, as we discussed in your mailing materials.

Finally, cost-based reimbursement reduces the incentive for cost control, and we illustrated this in your mailing materials by showing the higher cost growth at critical access hospitals than at PPS hospitals in recent years.

So the two limitations we discussed here are greatest for critical access hospitals with really low volumes, and this problem of low volumes at critical access hospitals is evident when we look at the following chart.

This graph shows that the admissions have declined by one-third for the average critical access hospital over the past decade. This is the yellow line showing volume down to less than 400 admissions or about one per day at the median CAH.

For the 10 percent of CAHs with the lowest volume, the red line, volume has dropped in half with about 10 percent of CAHs admitting fewer than 90 patients per year. That is about two patients per week. It is difficult to efficiently staff a hospital at that low a

volume, and there is also a concern that clinicians may not have the advantage of gaining experience with large numbers of inpatient cases.

Now, as admissions have declined, we have seen some increase in closures. In rural areas, 41 hospitals have closed over the past three years. The distance from the closed hospital to the nearest open hospital varies widely. Three of the closures were within 10 miles of another hospital, 24 from 10 to 20, 13 from 20 to 30 miles away, and one was more than 30 miles away from another hospital.

Unlike the early years of the critical access hospital program, some CAHs are now closing despite receiving cost-based reimbursement from Medicare. This tells us that while cost-based reimbursement has increased payments to many providers, it does not always keep the hospital doors open. As we show in your mailing materials, there were seven CAHs that closed in 2014. In the year prior to closure, the median closed critical access hospital received inpatient and post-acute payments that were $500,000 above PPS rates. However, the extra $500,000 was not enough to keep the hospital doors open. That was

absorbed by the higher inpatient costs at these hospitals. This raises the question: Is there a way to direct existing Medicare subsidies toward emergency services in order to improve efficiency and access? Could we offer these rural hospitals the option of a financially viable outpatient-only facility?

The goal of an outpatient-only model could be as follows:

First, we have always stated this would be an option, not a requirement for small rural communities.

Second, the model should preserve access to emergency services.

Third, it should improve efficiency.

Fourth, we want to have community commitment to the option, and this could be assured by requiring matching grants from the county or local sources.

The first option is a freestanding emergency department model. In this case the facility would maintain an emergency department that is open 24 hours a day, 7 days a week. Medicare would pay the facility outpatient PPS rates just like it was a hospital-based ED. This would level the payment rates between freestanding EDs and full-

service hospitals in these isolated rural areas. However, as we discussed, that may not be enough given the really low volumes at some rural facilities. Therefore, there would be a fixed grant to help with the standby capacity costs of the facility.

In order to receive the fixed grant, the hospital would have to be willing to give up acute inpatient services and give up cost-based reimbursement of its post-acute-care services. It could still lease the hospital beds to a SNF that would then receive regular PPS SNF rates. And the conversion of rural hospitals to SNFs is not an uncommon phenomenon.

Finally, this would be seen as a choice for the hospital and not a requirement. Many hospitals will continue with their critical access hospital or PPS status. But this would provide a clear option for those who are struggling with declining inpatient volumes.

The second option is for smaller communities that cannot support a 24/7 emergency department. In these communities there may simply not be enough patients, or there may not be enough clinicians -- physicians, PAs, or NPRs -- to cover an ER 24/7.

In this case there could be primary care clinic that has an affiliated ambulance service. The clinic would be open 8 or 12 hours a day; the ambulance service would be available 24/7. A similar model is being evaluated by the Kansas Hospital Association.

The clinic would get two types of payment. One is a PPS rate per unit of service. The second is a fixed grant to help with the standby capacity of the ambulance and the facility. For example, they could use the fixed grant in part to help cover the cost of hiring a paramedic to coordinate the volunteer ambulance service.

While special payments may be needed to keep hospitals open and keep the emergency department operating, we made it clear in our 2012 report on rural health care that special payments should be targeted at providers that are needed for access. We specifically said Medicare should make eligibility limited to isolated providers.

For example, if two hospitals are 5 miles from each other and they are both struggling with low volumes and both struggle to recruit physicians and other clinicians to cover their emergency department, it does not make sense to split the emergency volume between these two

facilities. To avoid duplicative services, the special payments would only be available to isolated emergency departments.

What this means in practice is that freestanding emergency departments would have to be some distance from full-service hospitals and other freestanding emergency departments in order to get this extra financial support.

Now, there are some issues to be worked out with both these models.

With the first model, it is clear that the product we are buying is 24-hour standby capacity at an emergency department. With respect to this option, a key question will be minimum staffing levels. For example, will hospitals receiving the grant be required to have physicians, PAs, or NPs in the hospital or in the emergency department 24 hours a day? What will be the maximum response time for the on-call physicians who may be backing up the NPs or PAs?

In addition, will the hospital be allowed to convert back to CAH status if the community changes its mind and decided, oh, we really did need inpatient capacity in this community?

Now, the second model, the clinical and ambulance model, has some more difficult issues.

First, it is not quite as clear what the product we are buying is. Is it primary care and ambulance service? But what level of primary care? Will it be open 7 days a week? What will be the minimum staffing levels? Will there be minimum ambulance response times or levels of technical training?

Finally, it may be more difficult to set eligibility limits on the second program. In the first case, there is a limited number of freestanding emergency departments right now and a limited number of hospitals that would want to convert to this model. However, as Kathy mentioned last October, there could be somewhat of a woodwork effect in the second model. Even if the program was limited to isolated communities, there are small communities that already have ambulances and a primary care practice, and they may all want to feel like they should receive the grant funding, too. So existing rural health clinics, in addition, may feel they should receive some grant funding just like the freestanding EDs. Therefore, limiting eligibility may be more challenging in that second

model.

So let's talk about the potential effects of these models. For the beneficiaries, there would be three primary effects.

First, and most important, it would preserve access to emergency services.

Second, the patient would have to travel further for inpatient care. There would no longer be inpatient care in their community. But you should recall that many rural patients are already bypassing their rural hospitals for inpatient care. Recall that 130 critical access hospitals have fewer than 90 admissions per year.

Finally, as we showed in your mailing materials, coinsurance would be substantially lower under this model than under the critical access hospital model. The coinsurance would be the same as at PPS hospitals.

For the providers, there are four key points.

The first thing to remember is this is an optional program. So if they want to continue with the status quo, they can.

However, for those that are at financial risk or simply operating inefficiently under the current model,

this could provide financial viability and greater value to the community.

In addition, the next point is hospitals often play a key role in recruitment of physicians to small communities. And it is important that under this model there will still be a local health care entity there to recruit physicians. And, in fact, the entity may be seen as a more desirable place to work given the financial stability provided by the grant funds to the entity.

Finally, cost structures will be lower. As we discussed in your mailing materials, critical access hospitals are now currently paid over $1,800 per post-acute day. This can make care in the critical access hospitals look expensive in any type of ACO model or any other model where providers are taking responsibility for the overall cost of care. Moving these communities to PPS rates will make it easier to incorporate these communities' physicians into accountable care organizations and other models that take responsibility for the cost of care, because the overall costs per unit of service will be much more competitive.

Now, there are several discussion issues:

First, we could discuss the two models. What are the products the program would be buying under each mode? Are there minimum staffing levels we should require? Is there one model that looks more plausible than the other? And are you concerned about what the eligibility standards would be for the different models?

Also, to assure community commitment, we could require a local or county grant to match part of the Medicare grants. We can discuss that.

Finally, in October several of you suggested that a facility that converts from critical access hospital status to a freestanding ED status should have the ability to convert back for a limited number of years, say five years. And the idea here is this might reduce some of the anxiety that these community boards would have about converting their hospital from a full-service hospital to an outpatient-only facility and may facilitate actually more conversions by having the option of going back.

We will now open it up for discussion of these issues and other thoughts you may have on efficiently preserving access to emergency services in rural areas.

DR. CROSSON: Thank you, Jeff and Zach. Very

clearly constructed, as usual.

Right now we're going to take clarifying questions, and then we're going to have a general discussion, and Herb and Sue will be leading the discussion.

Clarifying questions?

MR. THOMAS: Do we have any idea how many facilities we think may fall into this type of category that would be potentially impacted by this policy or opportunity?

DR. STENSLAND: If you look at the opportunity to move to a 24-hour freestanding ED, I think that one's a little easier. I don't know, maybe something like 100 hospitals or something. There are 130 of them right now that have fewer than 90 admissions per year, and maybe there would be 100, maybe 200, something like this, in the whole country.

MR. THOMAS: And I guess if you look at those that have 90, I mean, if you think about -- have you thought about what is kind of the scale that you would want to see this type of option used? You know, so if you think of 90, that's pretty small, obviously. I mean, you would

think that probably even a larger facility than that, this may be a good option for them. Have you thought about how that would scale up and what that might look like?

DR. STENSLAND: I haven't -- at least the way I've thought about it, I haven't thought about it as prescriptive of saying, okay, this is who should do it and who shouldn't. I thought of it more in the way as if we took the funds that we're already spending for critical access hospitals, say this half a million dollars, and we said, here, you can have this as a fixed grant, and then they can make their own decision of saying, okay, if we had this fixed grant, could we provide more value to our community than we are now with this model, and I think kind of leave it up to them, saying here is your pot of money, do the most you can for your community with this, and if they feel we can do more on an outpatient-only basis and actually be better probably at recruiting physicians, they would choose that model rather than the other one.

DR. MILLER: And, Jeff, the other criteria about how many might get picked up has to do with what distance requirement ultimately gets imposed as well, or defined.

DR. STENSLAND: Right. So there wouldn't be

grants for those that are like right next to each other. You know, in the extreme, you have critical access hospitals that are two miles, five miles from another hospital, and we wouldn't want to say, oh, you need two emergency departments in this small -- you know, you're not going to say this town of 10,000 people needs two emergency departments with two CAT scanners and two MRI machines. We wouldn't be promoting that.

DR. SAMITT: That was my question as well. Of the 90, how many meet the definition of "isolated," as you described? Or do all of them?

DR. STENSLAND: I don't know. We'll have to go back and look at those distance measures. I also should say we haven't picked a measure of isolated yet. That's kind of a thing for discussion. So if people around the table thought, well, isolated is 15 miles from another provider, a lot of them are going to qualify. If people around the table thought it's 30 miles, not that many will qualify. And so that is something that's clearly a judgment call, and that's something that we can empirically say is the right or wrong distance.

DR. MILLER: The reason I ask the question is

just to draw a couple of these points out. I don't want the Commissioners, but also people sitting in the audience, to think this is 130 hospitals, and the 90 refers to the numbers of admissions during the course of the year. So I just wanted to clarify those two numbers. And precisely this question of how you think through the distance will define what this -- the availability of this option.

I'm sorry, Jeff.

DR. CROSSON: Okay. So, I'm going to take the order of hands I've got. I have Bill, and Kathy, then David, Jack, Alice, and Bill, and Jon.

MR. GRADISON: On page -- you said Bill? Or did you?

DR. CROSSON: I'm sorry. Yes, Bill. Bill Gradison. Sorry.

MR. GRADISON: Okay. I guess that's me. On page 15, it says, towards the bottom, due to the 35-mile restriction associated with provider-based facilities, most isolated rural hospitals could not become OCEDs. As a result, there are currently very few rural OCEDs. I understand that. Are there any? Are there enough that one could learn perhaps some things from taking a closer look

at perhaps the handful that are out there?

DR. STENSLAND: Yeah, and we've talked to a few of them. There are a few that are operating as freestanding EDs. In the cases that I'm aware of, they have one of two things going for them. Either they're getting some local support from the county or some sort of a, like a hospital district type thing, where they say, we're going to kick in a half-million dollars a year to preserve emergency access, and some of these places, you know, have emergency trained physicians in there 24 hours a day, and so there's a certain cost to that stand-by capacity that they've got to cover.

The other ones I'm aware of are close enough to another hospital, so they're seen as a satellite of that hospital, and then they get the facility rate for the ED. I can't think of any of them that operate in a rural area that don't get the facility rate for being ED and don't have any outside support.

DR. CROSSON: Kathy.

MS. BUTO: Two questions, Jeff. One is, could you explain a little bit more about coinsurance, because I think I heard you say that it would be less than existing

inpatient, but I'm curious about that.

And then the second one is, what do we know about primary care access and access to outpatient services in some of the same areas? In other words, you know, with a limited number of health professionals in an area, I'm wondering whether we're just moving -- sort of like a shell game, we're moving those health professionals to another setting or site, but they're already pretty occupied providing primary care. So, I'm just trying to understand what -- I understand the emergency department part and the fact that you want to maintain that capacity, but I'm just trying to understand whether we're really just moving professionals to a different setting that might actually end up costing more than existing payments for primary care.

DR. STENSLAND: So, I'll start the coinsurance one first. So, the way coinsurance works for Critical Access Hospitals and also for rural health clinics is -- well, I'll stick with Critical Access Hospitals now -- is the beneficiary or their Medigap provider is billed coinsurance equal to 20 percent of charges. And, they take the coinsurance -- so, if your bill for the -- let's say

you're charging $2,500 for an MRI at the Critical Access Hospital, all right. So, the coinsurance for that will be 20 percent of the full charge, or 20 percent of the $2,500, or $500, okay. So, that's the coinsurance, is $500.

Then the net amount that the hospital will get from the beneficiary and the program is equal to their costs. So, if their cost of delivering that service was $500, and they got $500 in coinsurance from the beneficiary, then the program actually wouldn't pay anything additional. The beneficiary would be pulling the full weight.

And, because charges are a lot bigger than costs, coinsurance tends to be about, on average, about half -- about half of the total payment that the providers are getting in these rural areas, and it tends to be growing a bit over time because charges tend to be growing faster than costs.

MS. BUTO: Okay. And under the OPPS method, what you're saying is they'll be paying a percentage of the -- and that's been declining over time, because it used to be 50 percent --

DR. STENSLAND: Yes.

MS. BUTO: -- also based on charges.

MR. KUHN: FIDO.

MS. BUTO: Yeah, FIDO.

[Laughter.]

MS. BUTO: So, now it's 20 percent or some percentage of the fixed payment.

DR. STENSLAND: And that's been almost brought down to 20 percent. So, basically, the CAHs are kind of on the old method.

With respect to the recruitment, I think this is a very serious issue for all these rural communities. It's a big deal to them. But, I think if you kind of walk through what's happening, right now, 40 percent of rural hospitals employ hospitalists, okay. So, you have some people that are just working out there as a hospitalist, even in some small hospitals. In other cases, you have the primary care doctor having his primary care practice. He might also cover the ED. He might also go into the hospital at night to cover the hospital beds if somebody's having some medication management issue or they'll call him up at night.

So, the idea that as the hospital converts to a

freestanding emergency department, they'll still have the need for the outpatient care and the emergency care, but they won't have the need for somebody actually doing the inpatient care anymore. So, their actual needs for physician, NP, and PA services will go down a little bit.

And, I think in my mind -- some people may have different opinions -- is you actually might be able to recruit a little bit easier than you can now. At least when I talk to some of the rural physicians out there, especially the younger physicians, they're not so keen on this job where they say, you're going to see the people all day in your practice, and then at night, we want you to cover the ED, and if somebody has an issue at night at the hospital, they're going to call you up and ask you if they should be adjusting their meds.

And, by having -- eliminating at least that inpatient part, I think you're going to reduce the needs and maybe potentially reduce some of the burnout for some of these physicians. Sue would probably have more of a hands-on impression of this issue of recruitment and burnout and difficulty with young physicians wanting that lifestyle.

MS. BUTO: So, Jeff, just in your view and based on the work and the site visits that you've done, you don't think that we're talking about shifting primary care physicians into this new ED/stand-by capacity, in a sense, raising costs for the same services, you think that's really going to be -- the ED part of it will be an enhancement that's not there now and will leave primary care physicians and their practices.

DR. STENSLAND: Yes. I don't think there's going to be enough business in a lot of these EDs to keep somebody fully staffed. Maybe some of them might have a PA in there 24 hours a day. You would probably have to have some sort of rules, like you would say, you know, for all scheduled visits, we're only paying the regular fee schedule rate, or if you're an FQHC, the FQHC rate, or the rural health clinic rate, whatever it happens to be. For the unscheduled emergency thing that comes in the emergency department, well, then you'll get the emergency facility fee and the professional fee, something like that to separate it so it's not everything all of the sudden shifts into the hospital as a facility fee case.

DR. CROSSON: David.

DR. NERENZ: Bill asked what I was going to ask.

DR. CROSSON: Jack.

DR. HOADLEY: So, my question -- a couple questions about the grants, and I realize these may be just open policy questions, but when you think about the grants from the government to these new kinds of facilities, are you assuming that these are Medicare grants as opposed to coming from HRSA or something like that?

DR. STENSLAND: Yeah. I think there is some Medicare grants that go out right now just for some things like the -- what's the program -- the post-acute care coordination-type program.

DR. HOADLEY: Okay.

DR. STENSLAND: So, the idea is it would be a Medicare program grant, and part of this, in my mind, might be it might be a little easier to think of it as the Medicare program has already given these supplemental payments --

DR. HOADLEY: Right.

DR. STENSLAND: -- out to the Critical Access Hospitals. So, the same program could be sending the same amount of money, just directing it in a different

direction.

DR. HOADLEY: And, would you envision this as some kind of a formula that you would create to determine an amount? Would it be more of a, like a grant application, where they would indicate what their needs are and that would be evaluated? Do you have a vision for that kind of structuring?

DR. STENSLAND: You could do it either way. You could have a grant process. I think, also, the numbers aren't so big that it might be easier to just say, here is -- set the criteria and say, if you have this distance criteria in your hospital and you decide to go to an outpatient facility, you're going to automatically get this. It would kind of eliminate one hurdle, and I don't think it would be that many more, and it would also be difficult, I think, for any federal agency to tell rural communities, you get it, you don't get it.

DR. HOADLEY: Right.

DR. STENSLAND: And the other part was --

DR. HOADLEY: Well, and then sort of the amounts. I mean, is it going to be said, this is a certain volume, therefore, that creates, you know, some kind of formula

that creates an amount?

DR. STENSLAND: I think I am more inclined to just give a set number and give that same number to everybody --

DR. HOADLEY: Okay.

DR. STENSLAND: -- and say, this is the set amount that we think you need to help stabilize your stand-by capacity. I'm reluctant to tie it to costs, because as I said before --

DR. HOADLEY: Yeah.

DR. STENSLAND: -- you know, if you're in a nice ski resort community, your costs are going to be high because you can afford high costs. I don't want to say that the ski resort community gets more than this poor hospital in Alabama. So -- and I don't necessarily want to tie it to volume.

DR. HOADLEY: Right.

DR. STENSLAND: I don't want them to think that what we're trying to do is, oh, if you're really ginning up the volume, you're going to get a bigger grant, or something like this. I think by keeping it fixed, you can say, really -- again, this gets back to the product we're

buying --

DR. HOADLEY: Mm-hmm.

DR. STENSLAND: What we really want is for people in those rural communities to have somewhere to go when they have an emergency, and we're not stepping beyond those bounds. But, that's just -- but, that's certainly a discussion point for you guys.

DR. HOADLEY: Right. Right. No. And, in terms of a commitment, I mean, once you get that grant, you're kind of getting it as long as you're still operating that? There's not, like, a -- I mean, presumably we have some quality standards and some minimum something.

DR. STENSLAND: In my mind, I think if you're going to get these people to buy in, I don't think this can be, like, a one-time capital grant.

DR. HOADLEY: Right.

DR. STENSLAND: I think you're going to say, you know, your fundamental problem is this is about people, and you have, you know, PAs, NPs, physicians who are providing important emergency access and you just don't have the volume to cover all the costs of those individuals without a little extra support, and so that -- and we don't think

that volume problem would go away unless somehow the community grew a lot --

DR. HOADLEY: Right.

DR. STENSLAND: -- and then they would become a hospital. But, otherwise, it would -- I think it would have to continue on if you're going to actually -- if you're going to get this small town board to say, you know, we built this hospital with Hill-Burton grant funds in 1955 and it's been going like this for 50 years and now we're going to make this change to be an outpatient-only facility, which might be a little scary for these guys, unless you say that, here, you're going to get this grant moving on forward into the future, it might be hard to get them to do it.

When Sue comments, she might have more thoughts --

DR. HOADLEY: Yeah. And, I think it would probably be similar questions, and we can get into this in round two, on the community grant, if that ends up being part of the requirement, because there, I think it would be more challenging to say for either the community itself or for some private foundation funder that might assist a

community to commit beyond some fairly limited amount of time, but we can come back to that.

MR. GAUMER: I just want to underscore one thing with Jack's first question about the grants. Just in case it got by people, there is a precedent for this, for a grant to come out of the Trust Fund, the Medicare Trust Fund, and go directly to a hospital. There's a precedent for this out there, the Community-Based Care Transitions Program.

DR. CROSSON: Alice.

DR. COOMBS: Jeff, I was curious. If we look at the potential options, what happens to the patient flow of the inpatients, and say you give an example, possibly 90 or 100 hospitals being interested in this, because we're making some basic assumptions that people that are in those Critical Access Hospitals are going to go somewhere. And, so, from the non-Critical Access Hospitals, there must have been a pattern flow of when those EDs were set up in terms of what happens to -- if there are patients that need hospital services. They're in Critical Access Hospitals now. You take and you convert them to freestanding EDs, there's some corpus of volume. I mean, it may be low

volume, but it may be indications to have them in a hospital setting. What happens to that?

DR. STENSLAND: This could actually be a positive thing for the other hospitals, because most of the Critical Access Hospitals are not going to convert to this. They'll still be out there in rural areas operating --

DR. COOMBS: Right.

DR. STENSLAND: -- ones that have a little bit more volume. But, even if you're a 200, 300, 400, 500 discharges per year, you still probably have some low-volume issues in terms of efficiency and maybe even in the practice that your people get.

So, if this hospital here ends up converting to outpatient only, some of its patients will go to the neighboring communities that have kept a Critical Access Hospital or kept a PPS hospital. Some will probably bypass and go to the urban area for their care. But, when this hospital becomes an outpatient only facility and maybe reduces some of its outpatient services, like, it doesn't have an MRI, visiting MRI anymore, we would expect those inpatients and those MRI patients to, in large part, go to these other small communities, and it might actually help

these other small communities which might themselves be struggling with low volumes.

DR. COOMBS: Okay. So, we're making an assumption that there are some other hospitals in the area. And, some rural -- but, some of them have distances of 50 miles and greater before another hospital --

DR. STENSLAND: So, the idea is you would have to be stabilized in that emergency department and then be transferred out.

DR. COOMBS: And then the second question is, have you guys looked at EMTALA provisions and how that would impact some of these hospitals wanting to convert to EDs?

DR. STENSLAND: I would assume -- this is a discussion for you, and when the regulations we set up. But, I would assume if you're going to give them a grant, you would say EMTALA holds. You would say, you know, if you're an indigent patient and you come in and you need care, you have to take care of them. This can't be a program just for the insured.

DR. COOMBS: I was just wondering about the infrastructure that you would have to meet to be compliant

with EMTALA provisions.

MR. GAUMER: You know, there is wide variation on the state level about what emergency departments have to do and what they have to meet. So, that is something that the state level would deal with, as well.

DR. CROSSON: Bill Hall.

DR. HALL: The problem of access, rural access, transcends Medicare. I mean, the whole population has this that live in these areas. Are there any precedents for an innovative state or county subsidy of these facilities? What's the role of the states in keeping these hospitals alive or coming up with a solution? Why does this fall just to Medicare?

DR. STENSLAND: That could be an open discussion. Right now, with Critical Access Hospitals, a lot of states also pay cost-based reimbursement for Medicaid.

DR. HALL: Mm-hmm.

DR. STENSLAND: In some cases, there might be some other hospital district financing that the local government provides to the hospital to help with their costs of indigent care. And, I don't think there's anything that precludes those same flows of dollars going

to these freestanding EDs. Like, if you have a -- you could call it a hospital district and everybody is paying an extra $100 a year on their property taxes on their home to keep the hospital going. They could be paying $100 the next year to keep the freestanding ED going.

DR. HALL: Thank you.

DR. MILLER: [Off microphone.] I've been waiting for one version of this question to come up. I figured it would be Jon. Jon has raised this in the past, too. What we're doing here, and I just want to put this in your head and you think about it as we go forward on this, what we're doing here is we're saying there's already a set of subsidies that go out under Critical Access Hospital, and we can talk about how to potentially target that more accurately.

But, the other thing we're doing, and when you think about this in high philosophy, is we're saying this Medicare dollar would be exactly what you said. It's a subsidy for any patient who walks into that emergency room. And, there's a couple places in the Medicare program where this is starting to happen -- the uncompensated care fund. We are implicitly having this discussion here. And a high

philosophy question is, what is the Medicare dollar for? Is it for a Medicare patient or is it for all patients, and this is something that we need to keep our eye on as we go forward, because there's a sort of a Balkanization that we're actually discussing here. So, I was waiting for a question like that to come along.

DR. HALL: [Off microphone.] You told me last night --

[Laughter.]

DR. MILLER: I had had a lot to drink, so I forgot.

[Laughter.]

DR. CROSSON: And, we also have the same question with GME.

DR. MILLER: Right.

DR. CROSSON: It's come up before.

DR. MILLER: Exactly. It's the same issue.

DR. CROSSON: I have just one question. So, when you think about geographic access in urbanized communities, there's also an issue of travel time, because 30 miles in the Bay Area or here around Washington, D.C., can have very different impacts depending on where you're trying to go

and time of day and everything like that. Are we assuming here, because we're dealing with rural areas, that travel time is kind of moot, or is that not the case?

DR. STENSLAND: I think people have traditionally brought up this issue of, well, if it's winding roads or are they impassable, or what about winter. From a practical standpoint, I think distance is a pretty close proximity to time. But, I don't think there's anything that would say -- you know, we could shift and say it has to be within a certain number of minutes of travel time for another facility, and that would be fine. That would probably be more theoretically appropriate. But, then you have some sort of more of a judgment call going on with CMS saying what is the travel time from A to B as opposed to what is the distance from A to B, and if you're willing to put that extra burden on CMS, you can move to travel time.

DR. CROSSON: My guess is that depending on what part of the country we were having to research, CMS folks would be much happier to go to certain places and drive around than others, probably a little bit of added work.

Other clarifying questions? Yes.

DR. BAICKER: Just following up on Jack's

question, I was interested that there are some other examples of grants of this kind. Are there other examples of matching grant requirements where Medicare is requiring a locality to contribute?

DR. STENSLAND: Not that I'm aware of.

DR. CROSSON: Okay. So we're going to move to our discussion. We've got the discussion slide up behind us. These are some questions to address as well as others, and I'm going to ask Herb and then Sue to begin the discussion.

MR. KUHN: Thank you. And, Jeff and Zach, thank you for our work, the conversation we had in October and the conversation we had today.

In Missouri, we're probably like other states. We've had several rural hospitals close over the last couple years. I will say when that happens, it really rattles a community, and I have had the opportunity to both attend and participate in town hall meetings when one of these events happen. And I will tell you, it's like going to a funeral, and the five stages of death and dying are in full display in the entire community when this happens. You see denial. You see anger. You see bargaining. You

see depression and then reluctantly acceptance of what's happening in their community.

And the challenge that we have is that right now under the programs, you either have the hospital or you don't have the hospital. What I like about this conversation is it gives another option that there is something else out there to kind of hang their hat on, and so I think this is a good conversation.

I know when we publish this information, there will probably be some folks in rural communities and others that won't like this work. They won't like the tone of the report. They won't like the options. They might think they're too narrow, but I would just, hopefully, disabuse people of focusing on those minutia parts and instead look at what we're trying to do here, an optional program. We're not touching the critical access hospital program, and we're trying to begin a conversation, not with recommendations, but begin a conversation to give people options, so that it's not a death-and-dying scenario in a rural community; it's something else.

So let me share with you, just answer some of the questions you have here, and maybe focus on some others.

So first, I'm going to talk about telehealth, and on the Option 2 that you put forward, I see telehealth as a major contributor to make that option work. And we have a telehealth paper that we finished up last meeting that will be published in the June report along with this one, but there is no linkage between the two. Now, there's no recommendations in that one. There's no recommendations in this one, but there ought to be some kind of linkage at least showing that telehealth could be an important factor for this as we go forward.

And on that regard on that Option 2 is -- and I think you said, Jeff -- it could be a clinic with maybe two days a week, four hours a day. I don't think that's really what we envisioned here. I think it's more of a center, not a clinic, that really has regular hours of 12 hours a day and it's there to serve the community as part of that, so I would make that offering.

The second thing would be in the area of I guess what I'm calling regulatory form and the use of the grants. I think we ought to try to think about maximum flexibility, and I appreciate Jack and Kate asking the questions about the grants, but maximum flexibility -- because if you are

running an emergency department, you're going to get a number of behavioral health patients, and the fact that you need flexibility in order for your organization with those funds to make sure you can deal with behavioral health, population health, deal with promoting new technology, new efficiencies, quality, a whole variety of things, so I think the grant ought to be as flexible as possible to deal with those kind of factors that are out there.

On the issue of reverting back, that question that you had, I know Warner and I talked about this at the October meeting. I think that's absolutely essential. Over the last three weeks, I've had the chance to visit six different critical access hospitals across our state, and just Wednesday of this week, I spent an hour with the board, with one hospital. And I can't think of a more difficult job in health care right now than being a trustee in a rural hospital, particularly a critical access hospital. Those are hard jobs for those folks, and they're quite perplexed of what to do. So I think creating an option for them for almost a mulligan to do over, if things change, and put a limitation of five years like you said on there makes sense, but I think that's an important thing to

have out there.

The other thing what I was thinking about -- not thinking about a third option, but maybe some flexibility in these options where these facilities might have a way of partnering with successful regional providers.

I know at the last meeting, Warner talked about some things that they've got going on with critical access hospitals. I know Sue does, and maybe they can talk about that more. But I think if we really kind of want to support population health, bring it to these rural areas, the fact that bigger entities could avail themselves of those grants and those opportunities to make sure they keep that capacity in those rural communities, I think would be really important.

Two additional things here to think about, as I looked at this. One is, are there ways in additional regulatory reform that we can think about? And what I'm thinking about is the three-day prior hospitalization stay for access to SNF facilities. If someone presents themselves in an ED, the option that they have is maybe to transfer to a larger tertiary, quaternary hospital in the urban area, but what if they were able to just keep that

person for observation for 12 or 24 hours or put them in a SNF for two days? It saves that inpatient stay on the other end, and it's a way I think to kind of manage that care more effectively in that local community. So, again, I think flexibility, regulatory reform, just to make sure that we have that option out there.

And then the final thing I'd just mention is about quality. On page 5 and 6 in the paper, there's a discussion about NQF and the fact that the low end, the low number of patients in these facilities, so it's hard to get the quality measures, and maybe kind of merging groups together so you can get a better view of what's going on in rural hospitals. But I'd think about that a little bit, and then you kind of merge good as well as poor performers together, and does that give us the accuracy that we need? I think I'd rather see us maybe have a bigger conversation about low-volume measures for the relevant type of patients these facilities are seeing and that the service is being provided. I think if we could talk to the measure developers or encourage them to look at measures for these types of facilities and these types of patients, it would be far better than trying to merge all of that stuff

together that might not give us as accurate a picture as possible.

DR. MILLER: And can I just say one thing before you go? Because I would be curious about either of your -- anybody's comments on this, but as long as you're leading. I think sometimes in my mind I feel like I see a connection between the second two points, which is you do give them the option to go back. But if you ask for some contribution from the community, the community actually goes to through the process of thinking it through, and maybe you have less -- either option or reversing that option if the communities had to go through the stages of whatever they've had to go through to make this decision. So I'd be curious if you think about it that way.

MR. KUHN: I think having the community have some skin in the game, whether it's a hospital district -- I'll tell you a story that just played out in Missouri just two weeks ago. We had a critical access hospital close about five weeks ago. There was another one not too far away -- well, 45 minutes, 50, about an hour away -- that was at risk as well, and they had a local sales tax on the ballot to make a determination to keep that hospital going. I

think before the other one closed, that sales tax would have lost. I think it won by 90 percent because they saw the consequences. They saw what's happened. They put skin in the game. So I think it's important for them to have that action.

DR. NERENZ: Can I just quickly ask a question? Since we're on this, what is the rationale for any restriction on going back five years or whatever? Why have any restriction at all?

DR. STENSLAND: I think the idea in the restriction is right now there is some of these critical access hospitals -- it would all hinge on what the decision is, what you folks think and what Congress decides and what the limit is in the distance.

So right now, there's a 35-mile distance criteria for critical access hospitals. The vast majority of them don't meet that criteria. So, essentially, if you had some smaller distance criteria for them to convert over to a freestanding emergency department, they would only have a limited time to go back and kind of be grandfathered into being a critical access hospital that's closer than 35 miles from another facility. And the idea is that maybe it

is not a good idea to have that many full-service hospitals closer than 35 miles from each other, but maybe it would be okay to have a freestanding emergency department within 35 miles of another freestanding hospital, if that makes sense. It all kind of hinges on that, and that's a judgment call all for discussion.

DR. CROSSON: I was trying to think what was behind your question because I could imagine, for example -- and we've seen this recently -- all of a sudden, a corporation, say an automobile manufacturer, lands a facility nearby a rural community. That community just six years ago converted, and now they need a hospital. So I think once you got to the regulatory stage, for example, you could write in some exceptions to this that if there was a rapid population growth over a period of time, something like that.

DR. NERENZ: Well, that is one example, or else -- Herb's comment prompted it. What if the second community had also closed, and now, for some reason, the first community says, "Well, now in that circumstance, maybe we're back in business again"? And I'm just wondering why we would want to restrict any of those?

DR. STENSLAND: I just want to be clear. The community, no matter what, could always set up a PPS hospital. There would be no question about that, and if they are more than 35 miles away from other hospitals, they could always set up a critical access hospital. The only question is, how long do we let them continue to waive that distance requirement?

DR. CROSSON: Thanks. Thank you. Sue?

MS. THOMPSON: Thank you, and, Zach and Jeff, thank you for this work. I appreciate it very, very much, and, Herb, you did a great job outlining I think the sensitivity and the difficulty this question raises in these communities. And I won't be redundant, but just to underscore the very sensitive nature of this issue that we take on.

However, there's so many things about what you have done that is very, very good, and I just want to underscore I love the fact that you're thinking about giving the hospitals an option to go back. I think that's going to be very critical.

I love the fact that you have called out -- and we won't go into this in great detail today, but I think

the ability for these organizations to align with value-based contracts and ACOs is going to be very important into the future.

But last and not least, the recognition that likely the root cause of this situation that we're in is the difficulty in recruiting health care professionals to these communities. It's not just a fact of the difficulty of managing finance. If there is no prescribing provider to order the services that a hospital provides, it doesn't matter.

And you referenced the Hill-Burton hospitals that were built and the loyalty and the pride in that. In the State of Iowa, of our 118 hospitals, 80 of them are critical access, and I believe 98 percent or more of those 80 have had significant capital upgrades to their facilities in the last five or seven years. So we have many of these communities that are sitting on beautiful facilities that have a very difficult time finding physicians and advanced practitioners to come and serve their communities.

So my question is, do we have an opportunity here for the community and the Medicare beneficiary to think

about how do we improve not just access, but access to quality care? And I do worry about these small numbers and these isolated providers.

Now, my experience, again, in the state of Iowa is that most of our critical access hospitals are aligned with one of the two big systems. There are a few, not many, but there's a couple independent critical access hospitals that are still there. But most of them have aligned with a larger system, and that does provide for them access to specialty -- not only specialty services to help bring out patient opportunities to their facilities, but also quality oversight and just a broader community to work with. And I think that's an important piece here.

And I think as we think about the broader continuum that these critical access hospitals -- and they do serve an important role -- how do we put these pieces together from a policy standpoint that incentivizes them to understand? We're not just talking about access, but we're talking about access to quality. And I think our Medicare beneficiaries deserve that.

So I would invite us to think more broadly, and in that broad thinking, I worry about this definition of

distance. And I wonder if we can look into the future. Whether you're 2, 5, 20, 30, or 50 miles from another provider, is there a runway we need to give these facilities in the spirit of how do we improve quality? Because in these stand-alone, isolated, very few provider organizations, I think we have some real opportunities there.

I definitely agree with the comments about telehealth. I thought about the chapter we did last month. There's opportunities to link that work.

And just last but not least, there's so many opportunities here, and I do invite us to think more broadly.

DR. CROSSON: Okay. We'll continue the discussion now. I see Warner and David, Bill -- I'm sorry. Oh, Jon. Jon had his name in and had to leave momentarily. Jon, why don't you start, and then we'll go with Warner and come up this way.

DR. CHRISTIANSON: Yeah. So this is just a quick comment. I understand Herb's feelings about skin in the game and so forth, but I also -- if we really want to make this an option, there's a huge variation in the financial

situations of these counties and where these hospitals are, and it's not really an option in some counties, depending on the size of the matching grant. So I think we need to think carefully about this. There's plenty of counties that are subsidizing their community access hospitals now and continue to do that, and we could say, "Okay. They have skin in the game, then," but what about the small rural counties that are really probably the ones who are most interested in having -- consider this option? And then if we erect too large of a matching grant barrier to this, we preclude maybe participation by some counties in hospitals that we really would like to have consider this option seriously. So I think we need to think carefully about this matching grant.

I'm not sure. I think a county that goes through this process and says, "All right. After a history of 70 years or whatever of inpatient capacity, we're not going to have it anymore," that's going to be a really tough decision for them to make. And by the time you reach that decision, I think you've got some community commitment to that direction, and I'm not sure why we necessarily need to tie some more dollars from those communities to assure, as

you put in here, assure community commitment.

So I think the matching grant program has to be thought through carefully. There's just a lot of variation in the situation of these counties and hospitals.

DR. CROSSON: Go ahead.

DR. BAICKER: Sorry. But just following up on that point, I have mixed feelings about the principle of the matching grant as well. Having the communities have a stake in it sounds like a great idea, and in other programs, whether it's Medicaid or the old version of welfare, there was this matching grant component to induce extra dollars to come in. For Medicare, we spend a lot of time trying to say we're not cross-subsidizing Medicaid. If Medicaid is not paying enough, we're not paying more to make up for that. We're trying to target the Medicare dollars towards the Medicare beneficiaries, and there's already a bit of a "How do you allocate fixed cost?" problem. But that, I'm willing to engage in because fixed costs are always then going to benefit more than the specific beneficiaries we're funding, and that's okay. But drawing in a tie to state or local spending strikes me as potentially opening up a whole avenue of entangled

financing that we may not be comfortable with the long-term implications of or the distributional implications of, as Jon said.

So, while I can see it's a good avenue to get more community buy-in and resources, it's a pretty big change from how we view the principle of the allocation of Medicare resources in general that ought to be done with great care.

DR. CROSSON: All right. Warner. And then we will come up this way and go around.

MR. THOMAS: Just a couple of comments. First, on the matching grant, I think Jon's points are well taken that when an organization is going to make this transition, I think it's -- usually do have the community involved. I think maybe the way to think about a matching grant is actually if you want to go back, if you want to convert back from an outpatient facilities, maybe that's where the matching grant could take place because you're once again -- I think if you're downsizing one of these organizations, that's a very sensitive thing, and to ask the community to chip in to make that happen, that could be a big -- a big lift.

Secondly, how many critical access hospitals are in the U.S., roughly?

DR. STENSLAND: 1,300.

MR. THOMAS: 1,300, okay. So I guess I would go back to just underscoring a couple of comments from Herb and from Sue.

The telemedicine piece is critically important here. I agree tying those chapters together, and going to Sue's point that we don't have enough providers in these communities, and telemedicine is a way to help solve that issue. So I think incentives around use of telemedicine in these areas is -- could be critically important.

I think the other thing is, as I think about the 24/7 ED or the freestanding ED, I would encourage us to think a little bit more broadly about those services. Probably, a lot of these organizations, they really can't handle inpatient. They've got a very low inpatient census, but they may be able to have other outpatient diagnostics and imaging. It doesn't necessarily have to be complex imaging, but I think we ought to think about how it's a diagnostic center, not just an ED. And once again, not having to have people travel 30, 50 or more miles for

diagnostic care is something that ought to be considered in the scope of services.

And the other thing that I would challenge us to think about is our incentives or paths to repurpose facilities. One of the things -- and I think I've shared with some folks here -- is that we actually have taken what was really an inpatient hospital, ran a census of 10. We shut the inpatient census, have converted to essentially a freestanding ED. We run the ED and run the imaging, and now we're converting the inpatient to psychiatric beds because there's a real need for psychiatric beds in the area.

So I think if there could be thoughts around the repurposing or paths that could be created for the repurposing of many of these facilities -- I go to Sue's point. A lot of these facilities are very nice, probably nicer than some of the facilities we have, quite frankly.

[Laughter.]

MR. THOMAS: So it would be nice to think about how we repurpose them and have them take on another purpose.

I guess the last piece is to perhaps create

incentives or think about how we could create incentives for large organizations to approach and be collaborative with the critical access hospitals and to have larger integrated systems or whatnot be part of the solution in this process. And I think if there could be thinking or comments about that in the chapter as we go down this road -- because we're talking maybe about 100 today, but if there's 1,300, I can tell you we're going to be talking about more than 100 over the next 3, 5, 10 years, so thinking about what that path looks like is really important.

And my final comment, I think it's critically important that we not change the reference to these facilities as "hospitals." Even though they may be emergency departments with imaging and what not, I think it is critically important to communities to think that they have a hospital. Whatever the definition of the hospital is for that community, that is an important psychological factor for communities, and I would encourage us not to necessarily change the definition, the brand of these facilities, even though we may change the definition of the services provided in that hospital. And that may seem like

a minor issue, but I think you will find that's a major issue for communities.

DR. CROSSON: Thank you. David?

DR. NERENZ: I was just thinking about some of the challenges there might be in the daily operations and management of the 24/7 ED option, and this follows, I guess, a bit from Bill's initial question about are there examples of this.

You know, our prototype of an ED is often the busy urban ED with its long wait times and things are busy, and the description you have in the chapter about the freestanding EDs are generally -- it says they're in urban and suburban areas; they're driven by population growth. They're typically in areas where things are busy.

Now, here we're talking, I think on purpose, about the opposite. We're talking about situations where there's not enough patient flow to support an inpatient facility, and I'm wondering if the same challenges would apply then to the ED. And I'm envisioning a wonderful, nice facility with the equipment and the rooms and no patients, or at least not enough patients to really keep people busy in them, which then would seem to lead, at

least in part, to Sue's problem of, you know, who's going to want to work in such a place.

Then it seems like part of the solution to that problem, if it's real, is you have to graft this onto something else so that trained professionals can be available there, but also be busy and productive doing something else, which could touch on Warner's point of the imaging or diagnostics.

I don't know what the answer is, but I am -- again, to Bill's, do we have examples of -- or in other countries, even, of situations like this where you can have the emergency care capability but in areas where the flow-through is really very low?

DR. STENSLAND: So I think in all these examples -- and I probably should change the chapter to make it more explicit -- at least in my mind, we were thinking there would always be a primary care clinic there. So you would have a primary care clinic. You would have basic diagnostic, basic lab, CT scan, X-rays. That would always be there. But the difference between this and, say, just being an FQHC or this and being a rural health clinic would be the 24/7 ED.

So I wouldn't imagine that you would ever have one of these things that's a 24/7 ED and then there's no clinic or there is no X-ray machine in town. You know, it would be part of that. And I think the ones that operate generally have physicians that are going to be doing two different things. I'm going to schedule some appointments in the rural health clinic, but then maybe I'll also cover the ED. Or maybe they'll have an NP in the ED that's 24 hours a day, and then the physician will come over there when needed. You know, there's some flexibility there.

DR. NERENZ: Okay. Well, and maybe our discussion and further writing can be a little more explicit about that. I presume it's necessary. I'm also just thinking that there may be some minimum volume standards or some volume to quality relationships in the ED environment the way we know about them in the inpatient environment that could be woven into this. Somehow there's got to be an image of how we deal with that challenge.

MR. GRADISON: First, I want to thank Warner for mentioning this question of the definition of a hospital. I believe some of the states have been grappling with this. Georgia comes to my mind. You might take a look because I

think they have been, if I recall correctly, talking about or discussing whether to redefine a hospital for purposes very similar to what we're talking about here.

I am not a demographer, and I appreciate there are going to be some sparsely populated rural counties and communities that are going to grow. But my sense of it is that the trend is going to be just in the opposite direction.

But the better the training programs we have for young people to learn technical skills, the quicker the movement will take place out of those areas because the jobs aren't going to be there. There really aren't a lot of opportunities to be computer programmers -- I had to pick an isolated example, but to make my point -- in some of these areas, but there might be 100 miles away or 50 miles away in larger communities. The significance of that in terms of what we're talking about, coming back to Warner's excellent point, is that I think the numbers will grow as the population of many of these -- not all, but many of these areas declines.

Next point. Distance versus time. I'm really troubled by the use of distance. I physically have seen

situations where there is a mountain in between. What I would suggest, which I think may be a little more helpful than that comment, is take a look at the VA's experience, because they were given a really hard time in the last year or two when they said, well, you can go outside the network, but it has to be within 50 miles, or whatever it was. And so I don't know how they worked that out, but when -- we're not trying to have CMS people drive all over the country with stopwatches, but you might learn something from the VA experience.

And, finally, about the question of a match, much of the -- not all, but much of the discussion so far around the table with regard to a match has had to do with the local community's match. I think that there should -- I'm inclined to think there should be a match, but I think the -- and that that ought to be part of the grant application, but that the funding could come from any source -- state, county, hospital district, private contributions, private foundations, some combination.

There are a lot of reasons I think that would be useful. I appreciate that it raises a host of policy questions in other areas, and I'm not suggesting we should

reach a decision on it. I am suggesting that when we talk of a match, it should have the broadest possible definition of where that match might come from.

Thank you.

MS. BUTO: On the matching grant issue, I'm not so enthusiastic about it, mainly because a lot of problems occur to me. Probably the principal one that occurs to me is that we seem to want low-capacity, low-utilization inpatient facilities CAHs to actually convert. So if we want them to convert, why create a barrier to that conversion, is my question.

The other question that arises is: What happens if the match is there the first year and the second year they can't get it? Do we pull the certification and close the facility? I mean, I just think of all these practical issues that are going to arise within individual cases. So we're not saying it, but I think we think this is going to be a better use of capacity and actually lower overall costs at the same time. And if we think that, why would we create a barrier? So that's just a question I would raise.

The other one is about I think there's a real challenge in the area of staffing these facilities, even

though they're more modestly set up. And we ought to at least mention the fact that whatever the conditions of participation are for outpatient facilities and EDs, maybe there needs to be more flexibility for these entities, because I can't imagine a fully staffed ED waiting for the patient to come in with an urgent or emergent situation in these locations.

So there's already locum tenens and other things, but I think we need to at least mention the fact that if these are going to be successful, given the challenges of actually getting health professionals to these areas, there may need to be some other adjustments that are made to make them successful.

DR. STENSLAND: Just to follow up a little bit on that, because I think there are some -- at least for the critical access hospitals, like the conditions of participation are really quite low in that if you don't have any inpatients now, you can lock the door and have no one in there. So if somebody follows the big blue sign and they get there and the door is locked, then, you know, they call the ambulance and they come and somebody opens the door. Or you could staff it with just an RN, or if you're

in some frontier areas, you might arrive, follow the blue signs, and get there and the highest trained person is an LPN.

So, you know, in terms of flexibility, the critical access hospitals are kind of, you know, extremely flexible in what we demand of them, and then so the question is -- I'm thinking you're thinking higher than that, but maybe not --

MS. BUTO: Right.

DR. STENSLAND: -- to the full extent of you want a --

MS. BUTO: Well, I didn't know what conditions you were --

DR. STENSLAND: -- board-certified physician.

MS. BUTO: -- going to have apply to the ED-only model.

DR. STENSLAND: Yeah, I think that would be a discussion question.

MS. BUTO: Okay. So that's my point. Let's at least discuss that.

DR. STENSLAND: Yeah.

MS. BUTO: Because I don't think we want to leave

that vague and -- it actually could be perceived as a challenge.

And, thirdly, I guess these things don't exist in nature yet, you know, so I'm wondering whether if CMS were to proceed down this road -- and it sounds like it's a good option, a good series of options to pursue -- they might want to test it first rather than make it available to everybody because you know there are going to be issues that we haven't thought of.

DR. CROSSON: Okay. Coming up this way, Mary.

DR. NAYLOR: Actually, that was -- I just want to reinforce --

MS. BUTO: [off microphone] nature.

DR. NAYLOR: Yeah. I don't know if they exist in nature, but I absolutely -- it sounds like Kansas is doing some work in modeling and so on. And it does seem to me that we should allow for rigorous assessment of a few of these alternatives that really engage the community in the design and really place a premium on the community's commitment to make sure the Medicare population is well served by Medicare dollars. So I don't know if we have enough of these models, CMMI is making that kind of

investment. I don't know.

DR. STENSLAND: There are some of these out there, and so -- there's just a handful, and so, for example, there was one that we talked to not far from -- it was in Arkansas we talked to one of these, and they -- before they set up, they went to go talk to the one in Tennessee, there was one of these in Tennessee, let's go talk to them how they're operating it, and then they kind of set up theirs. There's another in North Carolina. I think there's one in Wyoming. There's some more that are starting now. They're saying, you know, we're going to close the hospital, that we're going to try to keep this open as a freestanding ED because the hospital is not financially viable, but we don't want to give emergency services -- we're going to give this a whirl.

So these things are existing in nature in terms of functioning health care entities. I think what isn't there is a clear payment model for them, and they're kind of, you know, trying to cobble something together to work it, and this would be kind of a little -- the medical model I think is there. What's missing is the payment model, which might make it easier for these things to move

forward.

DR. HALL: Not to be redundant, just to focus on the unique needs of the Medicare population in rural areas, just as in non-rural areas. A lot of the problems that present themselves acutely to the ED in people who are 70, 75, 80 years of age don't really require a lot of high-tech stuff. What they do require, though, is the ability to do a pretty fast and accurate assessment of cognitive function. A lot of behavioral issues are often there. And one also has to be able to make some kind of assessment of the degree of independence people have. If you're going to send them out the door and they're going to fall and break their hip on the way across the prairie or the tundra, you want to make sure that you've ruled that out. We're talking -- I -- never mind.

And the most ideal gizmo on the block right now is telemedicine, because right now, without any investment in other equipment other than the ability to do real-time, relatively high-speed Internet connection, you can do all these things. It's being done in a lot of places. So I think we can also focus then -- if our vested interest here is in Medicare, there are a lot of patient care issues that

can easily be handled through telemedicine and some kind of a remote facility where people can come to. So we should keep that in mind.

The other is, this may sound a little bit out of the box, but for another reason, but I've visited a number of the Western states where they're trying to develop geriatrics programs out of regional medical centers in Arizona, Utah, and New Mexico. This was in the last six months. And there are some interesting examples of what is going on in any places that have a large Indian Health Service. Some of them have been disasters, but some have been very, very useful in terms of using telemedicine. At least I know in those three states it would be worth taking a look at what's going on. If I were to pick one state, it would probably Arizona that seems to be the farthest along in this.

DR. COOMBS: Thank you. Herb, I was really moved by you this morning and some of the things you said, and you really kind of changed my attitude about just the whole nature of this, the hospital that's really under full cardiac arrest. And so as I was thinking about it coming into the room, I thought, okay, if there's a volume there

for ED, it should be there regardless, right? So something must have been -- at the particular rural hospital, it must be that the flow is occurring, so there must be a business plan or some kind of operational success with that before, because there's a demand for it. I was having a hard time understanding, first of all, the hospital volume and where would it go. And then, secondly, this is a new flux of ED patients that just -- they just didn't appear there, but they would be -- by having an increase in the number of EDs, it would be that you would keep people from traveling long distances to go to other emergency rooms.

So one of the questions I have is: Is it possible for us to actually classify rural hospitals in different categories as to what you might do for them as a solution to their struggles financially so that in some cases, if it's volume, if it's the proximity to the closest institution, you might have a different kind of solution to those kind of problems compared to a hospital that's in full -- needs full life support? So if we were to do a 911 call for that kind of place that is just about to -- but then there's other solutions to the problems, like telemedicine, with Sue having the brick and mortar but

without the personnel to kind of complete it. So I'm wondering if we can go a step farther in terms of just breaking out, seeing if there's some broad categories that the solutions to the problems would be very different, because I'm thinking about the quality piece of it, and, Sue, what actually scares me, because you talk about door-to-balloon time with someone I in who needs, you know, the strep and stretcher, you know, the tPA and the stroke patient and the access to -- because if you don't have the personnel there to address the telemedicine person, then you still -- the patient doesn't have access to quality care. And, you know, my brother was in the middle of California and a very richly endowed health resource area where he did not get tPA. And it was because there was no neurologist on call, and that's in a very robust system. So I know it must be even worse in a situation like that.

So I'm just wondering if we could kind of separate some of these entities out and then have different solutions to them.

DR. CROSSON: Thank you, Alice.

DR. HOADLEY: So I want to pick up on two of the themes that we've been talking about. One is this question

of what exists in nature, and I was thinking back to a Health Policy Forum session that I ran probably 25 years ago, and I remember that the situation at that point was in Colorado, and there were like five counts all kind of in a row with each their little hospital, none of which were profitable. And I don't remember the specifics now, but the solution was repurposing I think at least three of the five and then concentrating the more traditional inpatient hospital volume into one or two of them.

And, Jeff, of course, you just gave us some other examples of things, and I guess it might be useful to see if there's some things we can learn. I assume most of these have happened without any particular Medicare involvement if they fall into a new category that Medicare pays for, like having a SNF or just operating an ED or an outpatient facility that they fall under those categories. But, you know, is there some -- and, obviously, we've heard examples over the years of things that converted themselves to SNFs or clinics or all these other kinds of things. But particularly on this ED side, are there lessons that we can learn from some of what's out there in terms of a bunch of these questions that people have talked about? Does that

help with the staffing issues, quality, you know, long-term sustainability of some these that have been around for five or ten years? So it just seems like maybe there's some ability to learn from that.

The other is on the matching funds, and I'm not going to at the moment try to put an opinion on sort of the pros and cons. But the thing I was thinking about was matching fund commitments or fund -- and maybe the word "matching" is not necessarily the right word because that kind of brings up the Medicaid, you know, we're going to have a formula that's this many dollars versus this many, but whatever we want to call it. But there's at least two categories that I think of. One is sort of an ongoing support, and that, you know, is Herb's examples of the tax districts, the special sales tax where, you know, you put it into place. And, obviously, politics being what it is, you've never committed it permanently into the future, but at least maybe permanently until the next vote and somebody decides they no longer support it, versus sort of more on the startup funding kind of category, and, you know, are there funds that are needed from some outside source to help get this thing designed and off the board -- off the

ground. And at the very least, we ought to just make sure we're thinking which we mean if we do want to go down that road and ask for local commitment. Is it about creating some ongoing source of funding that will kind of supplement what Medicare is providing? Or is it more like a one-time thing? And when you start thinking about some of the private foundation kinds of things, they generally aren't going to support ongoing -- you know, maybe over time that will work out, but more and more the foundation world is sort of startup notions or we'll give you three years to do something and then you've got to be self-sustaining.

So, you know, however we want to think of a local commitment, we should at least be very explicit about whether we're thinking of it as ongoing support versus startup kind of support, and then maybe by the time we think of this again I'll have more of a sense of -- I've heard some interesting pros and cons on whether having that is worthwhile.

DR. CROSSON: Warner, last comment.

MR. THOMAS: Yeah, just a brief comment. You know, as I look at the issues up there, I come back to I think the biggest issue here is telemedicine, because the

biggest issue facing these facilities is access to clinical knowledge and capability. And I think if we really want to facilitate people staying closer to home and getting more services in these facilities, we've got to sort out the right economic model and incentives around telemedicine. Maybe we start with these facilities because it could be a smaller pilot and really try to think about how we invest resources there, because that is going to help solve a major issue for these facilities. I tend to think that's the leading issue and indicator of whether these initiatives will be successful.

DR. STENSLAND: Could I just follow up on that a little bit? Because we're -- would you see addressing your concern if we said, you know, this grant money could be used to help support telemedicine capacity? They would also get the facility fee for telemedicine just like anyone else would be, and the distant physician would get the same fee they do now if they see somebody face-to-face. So you would have -- you know, you'd have like the face-to-face fee, just like in PPS; the additional facility fee which they could qualify for; and then the third pot of money would be the grant money that could also be used to support

telehealth.

MR. THOMAS: I think that could be -- that definitely could help. I think once again, thinking about how it could make economic sense for that facility to have folks stay at home, that sounds like that's a model that could potentially work.

I think the other is are there -- getting back to the idea that there's other systems around, large systems around like Sue's that can help, you know, a lot of these facilities, what incentives around telemedicine could they be given to do the outreach to help these facilities. Then you could look at both sides of that equation.

DR. CROSSON: Other comments?

MS. BUTO: Yeah, very briefly. It occurred to me that we probably shouldn't, following up on Jack's comment, rule out considering asking facilities -- or asking HRSA to put money down. In other words, if HRSA and CMS, in conjunction with the community, decide this is a good investment, that might be one way to deal with the basic funding issue, particularly for communities that have different abilities to raise money. It's a way of validating from another entity that, yes, this community

capacity is really needed. So just something to think about.

DR. CROSSON: Okay. Excellent presentation, good discussion. Jeff and Zach, I hope you have some help there to get you to hone this, and we'll be back to this issue a little later. Thanks.

[Pause.]

DR. CROSSON: Okay. I think we're ready to move on to the next presentation. Eric Rollins is here to give us a status update on the CMS dual eligible demonstration.

MR. ROLLINS: Thank you, Jay.

Before I start my presentation, I'd like to follow up on an issue that Kathy raised at the November meeting when I briefed the Commission on the Medicare savings programs. Many low-income beneficiaries who are eligible for the MSPs do not participate, and Kathy had asked if there was research on which strategies for increasing participation seemed to be most effective.

There have been some studies on this issue, looking both at the MSPs and other low-income programs. Most of the studies were done shortly after the start of Medicare Part D in 2006 and are now a few years old. The

studies generally found that state efforts to streamline the enrollment process were most effective at raising participation, for example, by simplifying applications, eliminating the use of an asset test, and making it easier for beneficiaries to recertify their eligibility. Efforts by community organizations to help beneficiaries enroll can also be effective, especially if they provide one-on-one assistance throughout the enrollment process, but they are hard to conduct on a large scale. Finally, the studies found that advertising campaigns by themselves were not very effective.

Now, I'll turn to the update on the financial alignment demonstration for dual eligible beneficiaries. This update includes our findings from site visits and phone interviews with stakeholders in four states, and I'd like to thank Andy Johnson and Carlos Zarabozo for their help in preparing this status report.

I'll begin by providing some background. There are about ten million individuals who qualify for both Medicare and Medicaid and are known as dual eligibles. Most dual eligibles, about seven million, are eligible for the full range of Medicaid benefits covered in their state

and they're the focus of the demonstration. For this group, Medicaid covers long-term services and supports, wrap-around services, and Medicare premiums and cost sharing. The other three million dual eligibles only receive assistance with Medicare premiums and cost sharing and cannot participate in the demonstration.

Dual eligibles are generally in poorer health than other Medicare beneficiaries and they account for a disproportionate share of spending in both programs. They are also vulnerable to receiving fragmented care, because Medicare and Medicaid have relatively little incentive to coordinate care across the two programs.

The demonstration aims to improve the quality of care and reduce spending for dual eligibles by better aligning Medicare and Medicaid.

Under the demonstration, CMS is working with states to test two new models of care for dual eligibles. The first model is a capitated model that uses managed care plans to provide all Medicare and Medicaid benefits, with the plans receiving a blended capitation rate.

The second model is the managed fee-for-service model. In that model, states provide additional care

coordination through Medicaid to dual eligibles who have fee-for-service coverage in both programs. States can receive retrospective performance payments from CMS if they reduce federal Medicare and Medicaid spending.

Moving now to Slide 4, CMS has approved a total of 14 demonstrations in 13 states as part of this initiative. No other states are expected to participate at this point. As you can see, most of the participating states are testing the capitated model. Only two states, Colorado and Washington, are testing the managed fee-for-service model, while another state, Minnesota, is testing an alternate model that integrates some administrative functions for Medicare Advantage special needs plans that serve dual eligibles.

The start dates for the demonstrations vary, but all are now underway, except for Rhode Island, which should start later this year. The demonstrations were originally going to last for three years, but CMS has announced that states can extend them for two additional years.

As of last month, about 450,000 dual eligibles were enrolled in these demonstrations.

The remainder of this presentation focuses

primarily on the capitated model, but we will touch briefly on the managed fee-for-service demonstrations, as well.

Under the capitated model, the states decide which dual eligibles can participate in the demonstration, so the specific eligibility criteria vary. However, both disabled and aged dual eligibles can participate in most states. In addition, most states are only conducting their demonstrations in certain parts of the state, usually counties around large metropolitan areas.

The centerpiece of the capitated model is the Medicare-Medicaid Plan, or MMP, which provides both Medicare and Medicaid benefits to its enrollees. There are currently a total of 61 MMPs participating in the demonstration. Most MMP sponsors had prior experience with Medicare Advantage, Medicaid managed care, or both.

Enrollment in the MMPs has been lower than many observers expected prior to the start of the demonstration. Overall, about 30 percent of eligible beneficiaries are currently enrolled in an MMP. Participation rates vary widely across states, from almost 70 percent in Ohio to less than ten percent in New York and South Carolina.

Under the demonstration, states are allowed to

passively enroll dual eligibles in MMPs, and most have done so. However, many beneficiaries have chosen not to participate, either by opting out before passive enrollment takes effect or by disenrolling from their MMP.

During our site visits, stakeholders identified three reasons why so many beneficiaries had chosen to opt out: Satisfaction with their existing care, including the desire to continue seeing their current doctors; a lack of information about the demonstration and how it might benefit them; and resistance from health care providers, particularly primary care physicians and LTSS providers, such as nursing homes and personal care attendants. With the benefit of hindsight, stakeholders believe that passive enrollment should have been implemented more slowly and that outreach efforts to educate both beneficiaries and providers should have been more extensive.

Looking now at Slide 7, MMPs are required to provide extensive care coordination for their enrollees. This care coordination has three key elements: The completion of an initial health risk assessment shortly after enrolling; the development of individual care plans using interdisciplinary teams of providers; and ongoing

help from care coordinators.

The plans that we interviewed on our site visits all had difficulty completing the assessments because they often could not locate enrollees. In many cases, plans had been unable to reach about 30 percent of their enrollees.

The exact strategies that MMPs use to coordinate care vary, and many plans that we interviewed have been modifying their approaches as they gain experience. Broadly speaking, though, plans stratify their enrollees into high, medium, and low risk categories. High-risk enrollees, such as beneficiaries who live at home but are at risk of going into a nursing home, receive the most extensive care coordination, such as regular calls and visits from their care coordinators and help scheduling doctors' appointments. Low-risk enrollees, such as relatively healthy beneficiaries who do not receive LTSS, may only receive monthly or quarterly calls from their care coordinators.

One particular challenge for MMPs is caring for enrollees who have behavioral health conditions. As a group, dual eligibles are much more likely to have behavioral health conditions than other Medicare enrollees,

and care coordination can potentially reduce their use of costly services, like inpatient hospital care.

During our site visits, stakeholders said that plans have encountered a number of challenges in trying to care for this population. Plans said that it was particularly important for care coordinators to develop trusting relationships so that they could effectively engage beneficiaries about their care goals and needs.

Some enrollees are either homeless or have unstable living arrangements, and several interviewees said that finding adequate housing for them was a recurring challenge.

Many interviewees also said there was a shortage of outpatient treatment options in their area, which made it more difficult to reduce the use of inpatient care.

Finally, some interviewees said that federal regulations that limit the disclosure of information about substance abuse treatment made it harder to share information among providers.

The three states that we visited were among the first to start their demonstrations, and each demonstration had been underway for at least 18 months. However,

stakeholders said it was too early to tell if MMPs would be able to modify their enrollees' service use, for example, by reducing inpatient hospital and nursing home care, and, thus, realize savings. Numerous stakeholders provided examples where plans had reduced the use of high-cost services for individual beneficiaries, but no systematic data is yet available.

The MMPs that we interviewed believed that it was unrealistic to expect any significant savings in the first two to three years of the demonstration due to such factors as the need to complete initial health assessments, continuity of care requirements that preserve enrollees' access to their existing providers for a period of time after joining an MMP, and the difficulty of reshaping patterns of service use that had largely developed in the unmanaged fee-for-service environment.

There is also no data available at this point on the quality of care provided by MMPs. CMS is requiring plans to submit a variety of quality data, but the data is not yet public. Even when that data does become available, our ability to assess quality will be hampered by the lack of measures for long-term services and supports, which are

very important for many dual eligibles.

Turning now to Slide 10, CMS and states pay MMPs through a blended capitation rate that has three components, one for Part A and B services, one for Part D drugs, and one for Medicaid services. Unlike MA and Part D plans, MMPs do not submit bids with their estimated cost of providing Part A, B, and D benefits. Instead, CMS pays plans for Part A and B services using county-specific base rates that reflect historical costs for dual eligibles and are risk adjusted in the same manner as payments for MA plans. Payments for Part D drugs are based on the national average of all Part D bids.

In addition, the payment rates for Parts A and B and for Medicaid are reduced as part of a quality withhold that is later paid to plans if they perform well on certain quality metrics. The quality withhold for most states is one percent for the first year of the demonstration, two percent in the second year, and three percent in the third year.

Finally, the payment rates for Parts A and B and for Medicaid are reduced to reflect the savings that MMPs are expected to generate. The expected savings vary from

state to state, but are typically around one percent in the first year of the demonstration, two percent in the second year, and three to five percent in the third year.

During our site visits, stakeholders in Boston said that their payment rates had initially been too low, which resulted in large financial losses for some of its MMPs and led one plan to drop out of the demonstration.

In contrast, the stakeholders that we interviewed in Chicago and Los Angeles generally thought that payment rates were sufficient, although some did think that the initial savings assumptions were unrealistic.

CMS has also announced that it plans to raise payment rates for Part A and B services based on analysis that the current risk adjustment model for MA plans tends to underestimate costs for full-benefit dual eligibles. The increase for most MMPs will be between five and ten percent.

I'd also like to touch briefly on the two managed fee-for-service demonstrations in Colorado and Washington. Under this model, the state assigns dual eligibles who have both fee-for-service Medicare and fee-for-service Medicaid to entities that provide care coordination. Beneficiaries

are not required to receive care coordination and they remain enrolled in fee-for-service regardless.

We conducted a series of phone interviews with stakeholders in Washington State to get a better understanding of their demonstration. Their demonstration operates in all but two counties in the state and is aimed at beneficiaries who have had at least one chronic condition and are considered high risk. The state provides care coordination as part of its Medicaid Health Homes Program and uses entities such as Area Agencies on Aging to assist beneficiaries by first developing a health action plan and then providing ongoing care coordination as needed.

Stakeholders said that the share of dual eligibles who have chosen to receive care coordination services has been relatively low, between ten and 15 percent. As with the capitated model, the entities providing care coordination in Washington have often found it difficult to locate enrollees. Given those difficulties, some interviewees expressed concerns that care coordination entities do not receive any payment from the state until they have completed a health action plan.

In January, CMS issued a report which estimated that Washington's demonstration had reduced Medicare spending by six percent relative to a comparison group during its first 18 months of operation and had saved the program about $22 million. That estimate is preliminary and will be updated as part of CMS's final evaluation. We believe that savings of that magnitude are too high, given the relatively small number of dual eligibles, about 1,700, who actually received care coordination during that period of time.

The next slide outlines our plans for future work related to the demonstration. First, we are in the process of getting enrollment data for the MMPs and will use it to compare beneficiaries who have enrolled to those who have opted out. For example, we are interested in comparing average risk scores for the two groups and seeing how much risk scores vary across MMPs.

Second, we plan to make additional site visits to participating states and are particularly interested in learning about service use, access to care, and the effectiveness of care coordination. Given the interest of several Commissioners, we also continue to pay -- plan to

continue to pay close attention to issues related to behavioral health.

Third, we plan to take a closer look at the payment methodology for Part A and B services and assess how payment rates for MMPs compare to rates for MA plans.

Finally, we plan to assess the usefulness of the MMP quality data when CMS makes it public.

Moving now to the last slide, I'd like to close with some potential topics for discussion. The first is the use of passive enrollment. How does the experience of the demonstration inform our thinking about when and how it should be used? During our site visits, stakeholders reported that many plans had difficulty absorbing large waves of passive enrollment, beneficiaries were often poorly informed about the demonstration, and some providers encouraged their patients to opt out. However, most plans that we interviewed said that passive enrollment had been a key factor in their decision to participate in the demonstration.

Second, if MMPs become permanent, what process should CMS and states use to select and pay them? For the demonstration, states have chosen the participating plans,

subject to CMS approval, and plans are governed by three-way contracts with CMS and the state. CMS currently pays MMPs using base rates that reflect historical costs for dual eligibles, but their accuracy is a measure of what Medicare would have spent without the demonstration and will become increasingly limited over time. Should MMPs ultimately be required to submit bids like MA plans? Should other plans ultimately be allowed to participate? And if the number of plans will be limited, how much say would CMS and the states each have in deciding which plans participate?

Third, how should CMS calculate performance payments if the managed fee-for-service model becomes a permanent feature in Medicare? Like the base rates for MMPs, the current methodology is based on estimates of what Medicare and Medicaid would have spent without the demonstration, which will become increasingly hard to estimate over time.

Finally, what are the potential implications of the MMP model for the Medicare Advantage program, particularly for special needs plans that serve dual eligibles? As a whole, D-SNPs do not integrate Medicare

and Medicaid as extensively as MMPs and they are also not subject to the same requirements for providing care coordination. Should the requirements for D-SNPs eventually be strengthened so that they become more like MMPs, or should D-SNPs continue as a separate option for states that are not interested in completely integrating care for their dual eligibles? And if Medicare offers both types of plans, how should payment rates for D-SNPs compare to the rates for MMPs?

That concludes my presentation. I will now be happy to take your questions.

DR. CROSSON: Thank you very much, Eric. Very nice elaboration of the issues, particularly given the fact that you're working off a relatively slim fact base at this point in time.

We're going to do clarifying questions in a minute. I'm going to ask Jack if he would be willing to start the comment period in a few minutes. Okay. Clarifying questions?

DR. CHRISTIANSON: Herb.

MR. KUHN: Thank you for this information. I agree with Jay that there's not a lot yet to go on. It's

early in the process, but it's good to get as much baseline information as we can.

I was curious about the enrollment and the information in the paper and others about the educational materials, and the reason I'm confused a little bit about this -- and any of the light you can shed on it -- is that Medicaid plans have been enrolling people in managed care for years. MA has been enrolling for a long time now. CMS has a very thorough process of how to clear that information and the content. Same thing with PDP, and now we're in year 11 of that program. Why all of a sudden problems with putting together enrollment materials on a program like this when they've had such great experience in all these other areas?

MR. ROLLINS: I think, to some extent, while they've had experience in these other areas, they haven't really had to deal with this specific kind of context where you've got a plan that's serving specifically the duals and providing the breadth of services that the MMPs are providing.

Also, in a lot of states, they were relatively new to the use of managed care, and so there was definitely

a learning curve on the state side in terms of getting up to speed and getting their materials ready.

DR. CHRISTIANSON: Cori.

MS. UCCELLO: So you mentioned that one of the reasons for opt-outs or low enrollment was the providers had resistance, and I was wondering if -- and I don't remember if this was actually discussed in the chapter, but was there -- did the programs undertake any outreach or activities to get provider buy-in among providers that treat this particular group of benes?

MR. ROLLINS: I think all of the states have engaged in some sort of outreach in education activities. The impression we got from our visits and our interviews, it wasn't that nothing had happened. It's just that looking back, they wished that a lot more had been done, and they realized in particular, a lot more specifically focused on the provider community could have made a difference.

DR. CHRISTIANSON: So I have a clarification question, I guess, for Mark. Could you clarify kind of the role of the Commission with respect to this demonstration? Are we trying to -- are we assuming this will be part of

Medicare in general in the future and we're trying to get heads-up? Are we being called on to give particular advice to the people running the demonstration as it moves forward, or what's the goal here?

DR. MILLER: So the reason that I wanted to come back to this is a couple things. First of all, this is very large and the first time the integration of the -- or at least when it was originally conceived, it was relatively a large demonstration, and it brought this integration of Medicare and Medicaid together and the notion that the dollars could be used for social services and medical services, and so it was different in that sense and pretty large scale.

And at that time, the Commission had a fairly extensive conversation and gave a fairly extensive set of comments along the entire range here -- financing passive enrollment, information for beneficiaries.

I expect that this is going to continue to turn out in the environment, even though it's not as big as it started off, and that I think it helps us to stay closer to it and potentially either give advice or get information from it because it deals with an issue that there's always

been a very -- there's been something of a black box where people say, "Oh. Well, some of these populations are precisely the kind of population that could benefit from a managed environment," but as it turned out, lots of managed environments didn't have a lot of experiences with these populations. And so I think watching this and watching it carefully to see if we can learn something is really important for the Commission. It connects to the behavioral health concerns that people have.

So I see it as kind of a two-way street that there may be things happening out there where we see good ideas that we want to support, and I'm sorry. I know this is longer than you might have expected, but there is some thought here.

And it's often -- it's not unlike what Jeff says. If you see a model out there that's working and you just think the payment system is getting in the way, that might be something that we could do something about, or two, if we think this is really leaving the tracks and the financing is all wrong or something like that, we may want to comment to CMS.

DR. CHRISTIANSON: So we may want to in fact

comment on the demonstration and suggest changes or things that we think would be --

DR. MILLER: If that's what we start to see out in the field, yes.

DR. CHRISTIANSON: Okay.

DR. MILLER: I see it as a two-way street. Yes.

DR. CHRISTIANSON: Okay. Building off of Herb's comment, I was kind of, I guess, underwhelmed by the findings to date, and given what we should already know about all this and particularly the notion that, gosh, these are hard people to reach, I think we pretty much knew that from a lot of other work in this area. It's early, so a lot of this stuff that I think we're given to react to, my first reaction was we knew that a lot of this stuff was going to happen before they went ahead with it.

Kathy.

MS. BUTO: Picking up a little bit on your comment, Jon, I think we also have mentioned over and over and again, the disproportionately large share of Medicare expenditures that go to the dual eligibles, just Medicare expenditures. And in the back of my mind also is the question of, since this is a state -- really state-directed

initiative using the combined funds, whether ultimately the dual eligibles are going to be treated more as low-income beneficiaries in state-defined programs, even though they are entitled to the Medicare benefit, or whether they may remain as fundamentally Medicare beneficiaries.

So, for me, there is a real issue of who are these beneficiaries, and particularly if we go down this road more extensively, are they becoming more Medicaid beneficiaries? And I think that is a very basic question having to do with how much oversight, quality standards, and other things will the Medicare program have. So I think there is a deep Medicare interest in this issue is what I wanted to get back on.

MR. GRADISON: Just curious as to what steps you've taken or MACPAC has taken to coordinate your views and exchange information on this subject.

MR. ROBBINS: So we do have regular discussions about sort of the work we're doing on the financial alignment demonstration. One of our colleagues from MACPAC is actually accompanying us on a couple of these site visits, so there are discussions back and forth between the two, the two groups.

MR. GRADISON: Thank you.

DR. CHRISTIANSON: Are there others who want to comment on Eric's presentation or what we've learned so far?

DR. REDBERG: So I think it was a good presentation. The data is a little sad, but I was struck in the report and also on Slide 8 at the frequent theme of the lack of adequate and stable housing, and it makes it hard to do care coordination, and it makes it hard to do care. I mean, you do wonder what kind of care they were in, but maybe they were just in a changing housing situation.

But it occurs to me -- and it occurs to me when I was on service recently and we have some dual eligible patients, and they get very expensive devices and things that -- I'll leave it at that. It's unclear how much it's really helping their overall health, for their 30,000, 40,000. But then we have to discharge them to the street because they have no housing. And I just wonder if we should think about housing as a health benefit because it's very hard to do care coordination in somebody that you have nowhere to discharge them to. The chance that they're

going to take these -- one patient that I was thinking of last time I was on service got several drug-eluting stents, was supposed to be taking dual antiplatelet therapy. We had nowhere -- we sent him out with his medications, and he didn't show up. He had nowhere to go, and I just think housing, it becomes pretty clear that it's really a health issue. It's not just a housing issue, and I feel like it's a better -- it's an important consideration as part of health care.

And actually, I think you had an example of maybe a kind of facility in Massachusetts that was supposed to provide some kind of 24-hour care, but even that was $600 a day. I mean, just providing some not-supervised housing for people that really have such inadequate or nowhere to go, I think would be a big improvement in their health care.

DR. CROSSON: Clarifying questions?

[No response.]

DR. CROSSON: I see no hands. So, Jack, would you like to kick us off in the comment section?

DR. HOADLEY: So thank, Eric, for bringing this to us, and it was very helpful.

I was thinking about the question that Kathy and Jon were talking about in terms of sort of the importance of this, and it does strike me that we are really looking at sort of a sector of Medicare beneficiaries who also happen to be Medicaid beneficiaries and trying to figure out how to do a better job of caring for this generally vulnerable population, and part of what's I think distinctive about a lot of these demos is they did bring in a fairly high number of people who are getting long-term supports and services, so again, sort of a measure of the vulnerability.

I do think the question of how much is this a Medicare versus a Medicaid responsibility is an interesting one. The experience in Virginia where I did a site visit -- and I hadn't kept up with it, but it's interesting that they are now the one state that is sort of phasing out of this because they are doing managed long-term care, mandatory managed care in their Medicaid side. So they're sort of saying, "Okay. We're going to deal with the Medicaid part, and" -- to some degree, I'm being cavalier -- "let the Medicare fall where it may."

So just sort of going to some of the issues that

you raised on the discussion slide but then at least one other one, I think this whole issue of the passive enrollment and the opt-out is a good opportunity for us to learn, with consequences not just for this particular population, but every time we talk about how to engage beneficiaries and things like ACOs or other kinds of demonstrations, we always come to the decision, how do you get people to understand the consequences of something that is going to affect their care, but where it's not sort of in that old-fashioned model of "I'm going to pick a plan to go into, and then that's my route," even though in some ways, this is ultimately picking a plan to go into. But it's really what's involved is trying to engage these beneficiaries in a way to understanding.

I think the things that you're seeing in this is that educating beneficiaries for something that's more complex and more involved does involve a level of engagement that's different than sort of the traditional marketing experience in health plans and Medicare Advantage plans and PDPs and so forth, especially when it's involving people getting long-term supports and services or other kinds of complex needs for behavioral health or whatever,

where they have a fairly involved network of providers that they're already working with. And I think this is where engaging the providers -- and, Eric, I think you're right. From what I've seen, states have done this, that it was on their agenda, but probably didn't do it thoroughly enough. And what I saw in Virginia was that it was often the nursing homes that were the source of some of the mass opt-outs because, of course, they have even more ability to sort of work with their population.

And it was particularly some of the smaller independent nursing homes who may have attended a seminar or something or had the state people come and visit them, but probably didn't really absorb it and were mostly afraid of the unknown, understandably. In some cases, there was follow-up, outreach, and then they did get a better solution, but I think figuring out ways to the providers -- and again, I sort of think of the analogy to the ACO world where trying to both think about how the providers got to think about this new way of doing things and interact with their patients on it. So the patient -- the beneficiary is hearing from their providers, but they're also hearing from plans or the program about this, and so there's all these

routes on how to coordinate that and make sure.

We could have a long discussion about sort of the opt-out numbers and some of that. I won't spend more time on that right now, but there were issues in terms of the passive enrollment. And you highlighted some of this in terms of just the data, and if the concept of passive enrollment was supposed to be done with a sort of intelligent passive enrollment kind of approach and states found that they couldn't get hold of the information from Medicare in terms of who the primary care doctors or who the additional doctors -- the states owned the information on what nursing home somebody belonged to, so they could handle that part, but they often had -- and some of that may be transition. It may have gotten better over time. But it does raise a lot of issues, and I think there's a lot of really complicated practical issues about timing and transitions between programs, if somebody opts out of this whole issue of going back into Part D and going back into either a Medicare Advantage or traditional Medicare. So I think there are some really useful issues.

I think the other one that I paid on -- and it wasn't one of the ones on your last slide, but it was just

the whole area of what's the success of these programs at delivering and coordinating care. And I think your main finding was that it's too early to assess. It's an interesting question. As programs get into their second and third year and we still can't tell whether they're accomplishing anything, that is a bit worrisome.

On the other hand, coordinating care for this population is hard. It involves a lot of different actors. We've heard comments about coordinating the coordinators because you've already got care coordinators out in provider settings, and then add the plan.

And this goes go to one of your points on the last slide. The plan players in this -- and I think one of the things that I've really tried to focus on is, what's the value-added for a plan, and how does that change across types of plans? And where I've seen examples in a couple of projects I've done has been where the more provider-based plans, whether it's a community health center-based plan or health system-based plan, seem to be the ones that can truly integrate the providers who are probably the ones that really know the patients the best, know the beneficiaries the best, and the sort of plan perspective of

managing the finances.

And when it's been the outside, the freestanding plans come in. They're trying to figure out -- and they're the ones, I'm suspecting, have more of the challenges and actually finding the people. If you're affiliated with a clinic and the clinic has a relationship -- yeah, the clinic does still have problems with some of their patients who are homeless, who are transient, and they lose track of them, but they've got a better shot than the plan coming in from the outside, is either trying to rely on the last state information that was available or trying to figure out a way to coordinate with their network providers. And so I think we may want to look at whether these kinds of initiatives should be targeted more to either provider-based plans or plans that come in with a real strategy for how to coordinate with providers and not just try to operate from the outside.

And I think a part of that is do the particular plans that come into this kind of an enterprise have the degree of experience with behavioral health services, with long-term supports and services, and the kind of clients that need those services. And I think that's been one of

the challenges here, is a traditional managed care plan may not have done much with long-term care. They've had to obviously deal with behavioral health, but that may not be something that they've got great experience in.

I could keep going, but I think I'll stop and leave those as themes for follow-up.

DR. CROSSON: Thank you, Jack. So we'll have further comments. I have David.

DR. NERENZ: Just a couple points and to reinforce the excellent comments that Jack made, and it also speaks to Cori's question, I think, of why would there be resistance to this or why would there be opt-out.

In this population, although we do have some people who have sort of fragmented, loose connections to care, at least our experience in Michigan is that most of these folks do have established and long-standing care relationships, many of which would be disrupted in this, and there's a lot of the opt-out. Each state is a little different.

Where we are, there's kind of two distinct components, even though they're brought together under one program. There's essentially the medical care side, but

then there is the long-term behavioral but long-term community support services. And for a lot of the disabled duals, particularly those who rely on those long-term support services, there is a strong sense of loyalty, of bonding and commitment to those agencies, and at least in our state's dynamic, there's a sense of threat that these new managed care entities that have not been active in that arena are now not only active in that arena, they essentially control that arena. And one way, if there's fear or resistance to that, is simply to opt out.

So when I saw the multistate opt-out numbers, I wasn't completely surprised because I think that's part of where it comes from.

That leads us into this larger question. Jack, you talked about coordinating the coordinators. I think as we sit around this table and we think about this project and others that have some feature of enhancing care coordination, our general sense, "Well, that should be a good thing," people should like that, well, maybe yes, maybe no. It depends on where you're coming from. Depending on exactly one's circumstances of dual eligible, before this thing comes on the scene, you might already

have a plan-based care coordinator -- or at least you can shortly get these folks a plan-based care coordinator, a primary care and medical home-based care coordinator, a medical specialty-based care coordinator if you have a serious ongoing condition. You can have a psych care coordinator, and you can have a long-term community service care coordinator. Now, either they exist, or they come to exist as part of this initiative, and then now it becomes parity after a while of who's running the show.

Now, some of the resistance to the thing is situations where a good care coordination relationship already exists, particularly in the long-term support services role, and the participants in that relationship don't want that disturbed. So the reason I highlight that is I think as a broader topic of discussion for us going forward, we could have some discussion about care coordination and what models do we think are successful, what models are less successful, if you can't determine that how do you sort out these issues, because we typically think we're solving a problem of not enough care coordination. But then often the solution creates overlapping care coordination.

The last thing is there were a couple of comments about, well, maybe the states haven't yet tried hard enough or they haven't been through enough. That's not necessarily the issue. Some of these conflicts are deep and conceptual and in some ways irreconcilable.

I sat in a number of planning meetings in Michigan as this was getting off the ground where folks on the long-term community support side expressed active overt hostility to the medical model. And in their view of the world, you don't talk about patients; you talk about perhaps clients. And it became clear this isn't a matter of just sort of bringing people together through a program and nothing but good things then follows. You have to recognize that there are very different views of what the human being's issues are, whether you call that person a "patient" or a "client," and then how the pieces fit together for that person.

So there's an attraction of bringing all these pieces together, but it is very, very hard to do it.

DR. CROSSON: Thank you. Other comments?

DR. SAMITT: Thanks for the great chapter. It was very informative.

So my organization has had some real-time experience with this. I think we enroll a little bit less than 1 percent of the total national enrollment at this point, and it's early innings, as others have said. I think there's a lot we still need to learn. But I think what you highlight in the report is very much aligned with our own experience in that the program is going through growing pains and sort of has a lot to learn and has some issues in various dimensions. And the ones that I would highlight would be the enrollment issues are certainly real, and the disenrollment issues are certainly real. In fact, what we've experienced is many beneficiaries opted out of MMPs without realizing that they did so, and so there seemed to be issues of communication challenges regarding enrollment and disenrollment, marketing challenges with enrollment and disenrollment, and coordination challenges, especially between things like MMP and Part D that feel clunky. It feels as if it's sort of a completely separate piece that in no way has connected in with existing programs, which it certainly should. So enrollment has certainly been an issue.

As has been discussed, payment has been an issue,

payment adequacy, and really kind of getting this right, with probably overaggressive estimates in terms of what is possible early in the program in terms of how quickly savings can be achieved through alignment of the Medicaid and Medicare elements of this program.

The two others that I would highlight, we have talked about care coordination and kind of the challenges in providing access to care coordination for this population, and then quality. And we've discussed this previously that how do you measure quality when this is such a distinct population and the traditional Stars-type program probably doesn't do it justice in really adequately determining quality comparisons. So when you think about performance payments or selecting plans, you know, quality should certainly be a component of it, but you want a fair representation of quality.

So, again, it's early innings. There's a lot to learn from the program. But one of the things that I think would be helpful for me is have we thought about lining up sort of how some of the other existing programs address some of these challenges. So when we think about how Medicaid itself deals with enrollment, payment adequacy,

quality, so Medicaid, MA, SNPs, D-SNPs in particular, what works and what doesn't work there, or perhaps even something completely new, and we line this up against the problems we're facing, the enrollment, payment, quality, care coordination, you know, maybe the solution here needs to be taking the best of what works in these various other programs and reconstructing the program in a way that kind of brings to the fore what seems to be working. And so it would be a blend of -- you know, the passive enrollment is right from our perspective, which isn't the case in MA. So passive enrollment may be right, but in terms of payment adequacy or payment methodology or care coordination or even marketing freedoms, perhaps that's more like MA. And for quality measurement, perhaps it's something completely new because Stars and MA is not adequate for the MMP programs.

So I wonder if we can kind of map out and compare and contrast the various programs as a way to educate what some of the suggestions could be to improve MMP going forward.

DR. HALL: Along those same lines, Eric, there was a reference to the PACE program in the white sheets you

sent out. Do you think there are any parallels there that would be useful? PACE has certainly had long experience. Obviously, it's a social daycare program so it differs, but...

MR. ROLLINS: PACE has been very successful within sort of its bailiwick. The problem with PACE has been sort of getting it to operate on a larger scale, and one reason, as you know, that does make it successful is it's sort of a completely integrated plan that sort of directly, you know, sort of a mini-staff model HMO. And that's hard to apply for the MMP model, which is much more sort of a broad-scale health plan that is serving in some cases, you know, 10,000 or 20,000 people over a fairly broad geographic area.

As I think I mentioned in the paper, I think that's one problem that New York ran into with its first demonstration, is they were sort of thinking of sort of PACE-like care coordination requirements, which were difficult to implement when you moved outside of the PACE model.

MS. BUTO: I had exactly the same question, but I wanted to add about PACE, Eric, do we know whether PACE

over the years has saved money for both Medicare and Medicaid?

MR. ROLLINS: I believe when we last looked at it, which is now three or four years ago, we came to the conclusion that PACE plans were getting paid more than it would cost to treat those beneficiaries in fee-for-service, and we recommended that they be paid closer to the methodology for traditional MA plans. Their impact on Medicaid spending I do not know.

MR. GRADISON: Just a couple of dots I would like in my own mind to try to tie together. We know or at least used to hear from ACOs that one of their big challenges was people going out of network, not only incurring a lot of costs out of network, but also the slowness of the ACO learning about the care that was given out of network, which made it pretty hard to do -- not just to save money, but to do effective care coordination.

One of my former students is running a three-year MCCI $6 million program involving children. It's a Medicare program in Massachusetts. Same problem in Medicaid, and that is, the slowness of getting records back in that case from the state Medicaid agency to assist.

I can certainly understand why in this instance there's the additional complication, and that is, getting the Medicare information to the Medicaid officials and back and forth to try to coordinate this. It may be that solutions have been -- maybe there have been solutions that have occurred in both the ACO environment and in the Medicaid environment to permit the exchange of information on more of a real-time basis since I last had conversations about those two programs. But I would like to suggest that's terribly important. And it's difficult for me as a layman to understand why there should be a delay since so much of this is presumably being handled electronically.

DR. CHRISTIANSON: Eric, do you have any initial data on the types of diagnosis and people that are dual eligible? And, particularly, I'm interested in how many are there because of behavioral health disability kinds of diagnoses?

MR. ROLLINS: We do not have that information yet. Once we get the enrollment data for MMPs, we should be able to more easily find those people in the fee-for-service claims we have to see what they looked like before they went into the plans.

DR. CHRISTIANSON: Yeah, so I think it makes a lot of difference how you think about the problems that the demonstration is having, and I go back to a time when I served on the board of a local agency that contracted the state and local government to serve the most severely ill, mentally ill people in their community. And back to what Rita said, and Dave to some extent, we started -- we actually were more of a housing agency than anything else. And we started with housing and finding people a place to live. And then the next thing we started with is -- and without conditions, like you don't have to be clean to live here. If you live here, maybe we can help you get clean.

Then dental care, because the pain involved in the oral problems people were having led them to self-medicate, which exacerbated their mental health problems, which made it difficult to get them to medical care, and it just kind of went on and on. But without a starting place of, you know, where are these people and how do we give them a safe place so that they can start thinking about their life, and we had lots of negotiations because we're in Minnesota so we have everybody in managed care. So we had lots of negotiations with the health plans that

contracted with the state about what we do, what you do. And, of course, the health plans approach things from a medical point of view. People get care. They go to a doctor's office. They get drugs and things like that, which -- so this whole set of activities that we were engaged in for this population was totally foreign to the way they thought about delivering care, back to David's point.

So this is extremely complicated for that population, so I think I'd be very interested to have some data as it comes out and share that with us about, when we talk about dual eligibles, how many people have these kinds of diagnoses.

DR. HOADLEY: So, yeah, I want to follow up on Jon's comment. I do think, you know, that kind of analysis will be really helpful. I mean, one of the challenges presumably is once these people are enrolled in MMPs, you know, how much you're able to look at in terms of -- but you've got -- presumably any of them that came from fee-for-service, you'll at least have the background information on sort of the mix of diagnoses and things they had when in fee-for-service. Some of these people have

come from MA, so, you know, I don't know how much you'll be able to look at using encounter data to get at that. But it does seem pretty important.

It also comes back to this challenge to me of thinking about the potential for savings, and, you know, this is a population that by definition is probably much of it -- we'll be informed about that, but much of it is probably underserved population. And, you know, it becomes a question of whether looking for savings is really the right answer, and then also the whole notion of blending Medicare and Medicaid funding streams together goes to these same questions. I mean, you could get savings on the Medicare side because you're investing more on the Medicaid side, and then, of course, once you've tried to blend those, you're supposedly not going to think about it that way, but we obviously still will and still do.

But, you know, to the extent that we empower these organizations to have the flexibility to use dollars in ways to deal if not all the way into housing at least with other kinds of social service supports and things -- and I think this goes back to my point about sort of whether the plans that are into these are really fully

ready to do that. And I heard one conversation from the health plan side on the subject of personal care assistants that are -- and this goes to some of Dave's comments, you know, a very core part of what some of the people with disabilities rely on. They said, well, our view is that we can find personal care assistants that will be in our network, and they'll be the one -- they'll substitute for the ones that these beneficiaries are using. And, you know, from the beneficiary side, that's just -- you know, that's just like a non-starter. I mean, if nothing else, that will have them opt out. And even if they were mandatory in or locked in or whatever, that's going to cause a point of tension. And it seemed to me like in this case the person we were talking to just didn't even understand really the role that those individuals played in the lives of these beneficiaries.

And so, you know, putting more -- the potential for thinking about are there more requirements on the plans that get brought into these to make sure they're ready to take on this kind of joint Medicare-Medicaid kind of, you know, funding stream and all the services that implies.

MR. ROLLINS: One quick point just to follow up

on the encounter data. So we do have some encounter data now, and our understanding -- we haven't probed deeply into this yet -- is that the Medicare side of the encounters for the MMPs is probably in there. Now, how complete it is I do not know yet. But that data set, as we understand it, does not have the Medicaid side of the encounters.

DR. HOADLEY: Is there any way to get visibility into the Medicaid data as part of this -- I mean, I assume that the duals office, or whatever it's called, in CMS, you know, at some point will have the ability or evaluators will, so --

MR. ROLLINS: They are definitely collecting it, and that's going to play a key part in the evaluations that they're planning to do. At this point I just don't have a good sense of sort of how ready the data is to the point where it's sort of worth it for us to get it from them and sort of start analyzing it.

DR. HOADLEY: Can you remind us of the evaluation plans and sort of timetable? Are there preliminary reports? I think, what, RTI is doing the major cross-state evaluation, as I recall.

MR. ROLLINS: RTI is leading the effort. There

are a number of subcontractors. As you can imagine, it's a big, big lift. Their plan is to do a series of preliminary reports for each of the states. I think Washington's managed fee-for-service report is the first one we've seen in that area. None of the other reports have been released yet. And then they plan to do a final evaluation, but given the timeline and with the two-year extension, we probably won't see those final reports for some time yet.

MS. BUTO: Eric, I was wondering whether -- and I know we're not thinking yet to Phase 2 of these debt limits, but these demonstrations, again, are really initiated by the states, so they're of their design in a sense, as agreed to by CMS. I'm wondering whether we ought to at least think about or put out there the possibility of D-SNPs through Medicaid waivers being able to take responsibility for this population -- in other words, with a combined funding. So go the other way, have Medicare take ownership of Medicaid funding and look for ways to optimize care for the same population.

I think that model has to be out there, too, not just the state-run or -designed approach. And I say that because I just think there may be different priorities and

different emphases, and it would be worth looking into. This is the one they've decided to take, and I understand it's probably the path of least resistance. But I recall some years ago, one of the states -- I think it was Wisconsin -- the Medicaid director said, What if we provided Medicaid funding to reward Medicare plans, MA plans, that are doing a particularly good job of serving the dual eligibles by some set of metrics that we agree on together? In other words, let's agree on what those are, and we'll provide funding to help reward those plans. So it was a different model where the state was actually enhancing Medicare plans, if you will, to improve the quality to that population.

And so I think there are a number of things that could be done on the Medicare side. I'd like to see us be open to that or see CMS be open to that in the future.

DR. MILLER: Just a couple things on that, and this is not the main point, but it's refreshing to hear some state said that at some point in time, because it's generally the other way. Yeah, I'd actually like you to find that quote for me.

MS. BUTO: The Medicaid director later came to

CMS.

DR. MILLER: Okay, so -- all right. So a couple years back -- this predates you being on the Commission -- we worked through the various SNP options, you know, institutional, chronic condition, and dual SNPs, and what we said at the time was we would -- there was sort of this -- there's always this question of should the SNP model be extended, and we said -- we looked at cost, quality, and various components, and we said the SNP dual-eligible models that were truly integrated -- the fully integrated dual-eligible SNP models -- did seem to have something to show in terms of the quality of care for the dual-eligible population. And as a Commission, among other sets of recommendations, we said that is the model where it's fully integrated.

Now, SNP community -- and, of course, logically, that makes sense. It's like if you're a dual-eligible SNP, then you should be doing dual-eligible stuff, right? And the SNP community, you know, is fairly frustrated about this because they have D-SNPs, and they say that it is very hard to get the state to coordinate and, you know, get a fully integrated model and all those things.

And so this is really just a long way around to your point, which is you're exactly right, and that's where I think some of the initiative came, you know, from states that said we'll do this and then you come to us and we'll decide how to do this.

And one of the other fault lines in all of this, beyond the passive enrollment and providers rejecting it and wanting people to disenroll, was tension among the plans where the plans would be in a state and say, well, I'm offering choices to different Medicare beneficiaries, but when you come into these demonstrations, the states pick which plans take the entire operation over. And that's yet another flash point that occurs in all of these and plays into your point of what is the beneficiary status here. And so that fault line just arises as well.

But the narrow point was we did some thinking about the dual-eligible SNP thing a few years back.

DR. HOADLEY: To sort of link that collection of issues to the question of this is a demo that has an endpoint, and I was particularly concerned about this when it was a three-year demo and it felt like some of these plans and states even were barely going to be rolling by

the time it ended. With two more years, this is not quite as immediate an issue, but the question of what comes next is one thing from a sort of program design and a testing and a demo and an evaluating point of view, but it's another thing from the point of view of an enrolled beneficiary who is -- if we're in a situation where those plans simply end or, you know, is there a sense that those could become D-SNPs or have some way to avoid once again disrupting beneficiaries who've -- the ones who at least stayed in it may have, we hope, settled into good patterns of -- you know, whether they're getting consistently better care, they're at least have some stability in their pattern of how they're getting care. So those are all questions you've got to ask. Do we want to keep that up? Do we want to -- we at least have to worry about transitions, and one of the potential transitions it does seem like could be to D-SNPs, with a lot of if's coming after that.

DR. MILLER: And just a minor point, I think back to Jon's point, which is why we're doing this, and, again, I know Jack and Kathy and Herb and probably everybody gets the sense of these things start, they're supposed to be demonstrations, we'll look at this, and then we'll stop if

it doesn't succeed. But, generally, that's not how it goes. They continue to stay in place for 10 and 20 years.

So I think, you know, understanding what's going on here, because I think in some version we're going to be living with this for a while, would be my guess.

MR. ROLLINS: And in some sense, too, I think it'll be valuable that Virginia actually is ending after three years, at least sort of a test case, sort of how do you navigate some of these issues.

DR. HOADLEY: Right, and those people are going to be mandatorily enrolled in Medicaid, managed long-term-care plans, and I think, yeah, we'll get some good examples. And then the question is: What are they doing on their Medicare side?

DR. CROSSON: Okay. Seeing no further comments, Eric, thank you very much. We'll look forward to your next update.

We have come to the end of the agenda. This is the time for the public comment period. If we have members of the audience who'd like to make a public comment, I'd ask you to come up to the microphone now so we can see how many individuals we have, if there are any.

[No response.]

DR. CROSSON: Seeing none, we are adjourned.

[Whereupon, at 10:58 a.m., the Commission was adjourned.]