PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE

PUBLIC MEETING

The Great Hall
The Hubert H. Humphrey Federal Building
200 Independence Avenue, SW
Washington, DC 20201

Monday, April 10, 2017
1:01 p.m.

COMMITTEE MEMBERS PRESENT:

JEFFREY BAILET, MD, Chair
ELIZABETH MITCHELL, Vice Chair

ROBERT BERENSON, MD
PAUL CASALE, MD, MPH
TIM FERRIS, MD
HAROLD D. MILLER
LEN NICHOLS, PhD
KAVITA PATEL, MD
BRUCE STEINWALD, MBA
GRACE TERRELL, MD, MMM

AGENDA PAGE

P R O C E E D I N G S

[1:01 p.m.]

CHAIR BAILET: Welcome. We are going to go ahead and get started. I have some opening remarks, and I'll turn it over to my Vice Chair, Elizabeth, and then we'll open up to the Committee members to make some opening remarks. And then I'll take you through our process for today, and then we'll get into the meat of our meeting.

I'm Jeff Bailet, Dr. Jeff Bailet. I'm the Chair of the PTAC. I want to welcome everyone for joining us today, and there are a number of folks on the phone as well.

This is our April meeting for the Physician-Focused Payment Model Technical Advisory Committee, or PTAC. We're delighted to have you all here.

As you know, this is our first meeting that will include deliberations and voting on Medicare physician-focused payment models submitted by members of the public. We would like to thank you all for your interest in today's meeting. In particular, thank you to the stakeholders that have submitted models, especially those that are here today. Your hard work and dedication to payment reform is truly appreciated.

We have spent the past year establishing our

processes and procedures for receiving and reviewing physician-focused payment models. We want to stress that our process is shaped by the input from stakeholders. Although we will begin deliberating and voting on proposals today, we are committed to listening to your feedback and evaluating our processes accordingly. We value your comments at every level, especially as they relate to our receipt and review of proposals.

We also want to remind you that the PTAC is a Committee of 11 members, not a Committee of one. To the extent that questions may arise in the process as we consider your proposal, please reach out to staff through the PTAC.gov mailbox. The staff will work with me as Chair and with Elizabeth as Vice Chair to answer your questions. In the interest of consistency, in responding to submitters and members of the public, please reach out to us through this process that we have in place.

Today we will be deliberating on one proposal, and tomorrow we will deliberate on two proposals. Discussion of each proposal will begin with presentations from our preliminary review teams, or PRTs. The PRT reports are reports from three PTAC members to the full PTAC and do not represent the consensus or position of the PTAC. PTAC reports are not binding. PTAC may reach

different conclusions and a different recommendation from that contained in the PRT report.

And, finally, the PRT report is not a report to the Secretary of Health and Human Services. PTAC will write a new report that reflects deliberations and decisions of the full PTAC, which will then be sent to the Secretary.

Following the PRT presentation and some initial questions from PTAC members, the Committee looks forward to hearing comments from both the proposal submitter and the public. The Committee will then deliberate and vote on recommendations to the Secretary of Health and Human Services.

Our job is to provide the best possible recommendations to the Secretary, and we are excited to begin this process.

So I want to turn it over to Elizabeth for additional comments.

VICE CHAIR MITCHELL: Thank you, Jeff. I will be brief.

I also wanted to thank everyone for being here. Thank you for your interest and for the proposals that we have received and just the commitment, I think, that we all share to the promise of payment reform, which is better

care at lower cost. So that's why we're all here.

And I want to reiterate our commitment to a transparent and inclusive process. We hope to get to yes. We would like to include as many models as is appropriate in the CMS portfolio, and we are looking for ideas from the field. That is why we are here, to find those good ideas and to help create opportunities to participate.

So we have a committed group, and as Jeff said, we have spent about a year coming up with a process that we hope is fair and open, and we invite your feedback on the process and on the content.

So thank you again for being here, and we'll turn it to the Committee.

CHAIR BAILET: Any of our Committee members have any opening remarks they'd like to make before we get started?

[No response.]

CHAIR BAILET: All right. So we have an eight-step process in deliberating and voting today. We will start with a summary of the deliberating and voting process for the public. We will disclose the potential conflicts of interest and threats to impartiality among our Committee members. Then we will have a presentation by the proposal review team, and that will go obviously to the full PTAC.

Then statements of the submitters, we have the submitters present, also public comments. We have some people who are signed up to make public comments. And then the Committee will start deliberating and voting on each criterion, and the Committee will ultimately end voting on the recommendation, the final recommendation to the Secretary. And then we will work with staff today to try and lay out the framework to capture the deliberation and the recommendation.

So unless there are other questions from the Committee, we're going to go ahead and start our process by introducing ourselves and including in that introduction any areas of conflict or new potential areas of impartiality. We as each individual Committee member will do that now and then proceed.

So I will start with myself: Jeff Bailet. I'm an otolaryngologist. When I was appointed to the PTAC, I was the president of Aurora Health Care Medical Group in Wisconsin. Since January, I have taken the position as executive vice president of health care quality and affordability with Blue Shield of California, so that is a new disclosure. The Committee is aware, the Secretary is aware, but I feel the need to disclose that today.

I'll turn it over to Elizabeth.

VICE CHAIR MITCHELL: Thank you. Elizabeth Mitchell. I'm the president and CEO of the Network for Regional Health Care Improvement, and I have nothing to disclose.

DR. FERRIS: Tim Ferris. I'm a primary care physician, internist, and pediatrician at Mass. General Hospital in Boston and Partners Health Care in Boston, and I have nothing to disclose with regard to this proposal.

DR. PATEL: Hi. Kavita Patel. I'm an internist at Hopkins, Johns Hopkins, and also a fellow at the Brookings Institution. And I disclosed on our disclosure form and just verbally that I have heard the proposal that's being discussed presented at meetings in the past.

DR. BERENSON: I'm Bob Berenson. I'm a fellow at the Urban Institute, a former practicing general internist, and I have nothing to disclose regarding the proposal.

DR. CASALE: Paul Casale, a cardiologist. I lead the ACO at New York Presbyterian-Columbia-Weill Cornell, and I have no disclosures.

MR. MILLER: I'm Harold Miller. I'm the president and CEO of the Center for Health Care Quality and Payment Reform. With respect to the proposal that we're hearing from today, I know Dr. Kosinski, who is the developer of the proposal, professionally not personally.

I know him because several years ago someone told me that there was a physician out in Illinois who actually had an alternative payment model with a private health plan, and that was such an unusual thing to hear about at that point that I went looking to find out who that was and came across Dr. Kosinski. And I have invited him to come and speak at some conferences about what he is doing, but I have had no involvement in the proposal that he is presenting today in any fashion, nor will I benefit from it in any way.

I have also been involved with helping a number of other medical specialty societies develop alternative payment models, but there is no conflict that I can see between any of that work and the proposal that is here today. So I've told my colleagues that I don't believe that I have any conflict of interest or lack of impartiality with respect to this.

DR. NICHOLS: My name is Len Nichols. I'm a health economist from George Mason University, and I have no conflicts with respect to the proposal today.

DR. TERRELL: My name is Grace Terrell. I'm a practicing general internist at Cornerstone Health Care, a multispecialty medical practice. I'm on the board of CHESS, which is a population health management company, and

I have just transitioned to the role of chief executive officer of Envision Genomics, which is a biotechnology company. I have no conflicts to disclose today.

MR. STEINWALD: I'm Bruce Steinwald. I'm an independent consultant in Medicare and health care financing issues here in Washington, DC. I have nothing to disclose on this proposal.

CHAIR BAILET: Thank you.

We are going to go ahead and start with Dr. Paul Casale, who will present the PRT report on Project Sonar.

DR. CASALE: Great. Thank you, Jeff.

Before I start with the actual presentation, just to provide some overview. So the PRTs, as has already been outlined, are composed of three members of the Committee and a lead is identified within the team. The proposal overview and summary of the PRT review are the next steps in our presentation, followed by key issues identified by the PRT, and then the initial evaluation from the PRT is done using the Secretary's criteria.

So as I mentioned, the PTAC Chair and Vice Chair assign two to three PTAC members, including at least one physician, to each complete proposal to serve as the PRT. And, again, one PRT member is selected to serve as the lead.

The PRT identifies additional information needed from the submitter and determines to what extent any additional resources and/or analyses are needed for the review. ASPE staff and contractors support the PRT in obtaining these additional materials.

After reviewing the proposal, the additional materials gathered, and public comments received, the PRT prepares a report of its findings to the full PTAC. The report is posted to the PTAC website at least two weeks prior to public deliberation by the full Committee.

As already identified and mentioned by Jeff, the PRT report is not binding on PTAC. PTAC may reach different conclusions and a different recommendation from that contained in the PRT report.

So with that background, I'm going to go through our PRT review, so just a brief overview on the proposal.

The Project Sonar proposal describes their model as a specialty-based intensive medical home intended to address "high-beta chronic diseases," those associated with high cost, high risk, and high variability in outcome and cost. In this model they presented information particularly around Crohn's disease.

And again, just a brief summary of the intervention. The model uses evidence-based guidelines,

including clinical decision support tools embedded in the electronic medical record to direct care. Risk assessment uses the American Gastroenterology Association Crohn's disease care pathway. An enrollment visit with a nurse care manager initiates the model and subsequent communication with the care manager through a Web- and mobile-based platform or by phone calls.

Patients are "pinged" at least once. This can be done via smartphone or other device of their choice to submit self-assessment data based on the Crohn's Disease Activity Index. And then the nurse care manager contacts nonresponders by phone to administer the questionnaire, again, for those who don't respond in other manners.

The patients receive follow-up from the care manager if their data falls outside the standards. If indicated, the nurse care manager communicates with the specialist and arranges an office visit or phone call, and use of the SonarMD platform, a cloud-based care management platform, which utilizes proprietary chronic care management algorithms, the clinical decision support tools, and predictive analytics.

In regards to payment, CMS would provide the alternative payment model entity additional payments for remote patient monitoring services for each beneficiary

enrolled. So there's a payment for the enrollment visit and then a per-beneficiary per-month payment. The APM entity would also be eligible for shared savings and losses based on retrospective reconciliation against a risk-adjusted target price. There are stop loss provisions and outlier protections also included. The APM entity would distribute shared savings to individual physicians based on the number of patients followed, ping response rate, and risk-adjusted cost of care.

So the initial review by PRT, the results are here, and I'm going to walk through each one of these next.

And, then just to highlight some of the key issues identified by the PRT, the proposal indicates that the model could apply broadly to diseases with high cost, high risk, and high variability in outcome and cost. But the evidence in the proposal only relates to inflammatory bowel disease, and in particular, Crohn's disease. The model makes innovative use of technology to monitor inflammatory bowel disease patients to prevent unnecessary emergency room visits and hospitalizations. But the platform chronic care management algorithms and clinical decision support tools and predictive analytics are proprietary.

A care management fee rather than a new payment

model may be sufficient to achieve the care delivery changes described in this model. The experience of the model in general is in a younger commercial population, and it may not necessarily translate to the elderly Medicare population. And then, finally, the proposal lacks comprehensive quality measures tied to payment.

So, with that as an overview, I'll go into each of the criterion in our assessment.

Criterion 1, which is the scope of the proposed payment model, which is a High-Priority criterion, the proposal indicates that the model could apply broadly to high-beta chronic diseases, but, again, details are limited to the submitter's experience with IBD, specifically Crohn's disease. And so within the scope, in 2015 the data that we reviewed, approximately 0.48 percent of the Medicare fee-for-service population had inflammatory bowel disease, and this accounted for 1.25 percent of fee-for-service spending. And while 20 large GI practices have implemented the SonarMD platform, practice feasibility, level of interest, and potential impact based on practice size and specialty are not included. And, thus, it's hard to conclude how the model would offer opportunities for others to participate in the alternative payment model. Because of the lack of information on additional disease

areas, it's not clear how this model, again, would offer opportunities for others to participate.

Under quality and cost, quality reporting would be based upon MIPS and Project Sonar-derived measures, but the examples for IBD seem fairly limited. The proposed quality reporting measures are primarily based upon laboratory values and patient response rates, more metrics tied to overall improvement in care, and patient satisfaction as well as patient-reported measures are needed.

We also discussed in our review that the submitters were in the process of piloting the use of hospital anxiety and depression score and the CDC Healthy Day core measures, although this was in the pilot stage.

Medicare beneficiaries with IBD, as I already mentioned, account for a small percentage of Medicare fee-for-service spending. Younger patients with IBD often have more active disease than -- or may have more active disease than older patients, so impact on emergency room and hospital utilization rates seen in the commercial population may not necessarily translate to the Medicare beneficiaries. And in our discussions, we also noted that some of the cost-saving measures that were suggested by the submitter included improved medication adherence and moving

infusion services from hospital outpatient to non-facility office settings. But there was no data provided in support of these statements.

Under Criterion 3 the payment methodology, again, another high-priority area,the proposal does not address how to manage payment when there are multiple chronic conditions and providers. A care management fee rather than a new payment model maybe sufficient to achieve the care delivery changes described in this model.

In the Medicare population, IBD patients may have fewer exacerbations of the disease compared to a commercial population. Thus, there may be limited variation in utilization; those opportunities for shared savings or losses may be small. And individual providers do not receive shared savings based on patient satisfaction or care outcome measures.

Criterion 4, Value over Volume. It was not obvious if office staff and arrangements might need to change in order to accommodate Project Sonar, particularly in different practice settings. The proposal does not sufficiently describe the mechanisms that would drive physicians to change behavior, so it's unclear whether the presence of a care management fee is critical to any behavior change or if it's more important for the patient

pings to drive behavior change.

The role, if any, of nonfinancial incentives is unclear, and while opportunities for shared savings and losses could be seen as one way to promote value over volume, the specific financial incentives in this model do not seem sufficiently structured to do so.

And I apologize. I should have started each criteria by saying how the PRT voted. So, I know it's up there, but I should say that the initial review on the first four criteria was "Does Not Meet Criterion."

On Criterion 5, the PRT felt the model did Meet criterion. The model allows patients to communicate with the care management via a web- and mobile-based platform as well as through phone calls.

The proposal indicates that small practices that may not have the volume to support a care management could engage in a shared service model. However, the proprietary nature of the SonarMD platform, again, as it relates to chronic care management algorithms, CDS tools, and predictive analytics, may be an obstacle for others to participate in the model.

On Criterion 6, again, the PRT concluded that it Meets criterion. Metrics such as cost of care, including ER utilization and hospitalization rates can be tracked

through the claims data as well as the ping response rates, which can be tracked through the SonarMD platform.

The proposal provided results from the ongoing pilot of the model with commercial payers. The quality measures proposed can be evaluated but are felt not to be comprehensive.

In terms of integration and care coordination, the PRT felt that the proposal Does Not Meet the criterion. The SonarMD platform enables the care manager to monitor a practice's patients and initiate physician involvement when necessary, but the involvement appears to be largely limited to the specialist. The model seems to have little integration with other clinicians, particularly primary care providers. Primary care providers could potentially access patient information from the SonarMD platform, but it seems that they are more likely to receive notes via fax.

And with the exception of the care manager, it is unclear how the front-line office and nursing staff would change in order to support this model.

Criterion 8 on Patient Choice, the PRT concluded that it Does Not Meet criterion. Patients make the decision to enroll and can interact with the care management via web- and mobile-based platform. However,

the experience of Project Sonar in the Medicare population is limited. It's a patient group and previously, traditionally has been less inclined to use mobile apps as a primary source of contact, and the potential technology gap would be addressed by providing traditional phone call care management, but it's unclear whether phone calls are for the same benefits as the web- or mobile-based communication.

In terms of patient safety, the PRT concluded that it meets criteria. The model activities that would likely improve patient safety include the remote monitoring of patients to identify clinical deterioration and initiate intervention early, reducing the need for ER visits and hospitalizations, and the risk assessment to help determine the appropriate frequency with which patients should be pinged.

And then, finally, Criterion 10, Health Information Technology, the PRT felt it Did Not Meet the criterion, recognizing that the model makes innovative use of technology to monitor inflammatory bowel disease patients to prevent unnecessary ER visits and hospitalizations, but the concern is that the platform and clinical algorithms are proprietary.

There has been a positive patient experience with

the use of this technology in the commercial population but again unclear how this would translate to the older Medicare patients.

And the model still seems to face significant interoperability challenges. In order to access notes from the specialists, primary care physicians would need to access a separate system or receive faxes.

And that's the end of the report.

CHAIR BAILET: Thank you, Paul.

I would like to open it up to the Committee to ask any clarifying questions of Paul or the PRT teammates.

Grace.

DR. TERRELL: I have several questions. One is you talked about the potential for the age to not be as relevant in an older population, but Crohn's disease has a bimodal distribution with a second peak between the ages of 50 and 80. Was there any evaluation on the part of the PRT to understand the prevalence of disease in the older population as it relates to that?

DR. CASALE: Yeah, go ahead. I'll let you --

DR. PATEL: I'll start. We actually knew that as well, and so we asked our data team, our contractors who are able to rapidly pull from the Medicare claims files, data on that to then quantify patients, total number of

Medicare beneficiaries, looking back over the last four years, just to see if there was anything different year to year -- but there was not -- and look at beneficiaries with inflammatory bowel disease, of which there were approximately 136,000 on average each year, beneficiaries with Crohn's disease, of which there were about 70,000, and beneficiaries with ulcerative colitis, of which there were about 65- to 70,000, but again, over four years, from kind of year to year, thereby looking at that bimodal distribution. And that's where we came up with kind of understanding what the prevalence would be in the Medicare population, so we did tease that out and asked our data partners to look at that.

DR. Terrell: A couple more questions, clarifying questions. So the idea of proprietary information has come up in more than just this proposal, and in one of the other PRTs, we were told that Medicare does sometimes permit technology that is proprietary to have a bill, a code, or whatever would be used. Was there an exploration with CMS or any of the folks that were advising us with respect to this particular point?

DR. CASALE: We did not explore with CMS. We just asked the submitters again to understand the proprietary nature of Sonar, is it the expectation that it

will remain proprietary, and an answer to that was that the expectation is that it will continue to be proprietary. But we did not explore it with CMS in terms of their willingness to accept that as part of the model.

DR. TERRELL: Final question -- oh, go ahead.

DR. PATEL: I'll just add, we knew, again, that the technology -- and we will hear form the submitters -- we knew the technology had these clinical algorithms, kind of the pings, the response rates, and that platform, as well as the analytics. The submitters did comment that the clinical algorithms that underlie the proprietary technology are public, or at least that is evidence-based kind of disease recommendations. But, again, looking at the total technology and really the analytics in that, kind of proprietary pings and some of those things, that was really what was felt to be part of what was offering this larger care management that the nurse care manager would draw from. And so we did not engage with CMS because that was something that was very unique to just this aspect.

DR. TERRELL: All right. Final question. There was a comment made about the lack of integration with the primary care providers. That presupposes that there ought to be, and although many of us have believed that and that has been the party line, there is also a lot of work that

has been done around the concept for certain individuals with complex chronic disease that the medical home concept would be better served by a specialist. So how much work did you all do in understanding the issues around those tensions right now in the concept of chronic disease management?

DR. CASALE: So I'll start, and then you can add on.

Certainly, as a specialist, I certainly understand that dynamic, but again, as was pointed out, one of the concerns is that the model has been primarily in a younger population, in which this might be their principal diagnosis as compares to Medicare when we looked at the data, when we looked at the tables that go up to 10 chronic care conditions. There were quite a few of the Medicare inflammatory bowel disease patients who had multiple chronic conditions, and so that it was going to be inherent. Even if the gastroenterologists were going to be taking primary care of the inflammatory bowel disease portion, that there would be a seamless information exchange. In the model that was presented, it did not -- we had a lot of concerns around that information flow back and forth, even if the gastroenterologists were taking primary responsibility for the inflammatory bowel disease.

DR. PATEL: And we, just to also kind of -- I think you were also asking, Grace, kind of what steps we took to understand what was unique about the kind of conditions suggested in the role of a specialist in terms of a medical home or just even a specialist's care.

So we had our literature review, and then the three of us tried to understand, even kind of at a deeper level with that initial literature review, what really would be kind of the state of evidence.

And we also drew the same conclusion that, in fact, this is a condition that largely is managed by the specialists, but even information being transmitted around medication changes or things that might have an impact because of other comorbidities, that was where there was a functional limitation because those communications were generally going to be done by fax or by the more conventional communication that exists today. So that was really more of a comment about not necessarily the primary care physician has to drive it, but there's still a coordination function. And that is obviously being done by the current specialist, but it's still kind of outside that really unique care management platform that was really being offered as the core of the proposal.

DR. CASALE: And just to add on one other thing -

- and, again, if you look at the data, I believe about a third of the patients had coronary artery disease. At least half have hypertension, you know, the usual things. And so those obviously need to be managed as well, so that coordination is going to be important for this patient population.

DR. BERENSON: Yeah. I'll be asking for any proposal related to a condition, the following kind of a question. Does the model itself -- well, given the fact that Crohn's disease is often misdiagnosed and irritable bowel, sometimes called Crohn's disease, colitis when it's limited to the large bowel can be mistaken for ulcerative colitis, Celiac disease, et cetera, et cetera, is there any -- and when we're giving extra money and especially shared savings, shared risk approaches-- is there anything in the proposal that assures us that the patient actually has Crohn's disease, or are we depending on a claim to designate Crohn's disease?

I am looking at this thing called the AGA's Crohn's Disease Care Pathway, and I'm wondering whether that in some way provides some assurance that patients who we are identifying as having Crohn's disease actually have Crohn's disease. Does the PRT -- is this something you looked into at all?

DR. CASALE: You know, I have to say I think -- and we could ask the submitters about this. My assumption was that this was an endoscopically, pathological diagnosis, and it went from there, but --

DR. PATEL: We did not -- as a part of -- as a PRT, we did not ask specifically about confirmation of diagnosis.

And I looked at the AGA pathway that you're referencing, and I believe that is based on some sort of endoscopic evidence of disease. But we did not question, and nor did the proposal state, that there was a definitive diagnosis up front.

CHAIR BAILET: Len.

DR. NICHOLS: So a couple questions for clarification, which is where we are now. Right?

So I, too, was intrigued with the possibility of the chronic care management fee being a simple substitute because, as an economist, I'm always looking for simple. But I guess I want to make sure that's actually applicable in this particular case because it seemed like -- doesn't the CCM require two chronic conditions to be present, and did you all think about the relationship between what I think the fee level is in the statute and what they're implementing and the calculation that was done by the

applicants on what was required for this particular ongoing PMPM?

DR. PATEL: I will take a first stab.

So we requested when we did that initial data request around kind of incidence of these diseases. We also looked at the comorbidities. So we felt very comfortable that given the numbers of patients, numbers of Medicare beneficiaries with inflammatory bowel, Crohn's, or ulcerative colitis, and then looking at comorbidities, that that would definitely trigger the CCM.

You're absolutely right that one diagnosis alone would not obviously allow for them to get the CCM, but when we looked at the data breakdown of presence of other chronic conditions -- for example, 69.1 percent have hypertension. So that would be a good example of kind of meeting the criteria for a CCM, that that was what gave us a little bit more kind of validity that yes, in fact -- now, a question to ask is would a gastroenterologist take care of those two conditions, and certainly we can discuss that. But there were certainly enough other comorbidities to trigger a CCM.

In terms of the dollars, the commercial setting in which they are doing it approximates about $600 a year. I am going back into my notes -- does that sound right,

Paul? I was just highlighting.

DR. NICHOLS: So that's 50 bucks a month.

DR. PATEL: Correct, about $600, which does approximately a CCM fee. So remember there is a split with the beneficiary paying some of that --

DR. NICHOLS: Right.

DR. PATEL: -- and Medicare paying some of that, but we felt like that was, again, a very nice potential, which is why we posed that in our PRT report.

DR. NICHOLS: Okay. All I was getting to is it may be that you and I both would tweak the parameters of the CCM to fit this, and the current one might not.

DR. PATEL: It's just --

DR. NICHOLS: If they did have, I think, 70 bucks a month, but anyway --

DR. PATEL: Which is why we were kind of -- what we wanted to understand was, are there currently -- is this really something that a care management fee like a CCM could offer a pathway for specialists?

DR. NICHOLS: Okay. And to jump on Grace's point about proprietary, because it is going to cut across a lot of these, I think, and so I'm really -- this is more kind of understanding how we should think about this or maybe how you all thought about it at this point.

But if I understood your answer to Grace's question, Kavita, you talked about how sort of the really proprietary part was the analytics, was the model that actually predicted which patient needs to be pinged immediately.

DR. PATEL: Right. And I indicated that.

DR. NICHOLS: And I guess the question is -- and this is not so much about this proposal, but again, how we should think about these things, I wonder if we might consider something where if something -- if applicants want something to remain proprietary, we sort of talk about a level of revelation to CMS and then figure out what you could share.

For example, if it is data analytics and they let us know which variables go into the model, then it would not be all that secret, would it, to figure out how to use that? But if it's hiding the variables that are in the model, then clearly, that's a level of non-recommendability.

So I just raise the question: How should we think about what needs to be revealed to the larger population, so it could be implemented program-wide without having to pay? And I don't have an answer. That, to me, is what's triggered by this question.

DR. PATEL: And just one other comment on the proprietary aspect that intersects with -- we were looking at Health Information Technology. We were also thinking about just if that potentially could add infrastructure burdens, which crossed-mapped to other criteria. So it was also kind of an understanding of will there be a burden to acquire such proprietary technology that almost creates an inflexibility.

DR. CASALE: Yeah, I think -- I'm sorry. I think that was the concern around infrastructure cost or burden, if this were to be defused more broadly.

CHAIR BAILET: Bruce.

MR. STEINWALD: My question is, I think, similar to Len's first question relating to payment methodology.

You said a number of times, Paul, during your presentation and in your report that the PRT wasn't convinced that a new payment model is necessary to achieve the goals of this model, and although we have seen sort of in the field, it's not uncommon to see an initiation fee and then a per-member, per-month fee in order to create financial incentives to change care.

So I'm wondering, what is it about this one that makes you believe that the goals could be accomplished more simply as compared to others that you've seen in the field?

DR. CASALE: Well, I think part of it was a particular outcome was focused on decreased hospitalization, decreased ER use as the primary outcomes, and that would directly be impacted by care management. So it seemed that there was sort of a closer line between a care management fee and the outcomes they were looking for, and it didn't necessarily sort of need an entire sort of new model around it.

DR. PATEL: I'll just add, you all have access to the full proposal. You know there is, as Paul mentioned, kind of an emphasis on hospital admissions, ER visits, and then there's this kind of lovely graph that talks about, you know, how you deal with the payment model, dealing with controlling hospitalizations and cost variation through care management and patient engagement, which actually strikes back -- we are not trying to -- I am not trying to say that the CCM is a substitute, but as an example, in the current fee-for-service schedule, there are those potential payment models which are not alternative payment models. They are part of the fee schedule that allow for people to look at patient engagement outside the face-to-face office visit and to also do the kinds of things that can lead to controlling hospitalization costs and ER visits.

So, again, it's not as much just looking at like

a landscape of payment models. It's actually thinking critically about, in the current fee-for-service schedule, or even with maybe tweaks to the current fee-for-service schedule, could you accomplish the same goals as set out by the proposer of what's in the payment model, and that's what the PRT came to a decision around.

You're looking at me quizzically, like --

MR. STEINWALD: I always look at you that way.

[Laughter.]

DR. PATEL: Generally everybody looks at me that way, but, you know, I don't take it personally. But I might add, I'm hoping I'm just trying -- what we went through was trying to understand what was in this model that could not be done potentially in the current fee-for-service schedule.

MR. STEINWALD: No, thank you. I wasn't getting that as completely as you just explained.

CHAIR BAILET: Yeah. Thanks. So my question sort of follows on Len and Bruce's, relative to the payment methodology. I'm curious, as you've interacted with the proposer about the link between the payment methodology, which is not only a PMPM but also their shared savings, and the question around how does that impact behavior, because that is one of the transformative elements of these models

that we're trying to evaluate.

I think there's some pieces of the bottle that are extremely elegant, recognizing the behavioral overtone of the disease and their assessment of the patient, and then they are deploying certain resources based on the behavioral issues, not just with this disease but clearly that's a big issue with comorbidities, and particularly in the Medicare population.

So I'm curious, were you able to discern the level of behavior change that this model distributed across these different practices that they saw, besides the patient outcomes -- ER utilization, hospitalizations -- but what about the actual clinical delivery? How was that changed based on the payment model, shared savings? Did that get people's attention to modify their practice styles, I guess is what I'm trying to say?

DR. CASALE: You know, I think part of the struggle is, again, the experience has been primarily in the commercial population and translating that to the Medicare or imagining how that might work, and although there were some in there I don't think there were a huge number. And so managing patients who might potentially have quite a few comorbidities, again, trying to think through the model in that patient group was a little

challenging, given that most of the experience was in the commercial population.

I think that in terms of behavioral, you know, again, I think physicians want to take better care of patients, and so it does decrease -- I think the effective part is having a care manager there and being proactive with this commercial patient population, younger population, does work. I mean, it does keep them out of the ER and keep them out of the hospital. So I think even if you don't get to the financial part, you get to have -- does this take better care of patients in the younger inflammatory bowel disease group? I think their pilots have been effective for those who are interactive, the pingers, the ones who respond. But, you know, the data also shows those who -- that don't respond, you know, the results haven't been as good, and so how do we translate that or understand how that might work in a Medicare population where we don't have as much -- where the model doesn't have as much experience?

So I think, does it change behavior? I think, again, you can see better care in that younger population in terms of managing them, being proactive. I think that's all good. And then there is the potential on the shared savings, although how exactly that's all distributed I

think wasn't as clear, in terms of who was going to get exactly what in terms of the money.

DR. PATEL: And just to add, and we have this in our report but there's so many moving parts, Paul mentioned the interest. Twenty large GI practices that have implemented the platform, very limited in the numbers. Again, it's a commercial population of which there was a very small handful of people over the age of 65 that were part of it, so kind of limited in understanding what the scale could be for the Medicare population.

But we do know, from their commercial experience that there was an average -- that there would be a savings of approximately $1,000 per patient per year, of which that would get shared, potentially, and the question is, again, if it's a smaller population, when thinking about the Medicare population that have this incidence and prevalence, and the savings of approximately $1,000, which, no matter how you do the shared savings, you could almost -- you could ask the question, is that going to have enough financial impact to get to what you're asking around behavior change.

In the proposal itself, there is not enough of a runway of experience to say -- there was not a mention of here is the definitive practice changes we have seen. We

did receive 28 letters of support -- Dr. Kosinski probably knows this. We read through many letters of support that talk about the excitement around this, and what we were trying to do is understand what would that -- going back to our criteria, how does that translate to scale and scope, and would that $1,000 of savings per year be enough to change practice behavior as well, which is why we ultimately decided that it did not meet that criteria on that value over volume comment and secretary criterion.

CHAIR BAILET: Thank you. Tim.

DR. FERRIS: Thanks to the PRT for all the work on this, helping us understand this.

I hoped you might elaborate on one point that was made, which was that the PRT was concerned that the individual providers do not receive shared savings, based on patient satisfaction and care outcomes measures. And I just wondered, since that was a little cryptic, if you could explain a little bit more about what you were thinking.

DR. PATEL: So right now the shared savings, the kind of -- in the proposal there was no comment about linking of the kind of potential in shared savings, or even the monthly payments. None of that was linked in any way to the proposed quality metrics or to any outcomes

measures. So the question and the concern there was would there be any financial ties to any of the metrics such that those finances were held at risk if certain thresholds of metrics were not met, and in the current proposal there was no linkage of those finances with those outcomes.

DR. FERRIS: So just to clarify, the concern that was raised was not about a concern about a specific proposed linkage. It was a concern that there was no linkage.

DR. PATEL: No linkage. Correct.

DR. FERRIS: Okay. Thank you.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you. One of our key criteria is scalability and I think that includes adoption by multi-payer, CMS and other commercial payers. And I'm wondering -- I'm curious about not only the interoperability of the technology, which you shared concerns about, but the interoperability of the model, as it were.

So if this -- could this be integrated with other care management models across populations, if it were to be expanded, or did you explore that?

DR. CASALE: I don't think we explored that. I mean, I think it potentially would have the ability to have

some interoperability across. Again, I think a lot of our -- well, not a lot but a certain amount of our discussion was particularly around the Medicare population, which is what this was being -- which we were focused on, and as I said before, I think their experience in the commercial has been positive and very favorable.

So in terms of multi-payer, I actually feel more comfortable in how this might work in the commercial population -- where I feel like the PRT had our most concerns was the lack of sort of data around how this works in the Medicare population and if it can work in that population.

VICE CHAIR MITCHELL: I'll just add for reference, on page 9 of their original proposal, the submitters did a nice job of laying out kind of what a commercial payer would supply, and kind of what the practice has to do. So to that end, we did talk about how, because of their commercial experience, they thought through very clearly kind of what structural components need to occur to have another payer, multi-payer kind of approaches.

But to your question about what, from a care -- how could this interdigitate potentially with other care management programs, we did not discuss that.

CHAIR BAILET: Okay. Bob.

DR. BERENSON: Yeah. I just want to make sure I understand the shared savings, shared risk model. Is it a total cost of care approach for patients with Crohn's disease, that there's a -- sort of a norm for spending, and if they come in, regardless of what the spending is attributed to, whether it's the Crohn's disease or any number of other conditions, they would get savings if it came in under that norm, et cetera, and it's not a targeted savings to Crohn's disease; it's total cost of care? Do I read that correctly?

DR. CASALE: Yeah. We asked the submitters specifically that because in our initial read we were -- it was not clear to us, and the submitters said that it's for total cost of care, and not just for the costs around inflammatory bowel disease.

CHAIR BAILET: Tim.

DR. FERRIS: So with regard to Criterion 8, Patient Choice, the PRT noted that there wasn't a lot of evidence around the effectiveness of the choices that would be made available, and I wondered if you had a discussion on the PRT about where we, as evaluators, should set the bar on that particular issue. Because one could make the argument, I think, that you can make choices available to

the patients, whether or not they avail themselves of those choices is -- in any population -- is going to be variable. But isn't it the job of the people making the proposal and implementing just to make the choices available? Do they have to go the extra step and say that patients actually have to make use of those choices, which gets back to my -- you know, is that a -- that's a pretty high bar for -- as a requirement.

DR. CASALE: I think that's a good question, Tim, and I think we talked about it. You know, when you look at the more expanded description of choice, you know, it talks about, you know, potentially how demographics of the patient population and social determinants of care are addressed, and that's a pretty high bar, right, as opposed to, you know -- because they obviously give you a menu in here of options on how to interact, and if -- so I think we struggled with, you know, where to set that bar and I -- you know, again, we sort of set it at we felt that -- recognized that they are providing some choice but that we would have liked to have seen data, particularly around the Medicare population, as to what they were choosing and, you know, how that -- and just not sure that it's there, only because of the small number of patients.

So it would have been helpful to have some

experience to make some judgment about that. But to your sort of broader question, I think we will struggle with that as we, you know, look at these PRTs.

CHAIR BAILET: So next steps. We're going to invite the submitter to the table. Please.

As you get situated, if you could please introduce yourselves, that would be helpful. Thank you.

DR. KOSINSKI: I'll begin. I'm Larry Kosinski. I'm a gastroenterologist in Chicago, one of the managing partners of Illinois Gastroenterology Group, which is one of the co-presenters. And I also started SonarMD as an offshoot of this project, and I sit on the governing board of the American Gastroenterological Association and I chaired both the Crohn's and ulcerative colitis care pathway task forces that were published in *Gastroenterology* in 2014. So anything you need to know about those pathways, I will be happy to share. And I also sit on the governing board of one of the advocate hospitals in Chicago.

Bridget?

MS. GIBBONS: Good afternoon, everyone. My name is Bridget Gibbons and I serve as the Chief Operating Officer for SonarMD.

CHAIR BAILET: Thank you for being here. Please.

DR. KOSINSKI: Okay. Good afternoon, members of the PTAC. And first of all I'd like to thank you all for the opportunity for allowing us to address the comments and conclusions of the PRT. It's obvious from the report that the team did spend quite a bit of time reviewing our proposal -- we do appreciate that -- but seem to have been in need of further information that we either didn't provide or could have provided more clearly. As a result, they were not able to give us a favorable determination.

We welcome this opportunity to provide some further information on Project Sonar, which will hopefully allow the full committee to appreciate the value of our proposition. It is our hope that the full PTAC will approve Project Sonar for at least a limited scale testing of the proposed payment model. A full response to all the concerns of the PRT was sent to the PTAC members last week. I will only hit some of the key points here in my short 10-minute discussion.

Project Sonar has been a passion of mine for five years, and I always open my presentations on Sonar with a picture of the ocean, with myself standing in front, looking out at the ocean. My chronic disease patients are submarines. They're submerged. They're out there. They're running silent and running deep. They only come up

if they're in trouble, which means two things have to happen. First, they have to recognize they're in trouble, and secondly, they have to realize that they can't fix it themselves.

Unfortunately, they make mistakes in both of those. Ultimately, we have to bring them into port. We have to put them in the hospital, but it's not just a hospitalization. It's a bowel obstruction. It's an ileostomy. It's a fistula. It's an abscess. It's something bad happening to a patient. If you just ask them how they're doing, they'll tell you they feel fine. They always feel fine, but it's only with the return of structured data on a regular basis where we can actually impact some change.

In the research that led to our project, Blue Cross Blue Shield Illinois provided us data on 21,000 commercial patients with Crohn's, and the most startling feature of that entire review was that less than a third of the patients who went into a hospital for one of these horrible complications had any contact with their provider in the 30 days before their hospital admission. We interviewed those patients, and what we heard back from them was overwhelmingly that they were going over the cliff without realizing it.

On the basis of this, we decided that we needed a patient hovering system, a sonar system, a way that we could ping the patients in between their face-to-face visits so that we could bring back structured data to the health care team, to the professional team, not just an app that a patient can record their symptoms on but something that interacts with the caregivers. This led to Project Sonar, which, in 2014, became the first intensive medical home that Blue Cross Blue Shield Illinois had ever entered into with a specialty group, and even though they have discontinued their primary care intensive medical home project, they've continued the specialty one.

We have been in operation for two years, and the 50 doctors in the Illinois Gastroenterology Group have had a very significant impact on the patients. Most recently, the pingers are showing a $6,000 per year decrease in costs as compared to non-pingers, in a disease process that costs $24,000 a year. So on the basis of the success we had in IGG, Blue Cross Blue Shield of Illinois has engaged us to implement Project Sonar across the gastroenterology practices in Illinois, and we've begun this process. Bridget has implemented five so far this year.

Our success has also resulted in other non-Illinois Blues plans coming into participation, both in

Minnesota and in New Jersey. But in states where no intensive medical home program exists, there are an additional 20 GI practices that involve over 600 physicians that are using the Sonar platform. These practices are participating even though they are not yet receiving any IMH funds. There is a hunger amongst the physicians out there to be part of the value-based transition.

As far as the specific issues that the PRT raised with us, to me they fall into three main categories: number one, limited scope of our project, we heard that clearly; number two, lack of adequate quality measures that drive changes in reimbursement, and I think we can clarify that; and a lack of need of change in payment methodology.

As far as limited scope is concerned, we agree with the PRT that Crohn's disease only represents a small fraction of the current Medicare fee-for-service population. But these are high-cost, high-risk, high-variability patients, and their costs are two and a half times their percentage of the population.

Ulcerative colitis, very similar to Crohn's disease in its cost, its morbidity and mortality, and this is a growing population. Even in the data that accompanied the PRT review, there was an 8 percent increase in incidence from 2012 to 2015, and most studies today show

that by 2025 there will be 2.2 million Americans with Crohn's or ulcerative colitis in the United States. And that should correlate to about 2 percent of Medicare's fee-for-service budget.

So although our original study group only was limited to IBD, we are confident, though, that the patient characteristics that have been the driving force behind our new care model are not specific to IBD, but are typical of most patients who deal with chronic disease on a regular basis.

Accordingly, we have moved beyond IBD and now are engaged in multiple non-IBD projects, the first of which is cirrhosis complicated by hepatic encephalopathy. Thirty-seven percent of the patients discharged with a diagnosis of cirrhosis have a readmission within 30 days, and 46,000 patients in the four categories of the CMS core measures have a comorbidity of cirrhosis. So we have initiated a study using the Sonar platform for patients with cirrhosis, focusing on the immediate 30-day post-hospitalization period where the patients will be pinged on a daily basis, either they or their designated surrogate, because they may be encephalopathic.

Although our practices to date have been GI based, there is no reason why this same platform cannot be

implemented in any practice type, specialist or primary care. Under the request of BlueCross/BlueShield Illinois, we have initiated investigation of a project in Type 2 diabetes, focusing on periods of high hemoglobin A1C levels, which are associated with high intensity of services. This project will be deployed in primary care groups in our service area.

The PRT is correct that the experience of Project Sonar has been in a specialty-based intensive medical home. We did not mean to exclude primary care doctors, but conditions like IBD are predominantly managed by specialists. We welcome the use of Project Sonar in primary care practices and equally welcome the integration of the platform across the primary-specialist interface. SonarMD platform is a Web-based platform that can be used concurrently by multiple providers at the same time. We believe that the deployment of the Sonar platform across all practices will allow more of the care to be pushed to the highest level -- I mean the lowest level licensed provider capable of providing that service and build efficiencies into the system. We therefore believe that the scope is not limited and actually can be applied in multiple disease processes and across most practice settings.

Number two is lack of adequate quality measures that drive reimbursement. Most metrics available today are process measures that are not directly associated with clinical outcomes. Since BlueCross BlueShield provides us with quarterly, now monthly claims data on our patients, we've used this data to scientifically identify quantifiable metrics that are clearly associated with favorable outcomes. The albumin example that we included in our PTAC proposal was just one example of this endeavor. Early in our development, we performed linear regressions on 26 risk metrics that were contained in the Crohn's disease care pathway, so we linearly regressed the cost of care against each of those metrics.

Serum albumin was the most powerful variable in the variation of cost. As a result, we monitor albumin quarterly. It’s a simple lab test, but it has a significant difference. And we're proud to say that in our control population, the albumin slope is downward; whereas, in our Sonar population, it’s rising.

So today, though, our most powerful metric is our average Sonar score. Even though we force our physicians to complete complex clinical decision support tools and maintain these metrics, the single most powerful driver is can you get that symptom score down, which means you've

engaged the patients, you've applied the right therapy, and that is a single metric we've plotted, and we included this graph as a supplement in our proposal showing that over a two-year period, they linearly parallel each other.

Other metrics that we have included, in addition to hospitalization rate and emergency room visits: appropriate use of biologic medications. Those fields don't exist in EMRs. We had to create these in the clinical decision support tool. Are they on time with their immunizations? Are they appropriately using steroids? The serum albumin I mentioned, the ping response rate, patient satisfaction surveys by outside entities, risk-adjusted average Sonar scores, and now we have implemented quarterly HADs and CDC Healthy Day scores because there is a 13 percent difference in cost in patients who are depressed at enrollment into the program, and that doesn't change so far. We have to figure out how to do that.

The IMH payment received from the payer is not distributed to the physicians but is maintained in a pool. The costs of the program are first paid for from the pool, which basically is the nurse care manager fees and the Sonar platform. And then the remainder is distributed to the physicians based upon the number of patients they're

following, the average Sonar score of their patients compared to everybody else, and their patient satisfaction. No physician is eligible for a distribution of Project Sonar funds unless the CDS tool fields have been complete.

The final area was lack of change in payment methodology. We are in agreement with the PRT's assessment here. Unfortunately, the current language of the complex care management codes do not allow us to participate. Number one, it is based upon minutes per month. This process does not clearly correlate with patient outcome and just imposes an unwieldy verification process on the practice. It doesn't reward practices for efficiencies that minimize staff time requirements. It requires two or more conditions, and I'm sorry, I'm not managing that patient's hypertension. That's the primary care doctor's responsibility. I would take it, but it's not usually one that we bear. And, finally, only one practitioner can bill for a CCM code per month per diagnosis. There's no ability for us to share CCM fees across providers, which would be indicated. The Sonar platform's agnostic to the provider and can, therefore, be deployed in multi-condition, multi-provider settings.

So, in conclusion, Sonar has been a passionate pursuit of mine for five years, but it could not have

succeeded by my efforts alone. My 50 partners in IGG have embraced the initiative and gone the full mile in its implementation. They implemented Sonar long before they received any care management reimbursement from BlueCross/BlueShield. And thank God we found a payer who actually thought in a forward fashion to partner with us. Like in a "Field of Dreams," though, we felt if we built it, they would come.

Even now, most of the care management fee goes to cover the infrastructure necessary for Project Sonar. Very little passes to the physicians. They persist based upon a true hunger amongst physicians to be part of the solution and not to be considered part of the problem.

Sonar has moved beyond IGG and has been deployed on hundreds of patients across the country, which has led to a decrease in morbidity and cost, not just hospitalizations -- decreased morbidity. I was humbled by my patients' testimonials that were submitted and posted on the PTAC's public comment site. Sonar has changed patients' lives. With an approval from the PTAC and HHS, we can expand our success to other chronic diseases and across other care settings.

Thank you.

CHAIR BAILET: Thank you both. We appreciate

your comments. Thank you.

We have questions now from members of the Committee. Harold?

MR. MILLER: You beat me to it.

CHAIR BAILET: I beat you to it, Harold.

MR. MILLER: I have four questions.

The first question is: With respect to the care management process, there has been a lot of focus on the pinging. But when I read the proposal, I think there's a statement in there, at least one place, that basically says that the nurse care manager is critical to this. And at least as I sort of read what you have in here, basically you have a nurse care manager who is assessing and contacting the patients and helping the physician decide what to do with them. And the pinging technology, sort of the smartphone technology, is a way of helping that be done more efficiently than it could be done otherwise with just home visits or telephone calls.

Is that an accurate interpretation of what you're doing? And in a sense, if you had to choose one, you would keep the nurse, if you had to give up the smartphone app, as opposed to saying we have a smartphone app and no nurse?

DR. KOSINSKI: Harold, you've depicted it pretty well. But when we first initiated Project Sonar, we were

using our patient portal because we did not have a platform, and we could never get more than a 27 percent response rate from the patients, and so the nurses did a lot of calls. And once we embraced the platform, for some reasons the patients -- and 20 percent of our patients are Medicare patients. Once we deployed the platform, we have over an 80 percent sustained patient response rate.

And so what the platform does -- how does it change care? This was just the beginning of the month. I get my Sonar pings on all my patients coming in through an HL7 interface into our EMR, and we can push it into any EMR. And so every month at the beginning of the month, every one of my patients' pings comes in front of my eyes. The nurse is managing it at the same time, but I see them.

And so any of you who are physicians know as well as I do, when you're done with the patient, your total focus goes on to the next patient you're taking care of. But through this kind of a platform -- and there's nothing really special about the platform. This could be replicated very easily by other companies, and probably will, but it brings the patient back in front.

And so I think you've depicted it well, but I think we're learning something --

MR. MILLER: So you've found that it has made it

feasible for you to do it in a way that wasn't feasible with just using a nurse and traditional technologies.

DR. KOSINSKI: Right.

MR. MILLER: But the nurse and the contact with the patient -- there is personal contact with the patient -- is critical.

DR. KOSINSKI: Right.

MR. MILLER: The second question is, if you have an IBD patient who has COPD or asthma or heart failure or hypertension or whatever, what do you do? Does that come up in the assessment that the nurse does of the patient, whenever you're talking to the patient? And then do you actually then do any coordination or outreach to whichever physician -- it may not be a primary care physician -- who is managing that other condition?

DR. KOSINSKI: If it's something where the other comorbidity directly interacts with the condition I'm taking care of. For instance, in our liver patients, if their fluid balance requires changes in their heart failure management, we have to coordinate with the primary care doctor all the time. That's a must.

In inflammatory bowel disease, infections -- we're immunosuppressing these patients. So I don't mean any offense, but I don't want my patients calling their

primary care doctor when they spike a fever. I need to know. If I have them on a biologic, I need to know if they have a fever. But the primary care doctor also needs to know. And we can push the Sonar scores to the primary care physician, and now the patients have the ability to add notes to it for the provider, which could be passed at the same time to us and at the same to the primary care.

MR. MILLER: Okay. The third question was there's references in the methodology to setting a target price, but there really isn't a very detailed description of how the target price gets set. Is your expectation that that is based on past average spending for the patients, then discounted by an amount that's necessary to pay for the care management so that you're -- the fee that you're getting, so that it starts at a budget-neutral level for Medicare, whoever the payer is, and then you're at risk -- when you talk about being at risk for up to 5 percent, is it 5 percent above what would be necessary, the savings necessary to pay for the care management fee? Or would it be up to 5 percent above simply historical spending? How exactly would you calculate the target price?

DR. KOSINSKI: This has been a moving target for us in this process, and at the time we submitted our initial PTAC proposal, we had never received control group

data from BlueCross, from HCSC. In January, we received that, and I did send that along with one of the responses to questions.

So, scientifically, where we're going with this is this way: We know what the cost of care is for a patient who is participating in our process in the diseases we are taking care of based upon historical information. We also know how our risk assessments can be used to better hone what that base price is and then an add-on based upon the risk assessments that are included.

The major variable, though, is we know what the platform can do to that cost of care. I mentioned that $6,000 difference. So where I envision us going with this would be that section of money there that's developed and the difference between pingers and non-pingers, it could be an at-risk spend, and it would be up to the practice to be able to take risk in there and know that they could provide that care for the acceptable amount.

Blue Cross to date has not wanted -- I don't think they want us to fail, and so it has been predominantly a one-direction risk model, but we don't get a pot of shared savings. What they do is they read just our PMPM based upon our performance. We perform poorly, that PMPM is going to go down or go away. And if we do

well, they've increased it on us a couple of times.

So I think we need to use science in how we calculate where this risk pool takes us.

MR. MILLER: Fourth and final question. It sounds to me like you are tracking a lot of things about these patients, and where are you tracking those things? Is that in an electronic health record?

DR. KOSINSKI: It's in the Sonar platform. All of the risk assessments, all the costs, the CDS tool measures are fed into the Sonar platform. We live in an era today where EMR vendors are proprietary, and asking them to change something is very, very difficult. There are a lot of companies that can catch the data and give it to CMS or give it off. But who's pitching it? We don't have enough pitchers out there. And you can't tell the major entities, "I need a field that tells me why you changed a biologic on this patient." So we've built that into the Sonar platform.

MR. MILLER: But you said, for example, serum albumin is one of the things that you found is critical. Can you ordinarily track that in the EHR?

DR. KOSINSKI: Yes.

MR. MILLER: Okay. So --

DR. KOSINSKI: If it's electronically sent.

MR. MILLER: Sure. But I'm just saying if that's a critical thing to track on the patient, you do it in an EHR and it could be done in an EHR.

DR. KOSINSKI: Right, yes.

MR. MILLER: Okay. Thank you.

CHAIR BAILET: Grace.

DR. TERRELL: Thank you, Doctor. Harold asked one of the questions, so I've just got two more.

There's a lot of information about the difference between your pingers and non-pingers. One of the questions I have for you is how much you've actually dug into those two, not just as a control group and a group that's using the tool, but as something where folks either will bounce back and forth or somebody will not be an adherent in the pinger group, whether there's social determinants of health, because it seems to me there might actually be a spectrum of behaviors. And as you're having to present data and get paid based upon a sort of, you know, yes-no, what are you doing about the fact that actual patients tend to sort of be yes-no-maybe, sometimes sort of possibly on Thursdays? You know.

DR. KOSINSKI: This has been the toughest question I've been faced with today so far, and it's the one we wrestle with the most. The 13 percent difference in

cost -- we started doing depression analysis early with a PHQ tool, a very simple -- and I'm not going to claim anything for that. BlueCross asked us to do that.

DR. TERRELL: Yes, PHQ.

DR. KOSINSKI: But at the end of the first year, we then filtered back and looked at how the patients did financially if they answered positively on their depression screen, and there was 13 percent delta that remained 13 percent even after our first year. So after our first year, we said we need to address this, we need to build. So that's where the HADs and CDC Healthy Days has come in, and we're currently working with social workers to see can we impact this better.

It's interesting. We send out five questions every month, and the middle one is a health-reported quality-of-life question, basically, a "How are you doing?" question, and they have to answer in four different categories. The patients who are depressed at enrollment always answer that one negatively, "I feel terrible," even if their symptoms are fine. I'm not as much worried about them because they're calling us and seeking care. The bulk of the patients, even when their symptoms are deteriorating, their health-reported quality of life remains favorable. They're going over the cliff.

So you've touched on where I think we need to continue our focus, because somewhere along the line we have to figure out how to get everybody participating.

DR. TERRELL: Yep. I would worry about a payment system, maybe -- I mean, this would be something we would have to solve -- where it rewards doctors for having the good patients.

DR. KOSINSKI: Yeah.

DR. TERRELL: And, you know, you wouldn't want a situation where somebody's not participating and there's less reimbursement or whatever that it could have consequences if we're not figuring out some of the patient reasons that might be the case.

My second question is you made the comment that there were folks doing this that aren't getting paid right now, and you all did this without getting paid right now. And I agree with you that there is a hunger in the medical community to find solutions above and beyond the sort of traditional fee-for-service system so that we can practice the medicine that we want to practice.

I would be curious to understand a little bit about those doctors out there now that are using this platform without any reimbursement for it. You know, not everybody is an altruist and not everybody can afford to do

that, so what percentage are doing it? And what does that imply about the sort of costs of care that aren't being paid for in the current system? And, you know, why are people actually doing this?

DR. KOSINSKI: Well, I think that's why so many of these practices are large. They have infrastructures. They have nurses. There are so many practices out there that don't even employ a nurse. They employ MAs, and I don't mean any disrespect, but I have a slide I show that says "MA does not equal RN."

And so that's why the larger practices have been the ones that have migrated to us. They have the infrastructure. They have the extra internal funds, and they have more forward-thinking leadership.

In Sonar, we did it for over a year without any reimbursement. I've got a practice -- I have got one practice out in Washington State. The doctor has got over 100 Crohn's patients on. They've never received one penny, but they want to change it.

DR. TERRELL: So it's been all large practices that have been able to absorb the cost there?

DR. KOSINSKI: Well, we do have -- we have our first solo practitioner that has now wanted to be on the system. So we have both ends of the spectrum now, but it

is much more skewed to the large practices, yes.

CHAIR BAILET: Len.

DR. NICHOLS: So thanks for coming. Your passion is obvious, and it's contagious. That's a good thing. It makes me remember why I agreed to be on this damn committee.

But, anyway, let me just say two questions. In the appendix, which believe it or not I did read, it's hard to -- so there's a discussion of the Project Sonar math and talked about how you don't have statistical significance, and you need a bigger sample.

If you could -- and I apologize if I missed this part -- how many Medicare patients does your network have now, and how many Medicare patients would you need to get that sample where you want it to be? We're talking about small-scale practices.

DR. KOSINSKI: Yeah. We're small here. We're small here. We're probably only in the -- we probably only have about 150 Medicare patients currently amongst the practices.

DR. NICHOLS: Okay.

DR. KOSINSKI: We have had significant interest from pharma to assist us in building our patient base. We have a goal of 5,000 patients.

DR. NICHOLS: Yeah. Okay.

DR. KOSINSKI: And the problem comes up when you're doing multiple regressions out of all these little numbers. You need more numbers. The selfish side of me says, "I want a bigger end so that we can prove more things."

DR. NICHOLS: Yeah. Okay. Appreciate that.

And so the second question has to do with this proprietary question.

DR. KOSINSKI: Oh. I'm glad you --

DR. NICHOLS: So you heard our exchanges before. Let me state what I think is the fear, and then, I mean, I'll just speak for myself. And I won't speak for CMS because I can't. Right? But I'll just speak for myself.

I think the fear is that if the -- I'll just say the analytic details are not revealed, and this thing works, and it takes off, and CMS decides to require it. Then, you sort of have a monopoly on what people have to buy.

DR. KOSINSKI: Mm-hmm.

DR. NICHOLS: Okay. So, really, the question is, how much information can you share and still maintain your patent and all that? And second, how would you respond? Because in an economist's mind, there's always a price at

which we can make this reasonable. Where does your price sit now in all of this?

DR. KOSINSKI: Okay. Well, I'm very happy you brought that up.

I've had a very altruistic approach at this, much to the chagrin of my business partners.

[Laughter.]

DR. KOSINSKI: And I have a big mouth and have told everybody everything.

But I'm also passionate that -- you know, I'm ending my term at the AGA governing board, and I've wanted to leave something. And if we look at the process whereby guidelines, measures, e-metrics are integrated into medical practice, they're thrown out there. We published these care pathways; we throw them out there. We don't know whether they actually made a difference.

So where my big vision of Sonar -- and it's totally not proprietary -- would be that Sonar assists in bringing the data back from these initiatives and feeds it back to organizations where the people who write the guidelines can rewrite them and recraft them, someone can replicate our platform pretty easily.

DR. NICHOLS: That's what I thought.

DR. KOSINSKI: And I think we can't by ourselves

create new guidelines. We can assist and become part of it.

So I'm not belittling the proprietary nature, but I do have a benevolent side of this where I see it solving a bigger purpose.

I don't know if I answered your question.

DR. FERRIS: I'm not -- unexpectedly, Len just asked my question, so I'm going to pass, and go to the next one.

CHAIR BAILET: Oh, okay. Bob.

DR. BERENSON: So I'm going to ask three questions. Well, the first two, I asked before, and you can sort of educate me a little bit. So how do we know these patients have Crohn's disease or inflammatory bowel disease?

DR. KOSINSKI: Again, another tough question.

We have a series of metrics, and in IBD, you have clinical, endoscopic, pathological, serological, combinations of data that provide someone a diagnosis of Crohn's or ulcerative colitis.

If you have tissue, no question, you can make your diagnosis, but there are not so much -- I'm going to twist your question just one little bit. It's not so much whether the diagnosis was correct, but is the risk level

assessed appropriately and should that patient be on a biologic that you're making money in your office or your HOPD for. And so I think we need to use science everywhere we possibly can, and although medicine is an art and a science, we need to push it as much to science as we can.

DR. BERENSON: So, but basically the trigger is a clinical -- I mean is an ICD code.

DR. KOSINSKI: Yes. In fact, our patients that were attributed to us by Blue Cross were our patients that had seen us for at least a year and had a diagnosis based upon ICD. It was 9 at first and now ICD-10 codes, and that's how Blue Cross attributed. And they eliminated anybody who was in another shared savings program of any kind, and so the only ones that have been attributed to us are our own patients that we have been consistent with that have been part of Blue Cross and that have those ICDs.

DR. BERENSON: Okay. The second one does go to what sounds like a total cost-of-care calculation. So I just looked at the table that staff prepared that's on the website, and patients with Crohn's disease, 16 percent have chronic heart failure; 28 percent have chronic renal disease; 19 percent have COPD; 26 percent, diabetes; 30 percent, ischemic heart disease. They claim that 40 percent have rheumatoid disease. I assume that's

arthritis.

DR. KOSINSKI: Arthritis from the IBD.

DR. BERENSON: Yeah. Well, okay.

But my question then would be, isn't the spending for Crohn's disease relatively trivial for in the Medicare population with those kinds of comorbidities, and isn't it sort of random whether you save money or don't save money?

DR. KOSINSKI: You know, you have me at a little disadvantage here because I only have access to the commercial data that I've been provided through my payer.

I can tell you in our commercial group, in our age -- our average age is in like 45, so we do have older patients with comorbidities. We initially were trying to only track our Crohn's-related costs, so I went through this elaborate assessment of any ICD that could possibly be related to inflammatory bowel disease, even to the point of uveitis and certain skin diseases. And we tracked about two-thirds of the costs were Crohn's-related, and this has persisted to a point where it's remained fairly stable. So now we don't go through that exercise. We take the total cost of care, and that's what we've been measuring. But in our population, it's about two-thirds of the cost.

DR. BERENSON: In your total population?

DR. KOSINSKI: Total population.

DR. BERENSON: And so then this is -- the last question goes to sort of my experience, which is somewhat dated right now, would be that Crohn's has a tendency to burn out in older age. Is this largely a disease of, I mean, the kinds of acute problems that lead to surgery and develop fistulas and all of those complications? Does it happen in 80-year-olds?

DR. KOSINSKI: I have used the same words with my patients to make them feel better that it burns out as they get older, but what actually happens in inflammatory bowel disease, the inflammatory years are the younger years. The fibrotic years are the older years, and the disease doesn't go away or actually burn out. It converts into a chronic fibrotic state. So you get obstructions, ischemia. You get ischemic issues. You get different things in the older population than you do in the younger.

But you are totally correct. The aggressive inflammatory phase is younger.

DR. BERENSON: So I guess the follow-up to that is, can you actually then head off those fibrotic changes through pinging and that kind of thing? In other words, are those more inevitable rather than in early intervention to prevent?

DR. KOSINSKI: The goal in IBD is very similar to

rheumatoid arthritis in that as controlling the inflammatory state, you will avoid the long-term fibrotic state, and the answer is yes. If we can treat these patients earlier --

DR. BERENSON: No, but that's my point, then. If that's the younger population, what can you do with a 75-year-old who has already been through the inflammatory stage? What does the intervention accomplish? is my question.

DR. KOSINSKI: We're in the nascent phase of anti-fibrotic medications these days, but it's tougher. You're correct.

CHAIR BAILET: Elizabeth.

VICE CHAIR MITCHELL: Thank you.

I'm curious about the payment model. You said that this is being done on fee-for-service or not at all, that people are just doing it. What would the optimal payment model be from your view, and are the barriers operational, or could you do something different or better, in your view, if it were perspective or some other payment methodology?

DR. KOSINSKI: A couple things. My first goal in the payment methodology is to move physicians away from one patient at a time making widgets to a focus on taking care

of an entire population of patients and being rewarded for an outcome. Right now, we're not.

So to move physicians to that state takes some money. It takes some investment. It takes some leadership, practice redesign, and so there has to be an investment, and that to me, the investment is the PMPM payment.

We can call it a CCM payment, fixed to CCM payments, and they're the same as our S codes that we're using with Blue Cross now.

But there can't be an open end on this. You can't say, "Well, you're going to get X number of dollars, PMPM." No, there has to be a measurement. What was the ROI for that?

I know with Blue Cross right now, they're touting a very high ROI when they look at the $600 that they spend extra per year and the $6,000 savings they're getting on that population. So, to me, the appropriate thing is an investment in a payment model followed by a risk-based adjustment going forward in that payment, so that it perpetuates itself and perpetuates the physicians to do what we want them to do.

CHAIR BAILET: Kavita.

DR. PATEL: Thank you.

I just wanted to comment how great it was to receive the proposal and understand your passion behind it, but I had a question, because your comment about the albumin, the serum albumin, just raised something.

Since it's such a significant kind of metric for you, as you mentioned, is there any conversation or has it been part of maybe potential conversations with your commercial payers about having that downside financial adjustment, if that albumin is not reflected? So I'm asking, if they do not see that improvement, is there any penalty, so to speak?

DR. KOSINSKI: Well, we've done this internally. The payer, as I said earlier -- I don't think Blue Cross Illinois wants us to fail, and our numbers are just not high enough for them to be hitting us with too much downside risk yet, but we're doing it internally.

DR. PATEL: In general, there is no downside risk at all right now based on --

DR. KOSINSKI: Well, your payment, your monthly payment would go down.

DR. PATEL: Would adjust, but it's based on that total cost biologic use.

DR. KOSINSKI: Right.

DR. PATEL: Just again, nothing else is factored

into that.

DR. KOSINSKI: Blue Cross' major concern is financial.

DR. PATEL: Okay.

CHAIR BAILET: Grace.

DR. TERRELL: We've been talking commercial, and we've been talking Medicare, but there's a lot of younger people who don't have commercial insurance. They have something called Medicaid. I hear there's a lot of that in Illinois.

DR. KOSINSKI: Mm-hmm.

DR. TERRELL: Do you have any data on the non-Blue Cross population? Surely, you're serving that population as well, or have you been able to provide that service, even if it wasn't provided with payment back, or is there any data that would allow us to think about it a little more comprehensively than just Medicare versus commercial?

DR. KOSINSKI: I'm glad we talked about this. I had the word "Medicaid" in my presentation. I took it out.

Two out of every three babies born in Illinois are born into public aid. It's a reality, and in our practice, it doesn't matter what payer you're on as to whether you get Sonar.

I don't have data. I don't have total cost data on the Medicaid population. It's not been provided to us. I would love to have that, my hands on that data.

CHAIR BAILET: Tim.

DR. FERRIS: So I want to also echo the comments made about the work necessary to do all this work and to go for the next step in Medicare.

I think I'll just characterize the fact that you've had a fantastic demonstration in the commercial population. I think the questions here today and your answers in addition to the proposal and all the work that has been done suggest that there is some legitimate uncertainty in the Medicare population, and I wanted to ask if some sort of assistance were available to you for trying to answer some of these questions in the Medicare population, would you be open to that kind of assistance?

DR. KOSINSKI: I always say yes to people giving me things.

[Laughter.]

DR. KOSINSKI: I wrote an editorial in one of the GI journals a few months ago with a colleague about "high beta" illnesses. I would love to know in the Medicare database what are the "high beta" illnesses, and by high beta, I mean if you take a table and you look at

gastroenterology services and you have GERD, IBS, IBD, colorectal cancer in the rows, and in the columns, we have number of encounters, total cost, cost per encounter, but the coefficient of variation of cost per encounter, if you look at it in IBD, colorectal cancer screening has a 0.6 rating. IBD has a 3.6 rating. I would love to know the other 3.6 illnesses out there where we can deploy this kind of a platform. I would love to be able to get data that would allow us to put some gasoline on this.

CHAIR BAILET: Paul.

DR. CASALE: So I don't really have a question. I just wanted to make a comment, adding on that I thank you for bringing this forward. Your passion is evident, and I think all physicians practicing whatever specialty of primary care would like to see movement in the same way.

And I just thank you, in particular, given my role as the lead on the PRT and having been intimately involved. So I just wanted to make that comment.

DR. KOSINSKI: Thank you. Thank you.

CHAIR BAILET: Harold.

MR. MILLER: Last week, I did the thing that doctors fear that their patients will do, which is I went digging on the Internet, and I did a bit of a search, and I found a number of articles about, amazingly enough,

inflammatory bowel disease in the elderly.

Journal of Crohn's and Colitis, 2015. "Inflammatory bowel disease amongst the elderly is common, with growing incidence and prevalent rates. Approximately 10 to 15 percent of IBD in the USA is diagnosed after the age of 60. This incident rate is conservative."

American Journal of Gastroenterology. "Elderly IBD patients are prone to similar medical and surgical interventions as younger patients, generally can be expected that one surviving an initial severe attack, a less severe disease course, with fewer relapses and hospitalizations, occurs in elderly patients with ulcerative colitis but not Crohn's disease."

The Crohn's and Colitis Journal, Inflammatory Bowel Diseases, did a study that's titled "Inflammatory Bowel Disease in the Elderly is associated with worse outcomes." "Patients older than 65 years accounted for 25 percent of all IBD-related hospitalizations in 2004. Older patients with IBD-related hospitalizations had substantial morbidity and higher mortality than younger patients."

Is any of that inconsistent with your experience?

DR. KOSINSKI: No.

MR. MILLER: Okay. Thank you.

CHAIR BAILET: Thank you.

Seeing no other questions from Committee members, we are going to thank you, Dr. Kosinkski --

DR. KOSINSKI: All right. Thank you.

CHAIR BAILET: -- for all of your work.

DR. KOSINSKI: Thank you.

CHAIR BAILET: Appreciate your coming. Thank you.

Now I'd like to open up the public segment for public comment. If the operator could open up the phone lines, we have three individuals who have raised their hand to provide a comment.

Oh, actually, okay. So do we want to do the phone first?

MS. STAHLMAN: Two people are here. Why don't we wait on the phone.

CHAIR BAILET: Well, why don't we go with the folks -- yeah. Why don't we go with the folks here.

Sandy Marks from the AMA.

MS. MARKS: Thank you. So last week the AMA sent a letter to the PTAC noting our disappointment that the PRTs concluded that none of the four proposals should be recommended to the Secretary for implementation, and I just wanted to amplify that letter with a few examples where it seems to us that the reviewers did not correctly evaluate

the proposals against the criteria that were published in the regulations.

So under the definition of physician-focused payment models, Medicare must be a payer. No criteria say how much Medicare must be spending on the services that are included in the payment model. The reviewers criticized the SonarMD proposal by saying that Crohn's accounts for just 1.25 percent of Medicare spending, but no one has defined a threshold amount of Medicare spending that needs to be involved for a model to be considered. Medicare must just be a payer.

The reviewers also criticized the Sonar proposal because the proposal said that a similar approach could apply to other difficult-to-control conditions but limited the detailed proposal to management of IBD. The fact that a proposal has the potential to be used for other conditions should be seen as a strength. It is unreasonable to suggest that specialists who manage one condition should design an APM for other conditions in order for the PTAC to acknowledge that strength.

Moreover, it seems unlikely to us that the specialists who manage the other conditions would accept an APM developed by gastroenterologists for them, if it had not first been implemented for the gastroenterology

conditions.

We are also concerned about the reviewers' comments regarding the payment model, which they characterize as fee-for-service supplemented by a care management payment, and there has been a lot of discussion of that today, but I just think it's important to point out that the Sonar proposal involves the linkage of payment to quality, involves financial risk, and requires use of HIT, which are the criteria for MACRA payment models. The Medicare fee schedule does not adjust payments for services provided to patients with IBD, based on the quality of their care, which a new payment model would do, and it does not provide a share of savings to physicians who are able to lower the rate of emergency visits and hospitalizations for their patients.

The reviewers also were concerned that the model did not provide shared savings payments to individual providers based on their patient reported outcomes, but the criteria say that the payment methodology must address how APM entities are paid, not how the individual physicians are paid.

So we are concerned that the negative preliminary reviews will discourage the organizations who have been working hard to develop APM proposals, and we hope the full

committee will look at all of the proposals with fresh eyes.

Thank you.

CHAIR BAILET: Thank you, Sandy.

James Gajewski from the American Society of Blood and Marrow Transplantation.

DR. GAJEWSKI: You did pretty good with my name.

CHAIR BAILET: Did I do okay, because I was nervous.

DR. GAJEWSKI: It's Gayeski [phonetic].

CHAIR BAILET: Gayeski [phonetic].

DR. GAJEWSKI: It's Polish phonetics.

Thank you for allowing me to speak here, and I actually do want to also applaud this society for presenting this model.

As a blood and marrow transplant physician who also does hematology and some oncology, I have to deal with a patient population where I, as a subspecialist, am the primary care physician for six months to a year. You could describe our practice either as an inpatient or an outpatient hospitalist practice. But I applaud that.

My concern for all of our alternative payment models is access to care and that we preserve access to care without cherry picking of patients, and this is going

to be a problem as we do it, because the human body is not usually just one disease. We are multiple organ systems that interact with one another. So how we do the acuity adjustment, how we do these risk assessments are very important, and much of our coding data lacks even primary disease acuity, let alone truly this interactive effect, and how do we deal with comorbidities where we have high doses of steroids, like diabetes, and we have to look at outcomes with diabetes as well as outcomes with inflammatory bowel disease? These things are going to be a problem.

Even probably more problematic are all the things that we have never coded in the claims data: mental health conditions; family dynamics; impending divorce; poor financial assets such as difficult to get medications, difficult to get the doctors; families with small children, where you are stuck between taking care of your own health or a small child. We don't have that adequately coded, yet all these things are going to impact outcome. And the thing -- if we can't both document and get credit for that and do acuity adjustment, there will always be cherry picking of patients, and somehow we have got to avoid that, because that will do the greatest disservice to both the population in this country as well as to any individual

patients. We need to pay attention to the outlier clauses that we are going to need, because they are going to be absolutely vitally important for these things.

I also worry about the assessments of patient's personal feedback, because there are a lot of diseases with psychosocial overlays where there has to be tough love. I, as a cancer provider and hematologist, have to prescribe a lot of narcotics for chronic pain in my patients. My patients also become addicted. I have to set limits. Well, those patients I set limits for, they don't give really good patient satisfaction surveys. Those patients who I am up-front with about bad cancer outcomes also don't give good satisfaction surveys.

I think the issue of interrelationships of proprietary software is a problem. As many of you know, I do some work with the CPT Editorial Panel and the RUC Committee. When transitional care codes first passed and was approved by CMS, we were to bill 30 days after the discharge. One of the major vendors of an EHR, which was used at my institution, said, "This violates our billing software. Go change CMS. We are not changing our software." These are issues we are going to deal with.

I also think issues of tracking these labs -- I was impressed with the albumin and I wanted to actually ask

an internist about pre-albumin being a better measure.

[Laughs.]

DR. GAJEWSKI: But the issue, though, we have is a lot of commercial payers and Med Advantage plans have outsourced labs to companies that do not interface well or allow good tracking with the EHR that the cognitive longitudinal care providers are doing. These are problems that we have to look at and address.

Anyway, I thank you all for the comment and I thought it was a very good presentation.

CHAIR BAILET: Thank you.

We have Leslie Narramore on the phone, from the American Gastroenterological Association. Operator, is she present?

OPERATOR: If you could like to ask a question, please press star and then the number 1 on your telephone keypad.

Ms. Narramore's line is open.

MS. NARRAMORE: Hi. Can you hear me?

CHAIR BAILET: Yes. Yes, we can.

MS. NARRAMORE: Oh, excellent. Thank you so much.

So good afternoon. My name is Leslie Narramore and I am the Director of Reimbursement at the American Gastroenterological Association. I am speaking today on

behalf of the AGA to provide comments on the Project Sonar proposal submitted to the PTAC by the Illinois Gastroenterology Group and SonarMD, LLC.

So first I want to say that we agree wholeheartedly with Sandy's comments, on behalf of the AMA, and just to kind of reiterate some of the comments that you've already received from us, the AGA has long been a leader in the development of episodes of care and value-based care models, even before the passage of the MACRA legislation, and we appreciate the opportunity to provide feedback on physician-focused payment model proposals that offer new ways for CMS to pay physicians for the care they provide to Medicare beneficiaries.

Project Sonar is a model program for chronic disease management for inflammatory bowel disease patients, piloted with BlueCross BlueShield of Illinois, that has proven effective at both managing costs and enhancing quality. The model is based on the AGA's IBD clinical service line, which contains evidence-based care guidelines and other clinical decision support tools for IBD, to help engage both providers and patients to change behavior and improve outcomes.

We support the Project Sonar proposal as an option, and we welcome the development and acceptance of

other models for gastroenterologists. Thanks.

CHAIR BAILET: Thank you. We have no one else on the phone but I would like to open it up for anyone else who is here, that might want to comment, or anyone else on the phone who might want to comment. We'll start with the folks in the room.

[No response.]

CHAIR BAILET: Seeing none, are there any folks on the phone that may want to make an additional comment?

OPERATOR: Please press star and then the number 1 if you would like to ask a question.

[No response.]

OPERATOR: And there are no responses on this end.

CHAIR BAILET: Thank you. So we are now going to start our deliberations as a committee. Do any members have any comments before we start, or are we ready to begin our deliberations?

Len.

DR. NICHOLS: Remind me what deliberations mean. Are we about to vote, or are we going to talk?

CHAIR BAILET: Yeah, we're going to -- well, we're going to go through -- we're going to go through each of the criteria --

DR. NICHOLS: Okay.

CHAIR BAILET: -- and formulate our own positions on that, and you guys, we -- you know, this is a dialog. We can talk about a particular perspective on each of these criteria, and then as we go through each one we will vote, using our electronic keypad here, and the tabulations will be displayed on the screen behind me.

DR. CASALE: Jeff, sorry. Jeff, would it be helpful, as we talk about each criteria --

CHAIR BAILET: To have it up there --

DR. CASALE: -- to put the slide up.

CHAIR BAILET: Yeah. They're going to put it up. Yep. I think that's great.

MS. STAHLMAN: Give us a moment to get that going.

CHAIR BAILET: So here we are with Criteria 1, which we designated as high priority, and this is the scope of the proposed physician-focused payment model. This proposal aims to broaden and expand CMS's APM portfolio by either addressing an issue in payment policy or in a new way, including APM entities whose opportunity is to participate in APMS.

MS. STAHLMAN: He's going to put something on the screen.

CHAIR BAILET: What's he going to put?

MS. STAHLMAN: He's going to put up the voting.

CHAIR BAILET: Very good.

MS. STAHLMAN: Hold on just a minute. We're going to get a new screen.

CHAIR BAILET: Okay. But as that screen is coming up, I think we have the opportunity to discuss what we heard today, relative to this criteria, and exchange any points of view amongst ourselves that we feel compelled, based on the information that has been provided for the proposer but also from folks who have commented.

So this is --

MS. STAHLMAN: Here we go.

CHAIR BAILET: -- this is the grid relative to the vote tabulation: 1 or 2, Does Not Meet; 3 or 4, Meets; and 5 or 6, Meets and Deserves Priority Consideration.

MS. STAHLMAN: So you can ask them if they want to deliberate --

CHAIR BAILET: Yeah.

MS. STAHLMAN: -- or if they would like to talk about it.

CHAIR BAILET: Right. Do we want to talk about this or are we going to go ahead and vote? I see Harold's card up. Harold?

MR. MILLER: My reading of the criteria, which is in the regulations, is that what we are determining is whether this proposal either addresses an issue in payment policy in a new way or includes APM entities whose opportunities to participate in APMs have been limited.

My clear sense from this is that this gives gastroenterology practices an opportunity to participate in an alternative payment model for the patients that they manage. There are no current gastroenterology models that are implemented by Medicare, which, to me, means that the proposal Meets the criterion.

CHAIR BAILET: Thank you. Bob?

DR. BERENSON: Yeah. I tend to agree with that, and, in addition, would say that the fact that it doesn't, in and of itself, represent a huge amount of Medicare spending, I think is off the point. I think there will be a great interest in developing models that change how specialists interact with patients. I refrain from using the term "medical home," because the American Academy of Family Physicians submitted a letter on a different proposal in which they feel very strongly that a medical home has a very particular meaning, that specialists can't achieve, so come up with a new term. Call it a lodge or a shelter --

[Laughter.]

CHAIR BAILET: Tepee.

DR. BERENSON: It is -- I think we want to know, you know, what has been called the specialty medical home, which I would say we want to reserve medical home for primary care, that's taking management across a whole range of conditions, but that there would be a model for having that kind of interaction with a patient. I'm somewhat persuaded that the chronic care management code doesn't do it today. So I do think it would meet this criterion. I'll have some concerns about some of the other criteria, but I don't think -- I think we probably want to be trying to find models that are a specialty lodge.

CHAIR BAILET: Thank you, Bob. Grace and then Paul.

DR. TERRELL: As a primary care physician, I disagree with the concept that, by the way, that family medicine has about that. It's who basically is taking primary responsibility for the patient and that's not always internal medicine, pediatrics, or family medicine, as we all know.

But irrespective of that, I think that one of the issues that all of our questions and all of the comments was getting at, and it will continue to be an issue, I

think, that the PTAC is going to have to wrestle with, and that is the difference between broad and specific. You know, I believe that there are those who come to us with the idea that something that is just in their practice or that is just for their particular circumstances meets the criterion and are coming before us, and then there are others who are looking at things that are quite broad and want to have something that might impact each and every specialty in case.

And as we are doing our deliberations, this is a big deal. This is may actually be the issue that we're going to have the most difficulty with as a committee. My general belief is, with respect to this one and Criteria 1, that it's just right, and by that I mean it's specific, it's for a particular specialty, it involves more than one particular practice, and it could be exploited across more than one setting or scenario.

But we’re going to get folks who are going to bring us things, I believe that are going to be more specific than this, and we're going to get folks who are bringing things that are quite broad, as we know, and we'll probably deliberate on them more extensively. If we don't get an understanding among ourselves about this, it's going to be very difficult for all the proposers to understand

how to actually figure out what we're thinking and address it appropriately. There are a lot of good ideas out there, and some of them are at the practice level and some of them are at the -- sort of already at the national scope level.

So with respect to this particular one, the answer is it could be broadened. It could be expanded, and it already is above and beyond just a single practice.

CHAIR BAILET: Paul.

DR. CASALE: Just responding to Harold's comment about -- and I struggle with it. You know, APM entities whose opportunities to participate in APMs have been limited, I guess is part of what Grace is -- you know, how do you define that?

So, for a cardiologist, you know, there's BPCI. You know, you could have done acute MI. So when Harold says there is no GI, you know, I'm trying to -- or one of the struggles I have is the opportunities, because there are some opportunities out there currently, for specialist within BPCI, as an example, to participate.

But I think my broader comment is more related to Grace's. It's the same struggle around limited and broad, and again, we may just continue to struggle with this, but that was part of my thinking around how to square this.

CHAIR BAILET: Len.

DR. NICHOLS: So I guess I'm now confused, Paul, because I thought there's no BPCI for GI.

DR. CASALE: Well, again, GI bleed. I mean, you could argue --

DR. NICHOLS: Oh, okay.

DR. CASALE: -- well, you know, so is that a GI?

DR. NICHOLS: Okay. So what I was going to say is, I think you go back to Harold's point. There are two elements of this, right, and by my lights there's not much for GI docs out there, and that should be sufficient. But, to me, the bigger reason to embrace this as a possibility is Grace's point about how this could be expanded.

What I love -- just so you're wondering -- is the Web-based analytics that could be applied in a number of different directions, because you've all heard my stories about EHRs. I think anything we can do to get out of the vendor's hands is a good thing, and Web-based analytics has all these potential ramifications.

But second, the potential can only be realized if we get to the data he couldn't see, and that's where we've got to figure out a way to square that circle.

CHAIR BAILET: Kavita.

DR. PATEL: It's very clear that we're having to deal with what's kind of the Secretary's criterion, kind of

this very -- it's very limited language, so it gets exactly to what Grace said.

I mean, we chose as a PRT to think about the words "broaden" and "expand," not looking at any certain threshold, but literally thinking what does that mean to be broad and expansive and also thinking, addressing an issue and a payment policy in a new way, and clearly, I think we talked about why we did not think that that was necessarily new, or including APM entities whose opportunities have been limited.

And I actually -- we talked about GI and the fact that even with BPCI -- and arguably, there are some gastroenterologists in ACOs, that you're correct that there aren't this proliferation of models out there for gastroenterologists. All you have to do is look at the literature scan that was provided to know that.

The question had been with the limited number of practices that have implemented as well as some of the opportunities, and it is a correct clarification. It is the APM entities. That it was not clear if this would broaden or expand the way it was currently submitted.

So I think just one thing I would like to impress upon all of you, because, look, you had the three of us -- Rhonda is not here to speak for it, but we had many PRT

conversations where we were really trying to -- we wanted to, at the outset of this, do as much as possible to be flexible to allow for physician-focused payment models to proliferate.

So let me just say that we were trying to go into this with eyes wide open and be as broad as possible, but despite kind of having that mindset, we were still struggling with not filling in the white space and interpreting what would be possible, but by kind of looking at what was just in front of us.

So I would offer to all of you that not just the specific criterion designated in the final rule, but then also those information requirements that we attached to that criterion kind of helped inform why we came to this decision.

So, anyway, I feel like we're at this point where we are going to kind of be flailing like an animal, so I don't want to --

[Laughter.]

DR. PATEL: But I do want to -- I feel like it would be remiss if it wasn't the fact that Paul, myself, and Rhonda were desperately balancing what was in front of us and what I would say is the "possibility" and we chose not to try to interpret what that possibility could be. We

really had to rely on what was written to determine that, and we did not feel like that was addressed in a broad or expansive way.

CHAIR BAILET: Thanks, Kavita.

And to avoid the flog, I do want to acknowledge a couple of things, and then I have a comment to make. As a Committee, we appreciate the fact that you guys are the astronauts, that this is new for everyone, everyone in this room. So there is some degree of interpretation.

We are all on the same team. We talk often as a Committee. We want this process to work. We want to be able to foster models that are durable and scalable and bring people into the tent.

At a hearing with a Subcommittee on Health with the Energy and Commerce Committee at the one-year anniversary of MACRA, they made it very clear that one of the reasons they stood this Committee up was to get specialists on the playing field with alternative payment models.

I believe that this model allows that to happen based on so far what I've seen, relative to this criterion.

I think it also -- I have had some experience using this pinging, if you will, in the heart failure, using predictive analytics, looking at cohorts of patients

who have a greater than 80 to 90 percent chance of being hospitalized in the next six months using predictive analytics, and retooling the practice outreach, pinging them, if you will, care management, having the physician and clinicians wrapped around the social issues and the beta-relative issues, it does make a difference. And our particular experience reduced inpatient heart failure-related admissions, not readmissions, but admissions by 60 percent.

So this kind of model, this clinical approach has merit based on what I have seen and clearly what has been demonstrated, albeit it, it's a small scale.

So I just wanted to make that point to my colleagues on the Committee.

Elizabeth.

VICE CHAIR MITCHELL: Thank you, Jeff, and again, acknowledging that this is our first time out, I actually think that this process is serving its purpose.

I think the PRT's analysis of what was in front of us was, I think, exactly right, and I have, I think, been persuaded by what we have heard today, that this is, in fact, expandable and could be broadened. The barriers of the proprietary nature of the platform are not restrictive, and that there is an interest to grow it to

additional conditions and specialties.

I guess the other comment I would make would be I think we are not wanting to hold these early adopters hostage to the environment in which they find themselves.

I read in you proposal that you asked, I think, every commercial payer, and one said yes. So there are external limits on how far it could be tested.

So while I think it was really important to acknowledge the limited scope projected, I think hearing, as you've said, Grace and Len, this could be expanded, I think I am now persuaded that it could meet this criteria.

CHAIR BAILET: Harold.

MR. MILLER: Two points. One is I think we need to revisit all this after we have completed all of our reviews, but we asked a lot of questions and for a lot of information on each of the criteria, and that was partly because we really weren't sure what information we would need to be able to evaluate the criteria.

But I think that the fact that we were asking for the information, we tried to make that clear, and the proposal did not mean that those questions were all criteria. And I do not think in any circumstance ever should we say that we are not supporting a model simply because the number of Medicare beneficiaries that it would

support, that it would help is small. I think even if there are a very small number of Medicare beneficiaries with inflammatory bowel disease and if there is a way to help them and there is a payment model to do that, then we should be looking to support that.

The fact that this model -- I would agree with Jeff. I have my own experience. I set up and ran a program to help keep COPD patients out of the hospital a number of years ago. The key intervention in that was a nurse care manager. The major limitation on the nurse care manager's ability to manage a number of patients was simply the constraint of being able to contact the patients frequently enough to be able to find out what was going on with them. So I think there is potential to expand this, and to me, we haven't really agreed on what a criterion determination is for a recommendation with priority, but to me a model that, in fact, has had some demonstrated success does, in fact, enable a specialty that has not been able to participate in the past and has the potential to expand to other specialties, which have already seemed to express some interest, to me, would make it a recommendation with priority.

CHAIR BAILET: Thank you, Harold.

Seeing no other comments, are we ready to vote on

this criteria? Seeing the heads nod.

Just for the folks in the audience, there is that circle with the zero out of 11. That tabulates the votes. There's 10 of us voting, and the 11th person is the Wizard of Oz, if you will, behind the curtain, who is controlling all of this. So I didn't want you to think that there is someone on the outside voting and calling in.

Without any further delay, we're going to go ahead and vote, and it's a simple majority. So we're going to go ahead and vote.

I can't --

MS. STAHLMAN: When we get the 10th one in -- has everybody voted? Oh, there somebody just voted.

CHAIR BAILET: There we go.

MS. STAHLMAN: There you go.

And Ann is going to read the results for the people on the phone, Mr. Chairman.

CHAIR BAILET: Please.

The voting is done.

MS. PAGE: Okay. So the voting is that we have one member who voted Does Not Meet. We have three members who gave it a score of 3, which means Meets the Priority criterion. Four members gave it a score of 4, meaning

Meets the criterion. And we have two members who gave it a score of 6, which means Meets and Deserves Priority Consideration. And since seven members gave it a score of Meets, that's a majority, and so the decision of the Committee would be that this proposal Meets Criterion 1.

CHAIR BAILET: Thank you, Ann.

We are going to go ahead and move forward unless members of the Committee want to discuss this particular -- based on the voting, any additional comments, or can we move on?

[No response.]

CHAIR BAILET: We will move on.

Criterion 2, Quality and Cost. The proposal is anticipated to, one, improve health care quality at no additional cost, maintain the quality while decreasing cost, or both, improve health care quality and decrease cost. We also designated this as high priority, and I see Harold -- I recognize Harold.

MR. MILLER: You recognize me. Oh, thanks.

CHAIR BAILET: I do. I do recognize, yes.

MR. MILLER: I would point out that I was not one of those kinds that wanted to be an astronaut, but I'm happy to do that.

Again, when we look at these, I think we need to

focus on what the criterion says. The criterion says the proposal is anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

This -- and I don't think we should ever penalize an applicant for actually having put it in place with any population, but unlike other things that are just ideas, this actually has demonstrated that it has decreased cost and has kept patients out of the hospital.

It is somewhat remarkable to me that we actually have patient statements that we got saying that this helped them, which is -- I think we will -- that may be the rare thing that we get in terms of proposals that we get.

And I recognize while the concerns were raised about whether this impacts the Medicare population, it seems to me that there is published literature saying that, in fact, this is a significant issue for the Medicare population, newly diagnosed and severe, and so, therefore, there is a reasonable anticipation that this would do the same thing for the Medicare population.

CHAIR BAILET: Thank you, Harold.

I have Paul and then Grace -- or I'm sorry. Grace first, then Paul. Got it.

DR. TERRELL: This is just a general comment for us to think about as we're going through this process for the first time, and we need to make sure that we don't put people in a Catch 22. And by that, I mean we limit them to 20 pages in their proposal. We read that and evaluate it. There's only so much if you've got 10 criteria that people can actually put in 20 pages.

And then our process, I think we've -- at least my experience, having read your report and been on the other two, it's that then we ask a real deep series of questions to try to get at all these things in more detail, as you clearly have as well as we do.

But that process in and of itself is because we don't want thousand-page proposals. This isn't a grants type of proposal. This isn't the NIH. This is a proposal to us for us to make a recommendation for then the Secretary to decide and determine what to do with it afterwards.

Within the context of that, within the context of only having 20 pages, the real issue is these questions and answers back and forth afterwards and making sure that our proposers as well as those of us that are evaluating and the PRTs having to write this up are having a process that actually is going to kind of get to the meat of all these

things that we're talking about here today.

I think we're going to get better after we've been through this a round or two, but I certainly would welcome from everybody, particularly those who are going through it this first time around, to give us some very specific feedback with how -- if you didn't feel like your points were being understood or if you did, what that experience was like, because I think it will help us without having to expand beyond that 20 pages, which I'm loathe to do. And I'm sure everybody else would be too.

CHAIR BAILET: Thank you, Grace.

Paul.

DR. CASALE: Yeah. I just think in my assessment on this quality and cost -- you know, I think as Kavita has already said, we looked at what was in front of us, and what was in front of us was very limited information about what happens to Medicare patients.

And I would respectfully disagree with Harold that a literature review is going to tell me how this model is going to impact that population.

So for me, I just didn't see how this was going to anticipate to lower cost in that population, and I think we've already gone through on the quality measures. And I am glad that they are piloting more of the patient report

outcomes and assessments, but I think at this point, I felt that they were limited.

CHAIR BAILET: Kavita.

DR. PATEL: I think we're absolutely going to have to talk about whether even any of these information requirements are relevant. They are not part of the Secretary's criteria. We knew that, but just taking the words "improve health care quality at no additional cost, maintain health care quality while decreasing cost, both improve health care quality and decrease cost," we know that clearly from the commercial pilot that we've seen evidence of decreased cost. And we have an impression of improving health care quality with a limited set of measures. Did we have a predefined threshold of what that needed to be? No, not at all. Did we think that it had to be a certain percentage? Absolutely not. But we were really trying to struggle with the age-old conundrum of what really is value and doing that in reflection of the impact on a Medicare population, not with a certain threshold.

We didn't actually say, "Oh, it's only 1.25 percent? That's not enough," because if it's a disease which has obvious quality implications, which all diseases do, we know that as clinicians, but we were trying to

understand how could -- what was in front of us, improve that health care quality, and did not feel like we had enough, to the point of going back and forth.

We actually did go back and forth with the submitters, and I brought this up even in our public discussion. We really did try to understand where the comment about serum albumin came into play, but then had a hard time, struggled with the fact that one of the most important clinical quality outcome indicators was actually not in any way tied to the proposed physician-focused payment model.

So I think all of us are probably thinking how can we interpret and be kind of reflective of the process but also take advantage of going back and forth, without doing what we were also worried about doing, which is to say, "Well, why don't you just rewrite this section this way, and then you would actually meet these criteria." And so we really tried as desperately as possible to stop short of that. So I'm going to underscore something that Tim just kind of briefly mentioned, that this kind of reiterates that --

DR. FERRIS: Yeah.

DR. PATEL: -- there's almost like a value in helping to give feedback, but we don't actually have that

as part of the regulation, part of the statute, or part of the process.

CHAIR BAILET: Yeah. Bob.

DR. BERENSON: So I have adopted the Harold precedent of going quickly to literature, and to some extent, supporting what Harold found and to some extent maybe not, here is a meta-analysis of inflammatory bowel disease in the elderly. I can't vouch for the authors, but it's cited by lots of folks.

And yes, in fact, it's not uncommon. This says 10 to 15 percent. "The clinical features of IBD and older are similar to those in younger. There's more colonic-only involvement, and this is important, and mostly in uncomplicated course."

And then one other sentence, and then I'll stop with this, "Management of late onset IBD is complex because of the problems with misdiagnosis, treatment of comorbid diseases, multiple drug interactions, impaired mobility and cognition, and difficult social and financial issues."

So it is a real problem in the elderly, and it can't simply say we're going to take our model from 30-year-olds and lay it onto the Medicare population. I think it needs the work to sort of figure out what the interactions are with other physicians. It's more

complicated than treating IBD in the younger population, so that's my concern about whether it meets the quality criterion. It's probably better than doing nothing, but it doesn't hit the potential of what we would want to do, which is specific to the Medicare population.

CHAIR BAILET: So my sort of thinking about alternative payment models and this transformation to value, as I looked at this proposal, I thought about the downstream ramifications that transcend the specific disease, and I saw a couple of things that I think touch on this particular criteria about quality and cost.

There are certain tracks that are laid down by this particular model relative to the patient engagement. It's a struggle that we've had for a long time in our industry, trying to get the patients more engaged in their care. I think that this model lays those tracks, and as we've said, people who have this disease, they don't just have this disease. They have other comorbidities, and so this approach to patient engagement, I think there can be a sentinel effect relative to other diseases and how they get engaged and work with the clinical staff to improve their care.

The other piece along that relative to quality, another track is the behavioral overlay or that behavioral

component that I spoke to earlier. If they're depressed, they're not -- it's not depression in the box of Crohn's disease. It's depression overall, and I think that this particular model illuminating this level of depression also can help us as clinicians address that depression as it relates to other disease states. So I just thought I'd make that point.

And I think one additional point that I want to make to my PRT colleagues and Rhonda, who is not here but I know spent a tremendous amount of time on all of these criteria and the analysis, we appreciate all of the work that you guys have done to set this up to allow this kind of discussion to occur, and I don't want to give anyone listening in on the outside that our particular positions based on the information and the discussion here in any way mitigates or diminishes the work that the PRT has done because, frankly, in my opinion, if they didn't do that work and they didn't work with the proposal submitter and set the table for us, we wouldn't have the rich dialogue today to effectively and hopefully efficiently evaluate these criteria.

So I just want to say, looking at my two colleagues here, I don't want them walking away feeling like we're at cross-purposes because we're absolutely not.

Harold.

MR. MILLER: First of all, I'd like to agree with what Jeff just said and thank the PRTs in all cases, present company excluded for tomorrow, I guess, but I think we've all entered -- this is the first time around for everybody, and we have not probably -- maybe to the surprise of the public is that we have not collectively discussed any of these proposals or had the opportunity to do that, so everybody has been kind of just figuring it out independently, and that can result in different things.

I put my card up, though, because I am a little mystified at this issue about quality measures because it seems to me that one of the ultimate quality measures is that you enabled a patient to stay out of the hospital, which is, in fact, what I understand the goal of this project to be. And, in fact, there is discussion nationally about trying to get away from all of the micro quality measures and to try to have something like percentage of days spent at home. So to me, staying out or reducing hospitalizations is a quality measure. It is a better measure than simply a total cost of care measure that has no quality at all attached to it, but says how we're saving money is, in fact, by doing that.

I think Bob was reading from the exact same

article of the pile that I have here, and they do talk about the complexity in the elderly, which is why it seems to me that it is a desirable thing to have a payment model where there is not just a chronic care management fee that is being paid without any accountability for outcomes, but having physicians saying, in fact, we will take the money and we will be accountable for achieving the results.

So if gastroenterologists want to take on a population that is complex and try to make it work, and we have some evidence that that could work, that seems to me to be a good thing.

CHAIR BAILET: Thank you.

Any other comments? Are we ready to go to the keypad? I feel like a game show here. Okay. We're going to go ahead and vote. So we have --

MS. STAHLMAN: So, Ann will read the results.

CHAIR BAILET: Ann?

MS. PAGE: Yes, we have one member giving it a score of 1, Does Not Meet; two members giving it a score of 2, Does Not Meet; three members giving it a score of 3, Meets; two members giving it a score of 4, Meets; one member giving it a score of 5, Meets and Deserves Priority Consideration; and one member giving it a score of 6, Meets and Deserves Priority Consideration.

So the majority give it a score of Meets when you aggregate these up, so the criterion will meet the Criterion 2, Quality and Cost.

CHAIR BAILET: Thank you, Ann. We have a fairly diverse opinion on this particular metric.

DR. BERENSON: Got a high beta.

CHAIR BAILET: Pardon me?

DR. BERENSON: It's got a high beta.

[Laughter.]

CHAIR BAILET: So is there any additional discussion that needs to be had at this point with the Committee members on this criteria? Then we'll move -- seeing none, we'll move to Criterion 3, Payment Methodology. Again, this is the third high-priority criteria. Pay APM entities with the payment methodology designed to achieve the goals of the PFPM criteria; addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM entities; how the payment methodology differs from current payment methodologies; and why the PFPM cannot be tested under current payment methodologies.

So I'm opening it up for discussion. Len, Bruce, and Tim.

DR. NICHOLS: So I took -- and I very much

appreciate your legwork. Let me be clear about that, because you helped me focus. But I took the thrust of the critique of the model to be, well, you know, you could use a chronic care management fee. And I think we've established that's actually not technically feasible in this case. You could adjust it, and Lord knows we all wish that would happen, and it may. But then, you know, I sort of feel like, look, you got a model here that's got the structure that you want an alternative payment model to have as a recognition of the fact that you're going to have to do a pretty intense evaluation at the beginning, a PMPM to cover all the cool stuff we don't pay for in fee-for-service, and a willingness to bear downside risk and putting yourself on the line for what that would be. And I would point to -- and I'll just say I and I think Elizabeth, too, and maybe others, there's a private sector payer paying for some version of this now, which is in some -- and citing a 10:1 ROI. They'll probably cite that for 20 years, whether it ends up being true. But, anyway, they think it's working. And I would hesitate for us to say this structural model is not a good one when, in a sense, the private sector has validated it.

So I totally get that the Medicare population is completely different, and we're going to come back to that

later. But as a technical matter on the payment methodology, to me this meets the criteria.

CHAIR BAILET: Thank you, Len. Bruce.

MR. STEINWALD: Since when is my name two syllables.

[Laughter.]

CHAIR BAILET: It's getting late in the day.

MR. STEINWALD: It's getting late in the day.

DR. TERRELL: You're moving to South Carolina soon.

MR. STEINWALD: That's true. All right.

I guess for me the crux of this issue -- and this one stands in greater contrast than any of the other ones for me that we've discussed -- is do you need a model to achieve the objectives or not. And if the chronic care payment needs to be tweaked, wouldn't it be simpler to do that than to actually launch a complete model?

And so, you know, I generally agree with Len that it has a nice structure to it, but this sort of overall question of do we need a model, does the system currently allow for achieving the objectives with minor changes as opposed to a payment model, I'm on the fence about that. So I'd like to hear what other people have to say.

CHAIR BAILET: Tim.

DR. FERRIS: So let me just say that of the different criteria, this one I had the hardest time with for this model. And that's because of a series of things that came up in conversation and in the review. And the first one is the opportunity for cherry picking, and this goes not to the issue of it has been tested in the commercial population but to the issue of it has been tested with a group who is incredibly forward-thinking and generous to the people that they are taking care of. And I believe our job is to recommend a model to the Secretary that will work for whoever is a Medicare provider who is implementing it. And I wish, but I'm quite sure that it's true, that not everyone providing services to Medicare beneficiaries is as high-minded and fantastically oriented toward their patients as this particular group.

And so I worry that this particular payment model has some opportunities for cherry picking. It has some opportunities for risk selection, cherry picking, however you want to state it. I'm also concerned about the total cost of care model in the Medicare population, which, as we've heard, is really very different than a commercial population. That affects the payment model. And I'm concerned about the lack of tie on the shared savings to quality.

I think all three of these things are really important to a Medicare payment model that differentiate them from how one might do it in a commercial model. And so I guess what I would say with none of these -- I would back up first and say I think this kind of model can work in a Medicare population. I am for this kind of model. I think it's a really great idea. But I would say the model as proposed from a technical perspective needs work. Like it's not quite there yet. I don't think it needs a lot of work, but I think it needs some work, because there are some mitigation factors. I can't just say personally to the Secretary, like, "Make this available to anyone providing services to Medicare because it's going to make the world a better place."

Something close to it might actually, and I think actually have a pretty good chance of that, but not what's in this proposal, because too many of these details have not been specified. And so I just wanted to say that it is specifically the payment model from my perspective that is not sufficiently well specified for the Medicare population and the Medicare payment system that gives me pause about this model.

CHAIR BAILET: Bob.

DR. BERENSON: Well, Tim said it better than what

I would have said. I agree with his comments completely. I would simply emphasize there needs to be some targeting of the subpopulation of Crohn's patients or IBD patients who don't have uncomplicated courses, because the majority do in the elderly. And, number two, I just think total cost of care is inappropriate for this. I would be much happier to use what Harold suggested in the last one, is hospitalization rates, quality metrics. The costs associated with IBD will be trivial compared to the costs associated with all these other conditions that these patients have. And even if CMMI likes total cost of care and the BPCI model, I don't.

So I just think, with Tim, that there's real potential for this model, but we need to work on the payment.

CHAIR BAILET: Thank you, Bob. Elizabeth.

VICE CHAIR MITCHELL: Thank you. I'm aligning with Tim and Bob here. I think this is the toughest criteria for me, and part of it just feels like a confession because it says why the PFPM cannot be tested under current payment methodologies, and I think we've demonstrated that it can. I think we're doing fee-for-service plus an enhanced payment for care management. So I think it's a bit circular. But I just don't see this as a

big departure from current payment methodologies, and I have the same concerns about potential unintended consequences.

CHAIR BAILET: Len, your card is still up. Did you --

DR. NICHOLS: Yeah [off microphone].

CHAIR BAILET: You were just testing me. Then we're moving on to Harold. Grace is next. Sorry.

MR. MILLER: First of all, to Bruce's question, I don't believe the criteria says that if it's possible somehow for you to do this under current payment systems that you fail the criterion. The issue is: Does it pay with a methodology designed to achieve the goals? Which it seems to me that it does.

That being said, I have the same concerns about the methodology that Tim raised and that Bob raised. And, I suspect, though, that we are going to get a lot of those same questions on anything that comes.

I struggled with what is the level of specificity that we and -- you know, sort of detail on all the things being addressed in a proposal to us at this stage from applicants, which is a pretty heavy burden to put on than whenever they don't even have the vaguest idea whether it's going to be approved at all, right? We have to think about

that. And the second question is kind of whether the perfect should be the enemy of the good, and so what does that mean? It seemed to me that one way to do that would be to look at what are the other models that are out there.

So, for example, cherry picking I think is an issue, but it's an issue in every other single Medicare model that they have. You know, the oncology care model does not prevent an oncologist from excluding patients that are going to blow their cost budget under the model. There is absolutely no protection against that there, and I'm not sure that anybody has quite figured out exactly how to deal with that.

I do think that there's a problem with the total cost of care methodology for this, but I think a challenge is that we said in our RFP that we wanted to see total cost of care methodologies as the preference. And I think it's a problem to say to an applicant, "We put out an RFP. We're looking for total cost of care methodologies," and then say, "Guess what? We don't like your total cost of care methodology."

So I think what I'm struggling with is I don't want them to have a total cost of care methodology either, but I think it's a problematic thing to say, "Hey, guess what? You went through this whole process. You've brought

in a model that sounded like what we were looking for, and then we decided that we didn't like it." And at this point, we don't have a good option for saying, "Recommend with some fixes." But that may be what we need to do, is to say it's actually pretty darn close in terms of overall structure, and it needs to be fixed in the following ways. Because when I look at it, I say it does need to be fixed in the following ways, but I don't see them as fatal flaws in the sense that you couldn't fix them. And every Medicare model so far -- I think Tim has experienced this personally -- comes out with benchmarking methodologies that don't really work all that hot initially and need to be adjusted. And to say to an applicant you have to come in with a perfect benchmarking methodology and everything all worked out in advance seems to me to be a pretty high hurdle to put on it.

So I think -- I'm not exactly sure what the right way to determine all that is, but it does seem to me we've got to compare it to what we've said, we've got to compare it to what other models have done, and we've got to compare it to what is reasonable to have somebody have worked out in advance, particularly whenever they cannot get access to the damn data that they would need to be able to actually model this and bring us a reasonable proposal.

CHAIR BAILET: Thank you, Harold. Grace?

DR. TERRELL: So one of the things I think we're struggling with here, and I think we'll continue to struggle with until we get our heads around it, is there's a difference between care models and payment models. And we are the Physician-Focused Technical Advisory Committee, but it's about payment, and so we get all excited when people bring us care models with a payment attached to it. And then we start criticizing the payment model because we get warm and fuzzy about the care model.

That's going to keep happening to us, and it's because we're asking the physician community to bring us things. And what they're doing is they're saying, "If I could just have a different payment model, I could provide this care." But they always start -- and if you'll pay attention to every one of these proposals, by and large, they start with a care model because that's what doctors do. They think about patients first.

So the issue for me comes to is there a way that we can be thinking about care models, and then Criterion 3 comes along, which is the payment model associated with that, that will, to Harold's point, be good enough, because I think it's going to be real crucial if we're going to get a lot of innovation out of the physician community, because

they're always going to start with care.

So I have a lot of experience with my organization, Cornerstone, developing care models, in pulmonary and nephrology and diabetes, an extensivist model, a Medicare/Medicaid model, congestive heart failure model, one for polychronic clinic patients that were stable, and we always came up with ways to save money for the system and provide higher-quality care, the first two models. But every single one of the current criteria that's out there, including the chronic care fees, don't work. And a lot of Cornerstone's experience has been trying very hard within, you know, what's out there right now in terms of accountable care and otherwise of having ways of providing care that's better with payment models that don't work necessarily, or at least without a lot of roundabouts for it. And you heard about some of the roundabouts today as they were giving some information. They're giving some of it for free, the folks, and others. It works in big groups and not small groups. So this is our purpose as a Committee, is to figure out how to do this, and it's not going to be easy, but it's going to be absolutely crucial.

My belief is that the -- I think Bob could be wrong about the cost of care being driven by a chronic

disease and, you know, I guess the data would tell you. You always find mixed data. But biologicals are a big deal in these particular diseases, and sometimes those costs can dwarf the management costs for many of the others, including diabetes. So that's just a point that we don't know necessarily unless you've already found the data out there.

I think that Sandy Marks was absolutely right when she said there isn't a model right now in the current chronic care management fees that also hold people accountable for cost and risk and payments up and down on that. And so the broad principles are in this. It may not be perfect, and it's not going to be perfect, but we're going to keep having this problem. We're going to keep getting care models that we're going to have to figure out some payment models for, and if our criteria are that nothing on the market now works, they're bringing us something that we think might work, it's going to lead to a lot of the discussions that are going to happen at the CMS, CMMI level of small-scale testing or technical help to get it to the next level. But I don't think that we should be throwing the baby out with the bath water because the baby in this is better care, and it's the care models.

CHAIR BAILET: Thank you, Grace. Kavita.

DR. PATEL: So I'll clarify. Paul, and actually in -- well, I'll hit a number of points.

One, we did not expect the methodology to be perfect. Nowhere in criterion is the word "perfect," so we did not apply some threshold of, does the methodology need to be perfect. In fact, I think if you applied that to CMS, nobody would say that current CMS payment methodology is perfect. So, absolutely, was there no intention of perfection to be a goal.

However, what we did try to do is understand how the payment methodology differs from current payment methodologies. I still don't think any of our payment methodologies are perfect, but what we were struggling with was, is there a difference in what's available now, both in the alternative payment model portfolio or in even current fee-for-service. So perhaps it was erroneous to overemphasize what was meant to be just an example, that is, that CCM is truly just an example. We probably could have put in a lot of examples, including the oncology care model, which, by the way, doesn't allow for the cherry picking because it's a trigger that's done by administration of chemotherapy, so I actually don't think that is has as much of the cherry-picking notion.

However, you could almost argue that if you took

the oncology care model, given the use of biologics in this inflammatory disease population, that that model, which is basically a specialty payment model with a PBPM, as well as potential shared savings, from a methodological standpoint, is kind of a parallel to what is proposed here.

So it was a complete struggle. I feel like whatever I'm going to say will do the opposite, so maybe I should start with the opposite. But what we really did try to do, in all seriousness, was understand how we could almost think through, is there something different about the payment elements from what is currently out there.

I think one thing that Sandy brought up in her AMA's comments, that we were incorrect in discussing, is that we do not need to deal with how payments are applied to the individual, because she was absolutely correct, this is about APM entities. So that was a good reminder that we need to just keep going back and thinking through APM entities, and not worrying so much about payments tied to individual providers. But even if we removed that, I would tell you that from a payment standpoint the methodology of a PMPM or a care management fee, even with some shared savings or shared losses, is very similar to existing payment models.

And then we did want to point out, in Dr.

Kosinski's -- in Sonar's responses, they did mention, and we do have inclusion around kind of what they call Crohn's-specific target pricing and Crohn's kind of adjusted utilization cost metrics. So in case that was not part of it. It's not just -- they suggested total cost of care -- just as a clarification -- but there was also the inclusion of kind of a Crohn's-specific. Again, it was to a commercial population. So we're all kind of talking about applicability to a Medicare population which speaks to the need for more of that data and kind of assistance to understand what that data actually looks like.

CHAIR BAILET: Thank you, Kavita. Bob.

DR. BERENSON: Yeah, no. To the point about where the spending is, we do have a Table 3 online, which finds that of $4 billion spent in Medicare in Part A, B, and D, only $145 million is on biologics. It's largely a Part A issue, so we don't have it sorted out in more useful ways than that.

But my point, I guess, would be is if biologics were a high-cost item, do we want a payment model that would determine whether you get a bonus or a penalty based on whether you're prescribing biologics? I mean, I'm not sure that's the right incentive system that we would want to create.

You're shaking your head.

CHAIR BAILET: Grace, can you put your microphone on?

DR. BERENSON: That's a side point.

DR. TERRELL: I'm just confused. I don't -- I mean, biologics should be used in the right situation, sometimes more, sometimes less, depending --

[Overlapping speakers.]

DR. BERENSON: Well, that is right, and if you have a strong financial incentive, based on shared savings and shared risk, you might not -- that might affect not reducing unnecessary hospitalizations but reducing the use --

DR. TERRELL: Well, we've got that now with fee-for-service as well --

[Overlapping speakers.]

DR. BERENSON: Absolutely. So if we're going to fix that we don't want to just replicate it somewhere else. But that's a whole different discussion. I think that -- I'll go back to the language, Harold. I don't think we told people they have to use total cost of care. I think we said that that was one, but I seem to remember that we emphasized that there are alternatives, because I, for one, was pushing that we didn't want to just limit opportunities

to total cost of care.

So if we said that was our preference, I think we need to reconsider that. Clearly, that's what CMMI is largely leading with. We can't disown it. It is absolutely appropriate for some payment models, like any population-based payment model, you want to look at total cost of care. A disease-specific payment model, I don't think, in most situations, it is appropriate and we should just clean up our language a little bit.

CHAIR BAILET: Harold.

MR. MILLER: So it seems to me there's two sort of categories of issues here. The first one is whether this payment model concept is necessary and/or different than what exists today. It seems to me that the answer to that is yes, it's different, and maybe necessary in the following way. It is not the chronic care management fee, in ways that Dr. Kosinski raised. It is a flexible, monthly payment that is not tied to minutes, and, more importantly, it is tied to outcomes.

There are many, many examples around the country of people who have gotten paid to hire a nurse care manager with some amount of money and have achieved absolutely nothing with it, because they hired the care manager and they did something or other, but they didn't actually have

any accountability for the outcome. So tying that payment very specifically to a set of outcomes of keeping patients out of the hospital is a very important thing.

In the project I ran years ago, we hired nurses and we said to the nurses, "Your job is to keep patients out of the hospital, and you have a goal of how many patients you have to keep out of the hospital," which, in fact, was a very liberating thing for the nurses because it enabled them to use their clinical judgment to be able to do that, and I think this model is different than one that says you've got to count up your minutes every month to be able to make something happen.

So that's one category of issues. So from my perspective, it passes on that.

The second category of issues that people have raised, though, is are there aspects of the definition of the model that are problematic and need to be fixed, and I agree that there are. To Bob's point, I think we struggled -- I am in Bob's court on this, that total cost of care is much more problematic than people think it is, but you do have to think about how you're not leaving out the key things from a lesser thing, and everybody knows that CMS' default is that they want total cost of care for everything. So, again, I don't think that we should

penalize an applicant for coming in to do what it is that they probably rightly believe that is desirable.

So it seems to me the other things we have to decide, whether they are fatal flaws or not. Cherry picking, to me, is an issue that needs to be addressed but it is not a fatal flaw. Sorry to disagree with you, Kavita, but the oncology care model is triggered by chemotherapy and any smart oncologist is going to have to think about whether or not they want to give chemotherapy to a patient who is going to blow their budget. So it does not protect against cherry picking.

That doesn't mean -- but I think the fact that physicians who come into this and want to make it work are not going to cherry-pick, but we should still try to build in protections to that. That does not see to me to be a fatal flaw, because it's a problem with every model that exists today.

I do think the other things -- my particular conclusion is that those other issues are addressable, and the question is should they be addressed before we approve it or after? I'm leaning towards the fact that I think that they are addressable after we would recommend it.

CHAIR BAILET: Thank you, Harold. Any other comments from the Committee?

[No response.]

CHAIR BAILET: Are we sufficiently spent to vote on this one? Very good. So without further ado, we are good. Ann?

MS. PAGE: Yes. We have three members voted 1, Does Not Meet; three members voted 2, Does Not Meet; three members voted 3, Meets; zero members voted 4; one member voted 5, Meets and Deserves Priority Consideration. So the majority, six votes, voted for Does Not Meet, and that is a majority, so that is the criteria -- that is the rating given to that criteria.

CHAIR BAILET: Thank you, Ann. We're going to move on, Criterion 4, Value over Volume. The proposal is anticipated to provide incentives to practitioners to deliver high-quality care.

Any comments from the Committee, or are we ready to vote?

[No response.]

CHAIR BAILET: Not seeing any, we are going to go ahead and vote on this criteria, please.

Ann?

MS. PAGE: One member voted 1, Does Not Meet; three members voted 2, Does Not Meet; four members voted 3, Meets; one member votes 4, Meets; one member votes 5, Meets

and Deserves Priority Consideration. So we have six members -- I can do math -- six members voting that Meets, or Meets and Deserves Priority Consideration, so it rolls down and the vote will be recorded as six members voting Meets criterion -- Meets the criterion, and that will be the decision of the Committee.

CHAIR BAILET: Thank you, Ann. Criterion 5, Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care.

I just have a small comment to make.

DR. FERRIS: We already voted.

CHAIR BAILET: What's that? Wait. You guys are already voting on me?

[Laughter.]

CHAIR BAILET: Holy cow. Teamwork and respect, everyone.

So having supported --

[Laughter.]

MS. STAHLMAN: He's going to close it out and do the vote again.

CHAIR BAILET: Jeepers, Wally. You guys are killing me here.

DR. NICHOLS: We are guessing what you are saying.

CHAIR BAILET: All right. Very good. Yeah, right, the mind meld.

So I have found -- I don't remember whether we had 45 or 50 gastroenterologists in my former practice in Wisconsin, but one of the challenges that the physician constituency raised around the GI physicians was getting them to pay attention to diseases where they didn't necessarily require a scope, that there was a lot of medical management required.

This particular model allows the headroom for that cohort of physicians to address this very labor-intensive, complicated, complex, E&M sort of weighted, if you will, disease state.

So I do think that this is -- while it's not the panacea, it does, again, using my phraseology, lay a track for getting the GI physicians to recognize that it's not just all about getting to the lab, but there are some other elements, that the practitioners want for their patients, and I think that this particular model speaks to that. So I thought I'd -- pardon me? Now you can vote. Like that's really going to sway you guys.

All right. Let's go. Let's give this a vote here. You guys are killing me.

MR. MILLER: You convinced me.

CHAIR BAILET: Yeah, thanks, Harold. You guys are buying the first round tonight.

DR. PATEL: Is it closed?

CHAIR BAILET: Well, we can't tell if it's closed but I can do the math, and it looks like we have 10 there.

MS. PAGE: Okay so zero committee members voted 1 or 2, which would mean Does Not Meet; four members voted 3, Meets; three members voted 4, Meets; two members voted 5, Meets and Deserves Priority Consideration; and one member voted 6, Meets and Deserves Priority Consideration. So the majority has voted that the proposal Meets this Criterion 5.

CHAIR BAILET: Very good. We're going to go to number 6, Ability to Be Evaluated. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

Seeing no comments from the Committee I'm feeling that we need to go ahead and vote.

Ann?

MS. PAGE: Zero committee members have voted 1 or 2, which would mean Does Not Meet; four members voted 3, Meets; five members voted 4, Meets; one member voted Meets and Deserves Priority Consideration. The majority has voted that this proposal Meets the Criterion 6.

CHAIR BAILET: Very good. Thank you, Ann.

Criterion 7, Integration and Care Coordination. Encourages greater integration and care coordination among practitioners and across settings where multiple practitioners of settings are relevant to delivering care to the population treated under the PFPM.

Harold?

MR. MILLER: I was troubled by this issue, and I just wanted to clarify. Although the references in the PRT report are really to primary care providers, it seems to me that there is a bigger issue, to the point that Bob was making earlier, is that if people have other significant comorbidities that are, in fact, potentially driving hospitalizations, et cetera, and that interact, then it seems me that it is pretty important to try to figure out how one is coordinating with them, if you are going to manage total cost of care, and even if you're not, because, as Dr. Kosinski said, it's hard to separate out exactly why anybody ended up in the hospital.

So it does seem to me that one weakness that I saw in the proposal description was a clear sense that somebody -- the nurse care manager or someone was making sure that everybody was informed, that if there was MedRec to be done or a resolution of potential conflicts that that was being done, et cetera, et cetera, et cetera.

CHAIR BAILET: So I -- Grace, go ahead. You go first.

DR. TERRELL: One way that this might be able to be addressed -- I would agree, Harold and Bob and others, but one way that this might be able to be addressed broadly in the future is actually through the care pathways and care guidelines that are part of the actual disease management itself. If we think about it as the need to coordinate across specialties, when there is more comorbidities as actual part of clinical guidelines, then this can be addressed not only in this particular approach but others.

So I would just use this as an opportunity, not only for the gastroenterologists but for all the medical specialties to be thinking about their care guidelines as having this as a crucial component of it. It may not completely solve the payment model per se, but since the guidelines are going to be embedded in the quality parameters it would be a way of potentially thinking about it broadly, across the specialties for chronic disease.

CHAIR BAILET: And I guess I am conflicted, but I would say that one of the challenges we have is driving care coordination. I mean, it's the siloed behavior that is impacting cost, and while this -- you know, there

clearly -- this is a specialty-specific model and I think there's an opportunity to flesh this out. There's clearly care coordination going on within the practice, but it's really that sort of broadening the footprint of this particular model. I think there's an opportunity there.

Paul?

DR. CASALE: Yeah. I would -- just to add on, I mean, I think, as Grace said, that we are going to be facing this a lot, because it's, you know -- part, as Dr. Kosinski pointed out, it's technological. You have these EMRs that are quite rigid. You try to work outside it. But any practicing physician knows they don't want to log into more than one system in their day-to-day work, so when you end up doing things like faxing and -- you know, it just sort of disappears into the EMR. So, you know, it's something we're going to need to -- we'll be seeing a lot of this and it's a difficult issue.

CHAIR BAILET: Thank you, Paul. Any other comments?

We're going to go ahead then -- we're going to go ahead and vote.

Ann?

MS. PAGE: Three committee members gave it a 1, meaning Does Not Meet; six committee members voted 2, Does

Not Meet; one committee member voted 3, Meets; and zero committee members gave it a 4 or a 5 or a 6. So the majority finds that this proposal Does Not Meet Criterion 7.

CHAIR BAILET: Thank you, Ann.

Criterion 8, Patient Choice, encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

Comments from the Committee? Harold.

MR. MILLER: This is one where I honestly did not understand why the PRT rated it this way because it seems to me, again, the model is that there are alternative ways of contacting the patient, if that's the issue. I think the criterion is about -- it says "encourage greater attention to the health of the population while also supporting the unique needs and preferences of individual patients," which by, in fact, contacting the patient to determine how they're doing and administering depression screens, et cetera, it seems to me that it does, in fact, support that.

So it seemed to me that there was a little bit too much weight put on the notion that the dominant mode of communication was mobile, particularly when there were

indications from the submitter in the material that many Medicare beneficiaries -- and they had, admittedly, a small sample -- are responding to that.

CHAIR BAILET: Thank you, Harold. Bob.

DR. BERENSON: Yes, this is a time when I think the focus of attention should be on the population at risk and in need rather than the broader population of Medicare beneficiaries where targeted interventions like this do make sense. So I guess in this case I would not sort of endorse the principle that we're asking for and would not hold it against the proposer. In fact, if anything, I want more targeting, not less targeting, of resources to those who actually are at risk of hospitalization and strictures and all of the bad stuff. So I would give it a higher rating.

CHAIR BAILET: Paul.

DR. CASALE: Yeah, I think when I mentioned during our other conversation, I think part, at least for me, in the thinking wasn't so much of the choice of technology but around, as in the example, you know, the demographics of the patient population. So the potential -- I guess as Bob -- the at-risk population, but do they have social determinants of health that would impact their ability to have a choice around how they would be

contacted, if they can be contacted, et cetera. And so that was part of at least my thinking around this criteria.

CHAIR BAILET: Thank you, Paul. Harold, you had your card -- okay. I think we're ready to vote.

Ann?

MS. PAGE: One Committee member voted 1, Does Not Meet; another Committee member -- one Committee member voted 1 -- I mean 2, Does Not Meet; three Committee members voted 3, Meets the criterion; five Committee members voted 4, Meets the criterion; and zero Committee members voted either 5 or 6, Meets and Deserves Priority Consideration.

The majority of the Committee members voted that this proposal Meets Criterion 8, Patient Choice, and that would be the decision.

CHAIR BAILET: Thank you, Ann.

Criterion 9, Patient Safety. How well does the proposal aim to maintain or improve standards of patient safety? Comments from the Committee?

[No response.]

CHAIR BAILET: Seeing none, let's go ahead and vote. Ann?

MS. PAGE: Zero Committee members voted 1 or 2, which would mean Does Not Meet; five Committee members voted 3, Meets; two Committee members voted 4, Meets; two

Committee members voted 5, Meets and Deserves Priority Consideration; one Committee member voted 6, Meets and Deserves Priority Consideration.

The majority of Committee members voted Meets for Criterion 9, Patient Safety.

CHAIR BAILET: Thank you, Ann.

We're here at the home stretch here. Criterion number 10, Health Information Technology, encourage use of HIT to inform care. So, Committee, I think there's some robust discussion. Harold, then Elizabeth.

MR. MILLER: Here I think that the PRT rating was too focused on the pinging technology and not on the fact that this model inherently is, in fact, encouraging tracking of information about patients and using that information about patients in EHRs because the accountability is going to require understanding what factors really do drive patients to be hospitalized, to respond, et cetera.

So, anyway, I think that if one says is this, in fact, as the criterion says, going to encourage use of health information technology to inform care, it seems to me that the answer is clearly yes, it does.

CHAIR BAILET: Thank you, Harold. Elizabeth.

VICE CHAIR MITCHELL: This may just be a general

statement, but I think I will be putting extra weight on information sharing for all of these models, and whether it gets there through an alternative way to cross EMR platforms and vendors or however it's done, I just think this is really important. And I am encouraged by how I now understand that this information might be shared more broadly. So I'm supportive.

CHAIR BAILET: Thank you, Elizabeth. Len.

DR. NICHOLS: So I was going to ask Paul, because I learned something I didn't get from the written stuff, and that was the ability to push the web-based analytics back to an EHR. It's input into EHR. You don't have to sign on the system. You could make it inserted. Did you learn something that would change your view, this fax business?

DR. CASALE: Well, in their proposal, when we had questions back and forth, it mentioned particularly with the primary care that faxing or that the primary care can sign into their system, were potentially the more prevalent options currently.

CHAIR BAILET: Bob.

DR. BERENSON: Yeah, I just wanted to ask the PRT if their major concern for Does Not Meet had to do with the proprietary nature of the software. Was that the basic

reason?

DR. CASALE: Yeah, I have to say for me I still struggled with that particular piece, you know, and -- yes, for me that is one of the major reasons why I voted the way I did.

CHAIR BAILET: Kavita.

DR. PATEL: So I'll also respond that -- and this goes back to kind of a larger question we'll have to have about how maybe CMS would deal with something that's proprietary. So that was one piece.

But, Bob, another piece was also the kind of desire to avoid unintended consequences of technology that is not interoperable, and so there were a couple of new pieces of data from what Dr. Kosinski said here, which was, one, that there was probably a willingness to open this up to not be kind of a proprietary cost basis; and then, two, that pushing back -- kind of that HL7 standard, then being able to kind of push that into other EMRs. I will say from a practical clinical perspective, my lovely employer and institution has a vendor arrangement with a certain EMR that, even when someone else wants to give us something, that particular EMR charges us to receive said information. So we know that in practicality, some of these things are not as easy.

But even having said that, that piece of information was new for us, but I do think that we probably have to have a discussion about how -- if Dr. Kosinski hadn't said that this was possibly able to be done kind of without that cost burden, you know, does that still mean something? Because it means other professionals would still have to log into something separate, even if it was free, and what that means for better coordination.

We do know that from limited literature of when physicians have to log into multiple interfaces, they tend not to do it. So we should have that discussion.

And it wasn't just something that like -- just to make a point in the sand, we talk a lot about coordination, and we use the refrain of specialists coordinating with primary care. We actually discussed at the PRT level that it was really more important, since this was such a specialty-focused model, and to Bob's point that better targeting is better, that it was even with the super specialists, that this was actually more about coordination, not just with good old primary care doctors, which I am part of, but more important with a lot of the super specialists that surround these patients because of the complex interactions with the specialty care.

So we were worried that the proprietary nature

and the fact that it was so targeted just for GI might limit the kind of Secretary's criteria of health information technology to inform care. So that was the concern.

CHAIR BAILET: Thank you, Kavita. Tim.

DR. FERRIS: So I guess I'm thinking about the health information technology a little bit differently, and maybe just to give some context, I think it's really unlikely that my organization would ever participate in anything like the platform because just think about the implications of that for taking care of every specialty diagnosis that we take care of. I mean, that's just not going to happen.

We have functionality in our EHR and our extended platforms that do everything that I read about and translating the guidelines, which we do all the time, into our EHR is an exercise, but it's just an exercise.

And so when I looked at this, I did not read this as a requirement, nor did I think CMS would -- their payment would be in any way like that platform. It would be the ability to reproduce that functionality in any platform.

CHAIR BAILET: Right.

DR. FERRIS: Because I'm just saying, since it

does fall under my span of control in my organization, there's no chance we could do sort of disease-by-disease platforms. No one would use it, and it's just simply not an extensible model. And so I view this as the ability to provide that kind of functionality independent of the platform.

CHAIR BAILET: Yeah.

DR. FERRIS: So I'm just saying that's the way I read this, and that's the way I would vote on it.

CHAIR BAILET: Okay. Well, I think your wish is about to come true because seeing no -- oh, Paul, did you have a comment?

DR. CASALE: Well, you know, part of the struggle, though, is you're trying to analyze what's in front of you, and you could imagine how it might integrate into your EMR. But that's not what we were evaluating, so there is this sort of tension around as we vote in terms of we're voting on this or we're voting on, well, you know, the guidelines can be put in every EMR and gone forward, and it wouldn't be proprietary. So I have to say I'm still struggling with that.

DR. PATEL: And I actually now see, Tim, kind of what you're saying, because we had a lot of discussion about like the ping response rate as an index -- I mean,

Dr. Kosinski even mentioned kind of the Sonar score as one of the kind of metrics, and we really did read that for what it was, tied to that kind of IP-protected technology. But, actually, in hearing what Dr. Kosinski said today and then just even that discussion, I can see where it's really much more of the functionalities, and we would have to think about how to kind of -- well, we wouldn't. Somebody at HHS would have to think about how to cross-map kind of what's underlying and unpacking all of this to, you know, everybody else that is in the vendor space. But we kind of went much more literally with like what was there. But I agree, it does change my frame of thinking just hearing, like, it's really much more about the functionality, and that's something that we probably have to discuss as a Committee.

CHAIR BAILET: Thank you, Kavita. Harold.

MR. MILLER: It seems to me that this gets at an issue Grace was raising earlier about care models and payment models. And at least as I understand the payment model here, the idea is that the practice gets paid X dollars PMPM and then takes accountability for whatever it is they take accountability for, total cost or hospitalizations or whatever.

The payment model is not you're being paid to use

the Project Sonar platform. If it were, I would not be very happy with the model, because it doesn't -- as Tim point -- you know, it somehow constrains you to a particular technology, which may or may not work in your particular setting. I think the issue, what is useful is to know that somebody has a concept for how they will, in fact, spend the money. That gives you some sense that that amount of money is, in fact, something that sort of would reasonably be able to achieve something that's like to accomplish the results. But then the payment model says up to you to decide how you do it, which is, in fact, equivalent to the way most other payment models do it. We pay physicians an E&M payment, but we don't tell them exactly what they must do in the course -- well, maybe people might disagree with that, but, anyway, it doesn't tell them how many MAs they have to have --

CHAIR BAILET: Okay, you can come and get him now.

MR. MILLER: Yeah, right. So...

CHAIR BAILET: I think Harold's done. All right.

DR. CASALE: Sorry.

CHAIR BAILET: Paul, go ahead. You keep flipping your card up. You're confusing --

DR. CASALE: Well, I have to tell you the

struggles. But part of this is that --

MR. MILLER: We know you struggled, Paul. We know.

DR. CASALE: I know. Part of the model, though, is the dependence on this ping. You know, this is a technology, you know, the ping response. So, again, as we think through it, you were sort of going to make some assumption that this can be done in other ways and other platforms, et cetera. But we really don't know that. I mean, we can imagine it could happen that way. But some of the technology that leads to these results is not generic.

CHAIR BAILET: All right. I'm going to let Tim go first.

DR. FERRIS: Just on that specific point. So we don't call it the same thing, but for every -- we do this across about 14 diseases right now, and we actually measure our response rate in every single one of them. So it's not like this is original, I'm sorry to say.

DR. CASALE: It's not original -- sorry, okay. I was just trying to think more broadly around every practice setting, you know, how would they use this?

CHAIR BAILET: Harold.

MR. MILLER: So the way I see this is a gastroenterology practice brought us a payment model to

support an approach that they are using, which is written in a way that enables other people to do something different, or similar, if they wish to. I'm sorry, but there is a lot of evidence that care management for patients who have serious illnesses reduces hospitalizations and ED visits. I have personal experience doing that, and many other people do.

But there is no Medicare model today that enables any specialist, not even, frankly, for primary care physicians, to be able to take a per-member per-month care management payment and take accountability for an outcome associated with it. So that to me is what it is that we are voting on today. And maybe we need some clarification of that. I don't think we are voting to pay for a pinging system that happens to be the one that was brought to us.

DR. CASALE: No, we're just talking -- we're voting on the HIT technology, right? That's where we are.

CHAIR BAILET: We're on 10. We haven't voted yet.

MR. MILLER: Yeah, but it has been raised by other people, and to me, the issue is, the criterion is, does it encourage use of health information technology? To me it does encourage use of health information technology more broadly, not just that particular pinging system,

because one is going to have to track things about patients in whatever implementation one does.

CHAIR BAILET: Very good. I think it's time. We're going to vote. Yeah, we're good. Okay, very good. We don't mess around here.

All right, Ann. Fire it up.

MS. PAGE: Okay. Zero members voted 1, Does Not Meet; one member voted 2, Does Not Meet; five members voted 3, Meets; four members voted 4, Meets; and zero members voted 5 and 6, Meets and Deserves Priority Consideration.

So the majority decision of the Committee is that this proposal Meets Criterion 10.

CHAIR BAILET: Thank you, Ann.

So the next step in the process, where the rubber meets the road, is Matt, the person behind the curtain. He will put up a summary of all of our deliberative votes. And while we're waiting for him to do that, I guess I would ask the Committee if we have further deliberation or comments that we'd like to make before we actually vote relative to making a recommendation to the Secretary. And while that's happening -- well, Len.

DR. NICHOLS: So this was great. I'm glad we did this. I feel better about my country. I feel better about my Committee. It's just, you know, this is how it's

supposed to work. And I'll just sum it up very briefly from my point of view.

We've got a pretty good proposal from creative, dedicated people that needs some work. Our problem from my point of view are the, I'll just say, straitjackets of the categories we set up for ourselves, and part of that has to do with our discussions with our friends at HHS that have to receive these things. But I would observe that if there is a proposal that cries out for technical assistance, this is at least one of them. Just a prediction. There might be one or two tomorrow. But the point is we need to think about how to convey that, and I'm open to all alternatives. But to me, this is an obvious place for where not that much technical assistance could address a vast majority of the concerns that have been legitimately discussed today. And I just would like that to be recorded somehow in one of the categories we're going to be able to go for.

So, you know, if you say no, you say yes, but it seems to me this notion of somebody -- not necessarily us, but somebody providing some technical assistance to beef up the parts of this that need work. I just think we need to do that.

CHAIR BAILET: Yeah. And I think that opportunity -- and we'll speak to it in a little more

detail after we vote. I think we have the opportunity in the comments that bolt onto the recommendation. I think we have the ability to share that perspective in the comments section when we send our recommendation to the Secretary.

Elizabeth, you had a question?

VICE CHAIR MITCHELL: This may or may not be orthodox, but I actually had a question for the submitter. I have no experience with this, but it seems to me this could be like putting your child in a beauty pageant. I am just wondering. Were there changes that you have for the process, or are there assistance needs or things that might make this different in terms of what you would bring to the Committee?

That could be a long answer. I'm looking probably right now for a shorter version, but are there thoughts?

DR. KOSINSKI: Can I answer after you vote?

[Laughter.]

VICE CHAIR MITCHELL: Good question.

CHAIR BAILET: No. You can go to the microphone at the front. Well, either one.

DR. KOSINSKI: Like I said, can I answer after you place your vote?

I've learned a lot today in listening to

everybody, and it was clear to me. We were trying to fit into 20 pages with 10 criteria, and we just couldn't say everything we wanted to say, about 10 things in 20 pages.

And then when we get to supplemental questions, I was trying to be brief. I was trying to focus specifically on the question that was asked of me and not elaborate and built a whole bunch of other stuff for you to read.

So I would love to debrief at length with you --

CHAIR BAILET: Thank you.

DR. KOSINSKI: -- if you vote for the project.

[Laughter.]

CHAIR BAILET: Yeah. Thank you.

So the summary, is it ready to be displayed?

Oh. And, Harold, please make a comment.

MR. MILLER: We have this category called Recommend for Limited-Scale Testing, which was, at least in my mind, intended to be a way of saying some models that come to us will have issues that need to be resolved in terms of refining the payment model that will be very difficult to resolve without actually putting it in place.

So I am trying to think about that from this particular perspective because I think we all agreed with varying degrees of severity that there need to be some improvements in the payment methodology.

One of the things that was driving that was lack of understanding about how this actually works in the Medicare population. Hard for me to imagine right now exactly how one figures that out unless one actually does something with the Medicare population, which means that it's hard to do that if you don't actually have a payment model to be able to support that. And I'm hoping that a bunch of gastroenterology practices will all just go do it voluntarily with a complex population that we've all said is a complex population. It seems to me kind of a bit of imposition on volunteerism.

Some of the other things could potentially be designed theoretically in the absence of that but would be hard to know how they actually play out. We have these sort of odd statistics now that say X percent of people have some other comorbidity, but we don't really have a clear sense of exactly what that means in practice. So there's lots of people, and there are lots of things, but is it severe? Is it not severe? We don't know those things.

So it does seem to me, as I think about it, that it would be -- there are technical assistances necessary, to Len's point, but it's hard for me to imagine exactly how one wouldn't be able to satisfy all of the questions

without actually putting it in place on a limited scale.

CHAIR BAILET: Thank you, Harold.

We have the summary up, and everybody can see it, but there are folks on the phone who can't.

So, Ann, do you want to just share the summary?

MS. PAGE: Sure. The chart the Committee is looking at right now lists all 10 of the Secretary's criteria, and it shows that the Committee voted that in two of those criteria, the payment methodology, which is a high-priority criterion, and Criterion 7, Integration and Care Coordination, that the Committee voted that for both of those two criteria, the proposal Does Not Meet the criterion.

For the remainder of the Secretary's criteria, the Committee voted that the proposal does Meet those criteria.

CHAIR BAILET: All right. Thank you, Ann.

So we are going to now do the -- we have a sort of two-pronged approach to voting. We are going to vote electronically, and then we are going to vote by voice. The Committee members felt it was important for folks to know where each individual Committee member stood relative to the recommendation to the Secretary.

I would just like to review what the numbers

mean, and this is a two-thirds majority threshold. So a vote of 1 means we do not recommend the payment proposal to the Secretary. A vote of 2 means we recommend the proposed payment model to the Secretary for limited-scale testing. Three means we recommend the proposed payment model to the Secretary for implementation. And I want to be clear that that's testing and implementation; that is, once we make a recommendation, then CMS takes it from there, and we don't want to overprescribe how they process our recommendation. But it is up to the Secretary. And then a vote of 4 means that we not only recommend the payment model to the Secretary, but we also recommend that it be implemented as a high-priority item.

So I believe we will electronically vote, and then we will go around by the Committee and give a voice vote.

MS. PAGE: Are we ready?

CHAIR BAILET: Are we ready to -- we may not be ready.

DR. CASALE: Can I --

CHAIR BAILET: Yes, Paul.

DR. CASALE: Just a clarifying question, because I know there was a discussion around technical assistance, and so I'm not sure where that falls in here, or was that

just not related to which category we --

CHAIR BAILET: Len.

DR. NICHOLS: In my opinion, you can put technical assistance where you want. What I would suggest -- what I'm going to do is vote the way I think it ought to go. So if you go limited testing, that means let's do the technical assistance before you do limited testing. If you vote no, then you're saying let's work out the details and try again.

CHAIR BAILET: Any other questions, comments by the Committee?

[No response.]

CHAIR BAILET: We're going to go ahead and vote, then, please.

[Discussion off microphone.]

CHAIR BAILET: I think we are going to have to pre-medicate Dr. Kosinski here.

DR. KOSINSKI: It's like the Academy Awards.

CHAIR BAILET: No. We promise you, it will not be like that.

[Laughter.]

CHAIR BAILET: Okay. Let the record -- we're on TV. That is not going to be like that.

Help the Doctor, Matt.

One more time with feeling.

All right, Matt. I know you want to slide it over. Well, I think we should let it play through, and then we can do the voice vote.

MS. STAHLMAN: Give him --

CHAIR BAILET: He's got it. I know it's right there. I can see it.

[Pause.]

CHAIR BAILET: It's that high-anxiety moment. Okay. No pressure, Matt.

[Laughter.]

CHAIR BAILET: This really is a fun Committee, by the way. I'm just letting you folks know.

There we go. Come on, Matt. We'll give him -- and then we'll just go around. There we go. Come on.

Do we need to vote again?

MR. ELLENBURG: We need to vote again.

CHAIR BAILET: We will vote again. One more time with feeling.

MR. ELLENBURG: No. I'm sorry.

CHAIR BAILET: All right.

MS. STAHLMAN: Or we could do a voice vote.

CHAIR BAILET: I think we could do a voice vote. Yeah, let's do a voice vote because that's where we're

going to end up, anyway, is we are dispensing with the technology, starting with Harold, and then we'll just go around the room.

MR. MILLER: I vote 2 for limited-scale testing because I think that based on all of the recommendations, the key issue is to refine the model, and I don't believe that the model can be refined with any technical assistance to the level that would be satisfactory without actually putting it in place. And I think that overrides the high-priority criterion that we had on the payment methodology.

DR. TERRELL: He said 2.

DR. NICHOLS: I vote 2 because I look at it like would we be better off with this being fixed or not, and I think yes.

DR. TERRELL: 2.

MR. STEINWALD: I voted 1. I thought, at least initially, we should adhere to what we had said among ourselves that if they failed to meet a high-priority criterion, we couldn't vote to implement. And I'm not convinced that we couldn't improve it without limited testing. In other words, I'm saying I think the payment methodology could be improved without limited testing.

CHAIR BAILET: Well, I voted 3 to make the recommendation. I didn't necessarily feel that limited

testing was required, although I know that it could help refine and sharpen the proposal.

VICE CHAIR MITCHELL: I voted 2.

MS. PAGE: I'm sorry. I didn't hear that.

VICE CHAIR MITCHELL: 2.

DR. FERRIS: 2.

DR. PATEL: 1.

DR. BERENSON: 2.

DR. CASALE: 1.

CHAIR BAILET: So we have our mathematicians here.

MS. PAGE: So, in this vote, the standard is that we needed two-thirds majority, whereas when the Committee was voting for a criterion, it was a simple majority. So for the voters now, a two-thirds majority would mean that we need seven votes to reach that standard, and so what we have right now is three Committee members voted do not recommend, six Committee members voted recommend for limited-scale testing, and one Committee member voted to recommend Implementation.

And according to our decision rules, you roll down to that which gives you a vote of seven. So the recommendation of the Committee would be to recommend for limited-scale testing.

CHAIR BAILET: Thank you, Ann. Thank the Committee members. I thought the process worked as we designed.

We're not adjourning now. It is the next final phase of the process is to talk about the recommendation to the Secretary and comments. Right? And this is just to get the framework detailed, and then we have an iterative process within the Committee members to work the comments to the point where they're ready for submission.

MS. STAHLMAN: So, in addition to any comments you made today that we will get from the transcriptionist, any other additional comments you'd like to make and report to the Secretary or comments that you'd like to highlight and make sure the staff is capturing when they take the first draft of that?

CHAIR BAILET: Len.

DR. NICHOLS: Well, I'm not sure it's in addition to what we've said since everybody said everything, but I'm not sure everybody said it.

[Laughter.]

DR. NICHOLS: But I think I just would highlight that at least I think this proposal would benefit greatly from having access to real Medicare data, and I don't know a better way to get it than what we just voted.

So to me, it is working with the team, with the Medicare data people, some of whom we know, but some of whom we don't, to really refine those parameters, and I would submit it also applies to applying to the quality metric link, what kind of quality links you really want here. I think we're talking about not just that one dimension, but all dimensions of the model.

CHAIR BAILET: Thank you, Len.

Elizabeth.

VICE CHAIR MITCHELL: Again, this may be already captured in the notes or the comments, but I want to be sure we talk about the interoperability, that should this move forward with CMS, we are talking about the functionality of the information sharing rather than this particular proprietary technology. I assume that goes without saying, but I'd like to say it.

MS. STAHLMAN: If the members would indulge the staff -- oh, sorry.

CHAIR BAILET: Bob has his card up.

MS. STAHLMAN: Sorry, Bob. I didn't see you.

DR. BERENSON: That's okay.

I voted 2 rather than a 1 because I think we just have to try to figure out how to change the incentives for procedural specialists in particular, and this seems like a

dedicated group and a reasonable condition. And I think we could learn a lot of sort of operational things by doing this. So, to me, that's a reason for really trying to get into the details but on a limited scale, because I'm quite skeptical of our ability to actually do this right on a large scale. So I think we would learn a lot.

CHAIR BAILET: Thank you, Bob.

Any other comments?

You have a question specifically for staff?

MS. STAHLMAN: I do have a question for staff. Could members talk a little bit more about Criterion 4 and your rationale for the way you voted on Criterion 4? Because it did differ from the PRT report, and we want to make sure the first draft captures what you'd like to say there.

CHAIR BAILET: Four is value over volume?

MS. STAHLMAN: Four is value over volume. If anybody has any remarks to make? Otherwise, we will go back to the transcript, but a little bit -- a few more words would be very helpful to us on that one.

CHAIR BAILET: Harold.

MR. MILLER: Well, I would say, first of all, I think from my perspective -- again, this is just my perspective -- that I think the wording of the secretarial

criterion is too narrow when referring to incentives. It's used too commonly. It's the notion that somehow it's not trying to overcome a particular barrier, and so what I view as the issue here is the proposal will, in fact, overcome barriers that practitioners face in terms of being able to deliver high-quality health care, meaning they get resources in the flexible fashion that they need to be able to do that.

Anyway, I think driving the change in behavior is the accountable for the cost, but I think that the notion that this is -- it is not just about an incentive and that somehow the model is not going -- in and of itself doesn't create an incentive without fixing the barrier. So, anyway, that to me is a key distinction in this is that it does actually provide resources rather than just trying to hold somebody accountable for spending and hoping for the best.

CHAIR BAILET: Grace.

DR. TERRELL: So the comments that were made earlier -- I don't remember who made them -- with respect to the fact that this particular specialty has tended to be rewarded for doing lots of colonoscopies and procedures financially within the current care model sometimes means that some of those individuals have been unable to provide

the type of care for chronic complex patients with gastroenterology problems would be a good place to start with this, because in any of the specialties where there is a need to provide better care for complex folks for which the current health care system, it's a thankless task. It's what volume -- what value over volume is about, if it's a way of actually getting at those thankless tasks that are about better care.

CHAIR BAILET: Thank you, Grace.

Tim and then Bruce.

DR. FERRIS: Just that I think this -- of the criterion, this one may have quite a bit of redundancy with the prior two because it folds them in, and so when I think about our response to 4, I actually think it's sort of a blend of responses to 2 and 3 because 1 is about value and payment and one is about equality.

This one may be -- the lack of discussion may reflect the fact that we were sort of spent on the prior two criteria, and it didn't really add much to this one.

CHAIR BAILET: Thank you, Tim.

DR. FERRIS: So it's just a thought.

CHAIR BAILET: Bruce.

MR. STEINWALD: Well, I am going to pogo-stick off of that back to Criterion 3, since we voted the way we

did, and then we voted to recommend for limited-scale testing.

I think it behooves us to be as specific as we can about what deficiencies we think need to be corrected in the payment methodology, and that could include some that are correctable just with using volume data and Medicare data, but it also could include some more reflections on the kinds of problems that we identified and the PRT identified that need to be addressed, either through obtaining "how to" data in limited-scale testing or by refinements to the model that could be accomplished a priori, because I think the PRT did have some important things to say about that.

And remember with implementation, it doesn't mean that Dr. Kosinski is going to be looking over every gastroenterologist's shoulder. It has to be implemented on a wide scale, the point that Tim made earlier, among general practice -- I'm sorry. Not general practice, but around practicing doctors who are not as mission-oriented, perhaps, as Dr. Kosinski and his colleagues are.

CHAIR BAILET: Harold.

MR. MILLER: Bruce, just foreshadowed the comment I was going to make, which is I do think the staff may have this, but I think we should have a list specifically of the

things that we think need to be kind of addressed or improved during limited testing in the payment methodology, one of which I think is -- and again, if others disagree, they can, but I think is a method of verifying the diagnosis, because when we suddenly have a model that is triggered by a diagnosis, which doesn't exist today --

DR. TERRELL: It created an epidemic.

MR. MILLER: -- we could create an epidemic. Yes, everyone will have IBD now. But I do think that making sure that we can measure that, and I think one of the advantages of doing limited-scale testing and working with people who are doing that would be to, in fact, try to refine a way of doing that. So that is one specific thing that we've built into it.

I think the issue of cherry picking is an important one to address. I think it's a tough one to address, but it's something that would be worth thinking about how to address. One of the common things you see in some of the CMMI models is we will monitor this closely to make sure nothing like that happens. Well, that's an interesting question, but exactly what is it that you're monitoring? And I think that would be worth thinking about for this because I think particularly when you extend it to other areas, so how do you determine that?

And I think the issue of trying to define an accountability measure that is focused on the things that the physicians can control -- and, for example, on the drugs, can appropriately deal with kind of the utilization of drugs without being at risk for price, but I think those to me are a couple of the key things that need to be fixed here. And it may be that there's some others that others want to add to that list, but I think it would be useful to be clear about what those specific things are that need to be refined either before or during testing.

CHAIR BAILET: Thank you, Harold.

Any other comments by the Committee? Because I have two announcements to wrap it up.

[No response.]

CHAIR BAILET: So I'll go ahead.

So, number one, I'm pleased to announce that the PTAC will be visited tomorrow by the Secretary, Dr. Price, Secretary of HHS. He will be providing remarks at our public session tomorrow morning, April 11th. The Secretary's remarks will begin at 11:00 a.m., Eastern Time, here.

MS. STAHLMAN: At 8:00 a.m.?

CHAIR BAILET: Like I said, 8:00 a.m.

MS. STAHLMAN: You're counting California time.

CHAIR BAILET: You guys, you have to realize I am from California. I can't believe -- a.m. I live in California. Yeah, it's okay. Eleven, anyway. Thank you.

So, again, I don't mean to confuse folks, really. It's eight o'clock tomorrow morning here, Secretary Price will be addressing the public.

Following his remarks, we will deliberate on two models, so we're excited about that and appreciate your patience and participation today.

The second quick announcement is that this Committee will reconvene upstairs for a few minutes to debrief today and really set the table for tomorrow.

So any other comments before we adjourn?

[No response.]

CHAIR BAILET: We are adjourned. Thank you.

[Whereupon, at 4:51 p.m., the Committee adjourned, to reconvene at 8:00 a.m., Tuesday, April 11, 2017.]