

PHYSICIAN-FOCUSED PAYMENT MODEL
TECHNICAL ADVISORY COMMITTEE

PUBLIC MEETING

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

Tuesday, April 11, 2017
8:00 a.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
Public Remarks to PTAC.....	5
- Secretary Thomas E. Price, MD	
Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group, Inc. (PMA): The COPD and Asthma Monitoring Project (CAMP)	
PRT: Len Nichols, PhD (lead), Tim Ferris, MD, and Grace Terrell, MD, MMM	
Committee Member Disclosures.....	16
PRT Report to the Full PTAC - Len Nichols.....	19
Clarifying Questions from PTAC.....	30
Submitter Statement	
- Daniel Ikeda, MD, FCCP.....	53
Questions from PTAC to Submitter.....	62
Comments from Public.....	98
Committee Deliberation.....	106
Voting	
- Criterion 1.....	108
- Criterion 2.....	111
- Criterion 3.....	112
- Criterion 4.....	123
- Criterion 5.....	123
- Criterion 6.....	124
- Criterion 7.....	124
- Criterion 8.....	133
- Criterion 9.....	134
- Criterion 10.....	139
- Final Vote.....	150
Instructions on Report to the Secretary.....	151

AGENDA

PAGE

American College of Surgeons: The ACS-Brandeis Advanced APM

PRT: Grace Terrell, MD, MMM (lead)

Harold D. Miller, and Bruce Steinwald, MBA

Committee Member Disclosures.....	162
PRT Report to the Full PTAC - Grace Terrell.....	165
Clarifying Questions from PTAC.....	190
Submitter Statement	
- Frank Opelka, MD; Chris Tompkins, PhD; and Jennifer Perloff, PhD.....	226
Questions from PTAC to Submitter.....	235
Comments from Public.....	288
Committee Deliberation.....	314
Voting	
- Criterion 1.....	338
- Criterion 2.....	339
- Criterion 3.....	340
- Criterion 4.....	341
- Criterion 5.....	342
- Criterion 6.....	342
- Criterion 7.....	343
- Criterion 8.....	344
- Criterion 9.....	344
- Criterion 10.....	345
- Final Vote.....	361
Instructions on Report to the Secretary.....	366
Adjourn.....	375

P R O C E E D I N G S

[8:00 a.m.]

1
2
3 CHAIR BAILET: Welcome. Good morning. Thank you
4 for coming. My name is Dr. Jeff Bailet. I'm the Chair of
5 the Physician-Focused Payment Technical Advisory Committee.
6 I have the privilege of welcoming Secretary Dr. Thomas E.
7 Price, who was sworn in as the 23rd Secretary of Health and
8 Human Services on February 10th of this year. He is the
9 third physician to hold this position. He brings to the
10 department a lifetime of service and dedication to
11 advancing the quality of health care in America, both as a
12 physician and a policymaker.

13 After his training and residency, Dr. Price, who
14 is a third-generation physician, following in the footsteps
15 of his father and grandfather, began a solo medical
16 practice in Atlanta, Georgia, which would eventually grow
17 to be one of the largest non-academic orthopedic practices
18 in the United States.

19 Most recently, Dr. Price served as the U.S.
20 Representative for Georgia's 6th Congressional District.
21 He held this office from 2005 to 2017 and earned a
22 reputation amongst his colleagues for being a tireless
23 problem solver and the go-to expert on health care matters.

1 Committed to advancing positive solutions under
2 principled leadership, Dr. Price remains a fierce advocate
3 for a patient-centered health care system that adheres to
4 six key principles: affordability, accessibility, quality,
5 choices, innovation, and responsiveness. As Secretary, Dr.
6 Price remains committed to these principles, administering
7 a wide array of services, supporting lifesaving research,
8 and protecting and serving all Americans.

9 Please join me in welcoming Secretary Dr. Price.

10 [Applause.]

11 SECRETARY PRICE: Thank you, Dr. Bailet, very
12 much. What a kind introduction. I appreciate that.

13 Good morning to all. It is wonderful to be with
14 you, to welcome you to the Great Hall here in the Hubert
15 Humphrey Building. I'm incredibly honored to serve in this
16 capacity and remarkably humbled by the opportunity that
17 presents itself. So I want to welcome you this morning,
18 Dr. Bailet, Ms. Mitchell, the entire PTAC committee, for
19 the work that you have done. I want to thank you for the
20 work that you've done and appreciate the opportunity to
21 address you this morning.

22 I know the sacrifices that you all make. You all
23 have other jobs. I know that people remind you of that

1 frequently when you're back home. So what you're doing is
2 a service not just to health care in our country, but to
3 every single citizen, and I thank you for that.

4 I also want to take time to thank the staff who
5 have been engaged in participating and helping these folks
6 do their job and do it better. We rely on a wonderful,
7 wonderful staff here at HHS, and I am privileged to be able
8 to help guide them as we move forward.

9 I am honored today to join you for this first
10 PTAC meeting to deliberate and vote on physician-focused
11 payment models, and, again, I want to commend you all for
12 the work that you've done, and especially commend those who
13 have submitted plans. It is a foreboding task to be asked
14 by your federal government to devise a payment model for
15 physicians and be out there in what I call the "real world"
16 and to think that anybody's not just going to pay attention
17 but going to care what they think, and so I want to commend
18 the folks who have submitted payment models and encourage
19 others to do the same. And we'll talk a little bit more
20 about that in just a moment.

21 I met with the Committee just for a few minutes
22 earlier this morning, and I mentioned to them that I think
23 I'm probably in a fairly unique position as it relates to

1 this task before us, and that is that I served in Congress,
2 as Dr. Bailet said, from '05 to just January or early
3 February of this year. And so I had the opportunity to
4 work specifically on the MACRA legislation. And with my
5 colleagues, we felt that it was incredibly important to get
6 physicians involved in defining or assisting in defining
7 what kind of payment model they felt would be the most
8 appropriate to facilitate their care of patients.

9 And so the PTAC was one of those things that we
10 were adamant about, we wanted to make certain was put in
11 place, because we wanted physicians to be able to have that
12 input. And now to have the opportunity to serve on the
13 administrative side, on the executive branch side, and to
14 try to put in place that vision that we had on the
15 legislative side doesn't always occur, and so it's an
16 incredible privilege for me to have that opportunity.

17 Physician-focused payment model, you know, when
18 you think about what this was named, "physician-focused,"
19 and you think, well, of course, you know, that's what we
20 ought to be doing, isn't it, the folks providing the care
21 out there? But if we're honest with ourselves, as a
22 nation, it's important that we appreciate where we find
23 ourselves now as it relates to the physician community.

1 And many physicians -- you read stories about physician
2 burnout. You never read stories about physician burnout 20
3 or 30 years ago, and now you read stories about physician
4 burnout. And we need to step back and say, "Why is that?"
5 Part of that reason, I believe, is the payment model and
6 the payment apparatus that docs find themselves working
7 under.

8 Dr. Bailet mentioned that I'm a third-generation
9 physician. My dad and my granddad were docs. My
10 grandfather practiced medicine until he was 94 years old.
11 Some said he probably shouldn't have practiced medicine
12 until he was 94 years old, but he did, and he inspired in
13 me a love of medicine. But you don't hear about
14 physicians, by and large, practicing anymore into their 80s
15 or 90s, or even their 70s. My peers, when they've reached
16 50, 55 years of age, a lot of them were looking for the
17 exit doors. And you think about the intellectual capital
18 that we're losing as a nation when docs 55, 60 years of age
19 say, "How can I end this professional run?" And so I want
20 to commend again the Committee for working in this arena
21 and being focused on what physicians feel out there.

22 And then payment model, I think it's incredibly
23 important to appreciate that what we're looking for is not

1 just a single payment model. And sometimes -- when I read
2 that earlier with my legislative hat on before, I thought,
3 well, are people going to think we're just looking for one
4 size fits all? And the answer to that is no. We want to
5 make certain that folks far and wide across this land who
6 are caring for patients have an opportunity to have input
7 into what a model for their care of their patients and the
8 payment for that care ought to look like.

9 So PTAC is incredibly important. The work that
10 you're doing is incredibly important, especially at this
11 vital, vital time. You will have the opportunity to
12 validate really exciting plans that folks have come up
13 with, and so I once again commend you for what you're
14 doing.

15 Dr. Bailet also mentioned the health care
16 principles that I've talked about, and they kind of morph
17 depending on what kind of focus we're putting on issues.
18 But accessibility, everybody wants a system -- and these
19 principles really run across the ideological spectrum.
20 Everybody wants a system that's accessible for everybody.
21 We want a system that's affordable for everybody. We want
22 a system that's of the highest quality, provides the
23 highest-quality care. And we want a system that innovates,

1 that incentivizes innovation, because that's the only way
2 that you maintain the highest quality of care, and then a
3 system that empowers patients. And in order to empower
4 patients, we've got to have a system that's transparent and
5 accountable and provides choices and is responsive to those
6 patients.

7 So this Committee actually runs across many of
8 those, whether it's accessibility, whether it's
9 affordability, whether it's the kind of quality that you
10 look at and try to determine whether or not a different
11 payment model will continue to incentivize the highest-
12 quality care, and then obviously the innovation that is so
13 necessary for our system. So I want to urge you to make
14 certain that you're looking far and wide across the models
15 that are coming before you.

16 I also want to urge others who may be listening
17 or may be responding to the call to propose a payment model
18 to not be bound by old ideas. This is a time of really
19 great innovation in health care on the clinical side. We
20 need to make certain that we're also innovating on the non-
21 clinical side, on the side that allows us to have the
22 finest and highest-quality health care system in the world.

23 So I want to call on physicians and other

1 providers all across the land, truly far and wide, to think
2 about what payment model might work better for them and
3 their patients, and to utilize the opportunity to put
4 forward that payment model, especially those in the rural
5 and the underserved areas. I know that the docs out there
6 in small communities, in the underserved areas, they
7 oftentimes feel that the rules that are coming down from on
8 high here from Washington are for those large, integrated
9 groups, that they're for the folks who are in the large
10 practices and have all of that administrative help beside
11 them. But I think there has to be a way -- if we're
12 listening to the folks actually providing the care, there
13 has to be a way to be able to allow them to have input into
14 a system that would work much better for them and for their
15 patients.

16 No more important time to do this than right now,
17 the opportunities that we have as we transition to a model
18 that, again, tries to identify and adhere to those
19 principles of health care, but make it so that we've got a
20 system that works from a financing and delivery standpoint
21 much more efficiently.

22 So the practicing doc out there, we need your
23 help. Your participation is absolutely vital to the

1 success of this wonderful, marvelous group that we've got
2 before us with incredible experience and expertise that
3 they bring to the table. They want to hear your ideas, and
4 I would urge you to make certain that you provide those
5 ideas and models for them as we move forward. This only
6 works with everybody's involvement, and so I encourage you
7 to do that.

8 I look forward to your recommendations. I look
9 forward to your continued work. And as I mentioned before,
10 we look forward to assisting you to make certain that we're
11 able to allow you and encourage you to do everything that
12 you can to come up with positive, positive solutions to the
13 challenges that we face in health care financing and
14 delivery.

15 It's an honor to be with you today. Thank you
16 very much. God bless you.

17 [Applause.]

18 [Pause.]

19 CHAIR BAILET: Good morning, everyone, and
20 welcome to this April meeting of the Physician-Focused
21 Payment Model Technical Advisory Committee, or PTAC. We're
22 delighted to have you all here. As you know, this is our
23 first series of meetings that will include deliberations

1 and voting on Medicare physician-focused payment models
2 submitted by members of the public.

3 We would like to thank all of you for your
4 interest in today's meeting; in particular, thank you to
5 the stakeholders that have submitted models, especially
6 those that are here today. Your hard work and dedication
7 to payment reform is truly appreciated.

8 We spent the past year establishing our processes
9 and procedures for receiving and reviewing physician-
10 focused payment models. We want to stress that our process
11 is shaped by input from stakeholders.

12 Although we begin deliberating and voting on
13 proposals today, we are committed to listening to your
14 feedback and evaluating our processes accordingly. We
15 value your comments at every level, especially as they
16 relate to our receipt and review of proposals.

17 We also wanted to remind all of you that PTAC is
18 a committee of 11 members, not a committee of one. To the
19 extent that questions may arise in the process as we
20 consider your proposal, please reach out to staff through
21 the PTAC.gov mailbox. The staff will work with me as Chair
22 and with Elizabeth Mitchell, the Vice Chair, to answer your
23 questions.

1 In the interest of consistency and responding to
2 submitters and members of the public, please reach out to
3 us through this process that we have in place.

4 Today, we will be deliberating on two models.
5 Discussions of each proposal will begin with presentations
6 from our Preliminary Review Teams, or PRTs. The PRT
7 reports are from three PTAC members to the full PTAC and do
8 not represent the consensus or positions of the PTAC. PRT
9 reports are not binding. PTAC may reach different
10 conclusions and a different recommendation from the one
11 that was contained in the PTAC report.

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

17 Following the PRTs' presentations, some initial
18 questions from PTAC members, the Committee looks forward to
19 hearing comments from the proposal submitter and the
20 public. The Committee will then deliberate and vote on a
21 recommendation to the Secretary of Health and Human
22 Services. It is our job to provide the best possible
23 recommendations to the Secretary, and we are excited to

1 begin this process.

2 I will turn to Elizabeth for any additional
3 comments and then any from our Committee.

4 VICE CHAIR MITCHELL: Thank you, Dr. Bailet, and
5 I wanted to just thank everybody.

6 As you've heard, we are very committed to an open
7 and transparent and fair process. We are eager to hear
8 from you, and our Committee has been very, very committed
9 to making sure that we are inclusive and really looking to
10 make this as successful as possible, understanding that
11 these are ideas from the field, and we are hoping to expand
12 the portfolio of models that are available.

13 CHAIR BAILET: Do we have any other opening
14 remarks from our Committee members?

15 Tim.

16 DR. FERRIS: Jeff, I just wanted to add that it
17 occurred to me during yesterday's discussion that not
18 everyone in the audience knows that we abide by the FACA
19 rules and do not deliberate on any of the proposals, except
20 in this public setting, and so have not discussed any of
21 these proposals, except within -- the PRT has. And I just
22 wanted to clarify that because I think that might not have
23 been clear yesterday that we are truly talking about this

1 as a group for the first time, here, now, in front of the
2 public.

3 CHAIR BAILET: Thank you.

4 Seeing no other comments from the Committee
5 members, I think it would be nice to start with
6 introductions and also disclosures of conflicts, and I'll
7 start with myself -- or just disclosures that we are
8 required to make to address any conflicts or impartiality
9 issues.

10 My name is Dr. Jeff Bailet. I'm an
11 otolaryngologist. I am the executive vice president of
12 Blue Shield of California. I am privileged to be here and
13 leading this esteemed, impressive group.

14 Elizabeth.

15 VICE CHAIR MITCHELL: Thank you.

16 Elizabeth Mitchell. I am the president and CEO
17 of the Network for Regional Healthcare Improvement, and I
18 have no disclosures on this proposal.

19 DR. FERRIS: Tim Ferris, internist and primary
20 care physician at Mass General Hospital, senior vice
21 president of Partners HealthCare in Boston, and no
22 disclosures.

23 DR. PATEL: Hi. Kavita Patel. I'm an internist

1 here in DC, and I have no disclosures.

2 DR. BERENSON: I am Bob Berenson. I am a fellow
3 with the Urban Institute and no disclosures.

4 DR. CASALE: Paul Casale, cardiologist at New
5 York-Presbyterian, Weill Cornell, Columbia, and I have no
6 disclosures.

7 MR. MILLER: Harold Miller, Center for Healthcare
8 Quality and Payment Reform.

9 I have helped over the past year, the American
10 College of Allergy, Asthma, and Immunology on a payment
11 model for asthma, but I have no financial interest in that
12 model, and I do not see any conflict between that work and
13 the proposal that's here before us today.

14 And I think also it's probably important for
15 people to know that there is no limit on the number of
16 proposals that the PTAC can approve, so it's not like as if
17 this is a competition amongst a proposal.

18 DR. NICHOLS: I'm Len Nichols. I'm a health
19 economist from George Mason University. I direct the
20 Center for Health Policy Research and Ethics, and I have no
21 conflicts.

22 DR. TERRELL: I'm Grace Terrell. I'm a
23 practicing general internist at Cornerstone Health Care, a

1 multispecialty medical practice in North Carolina. I'm on
2 the board of a population health management company called
3 CHESS, and I am the chief executive officer of a
4 biotechnology company called Envision Genomics in
5 Huntsville, Alabama. No disclosures.

6 MR. STEINWALD: I'm Bruce Steinwald. I have an
7 independent consulting practice in health care financing
8 and Medicare issues. I'm a former government official in
9 numerous positions, and I have no conflicts.

10 MS. PAGE: I'm Ann Page. I'm staff in the Office
11 of the Assistant Secretary for Planning and Evaluation,
12 PTAC staff, and also the Designated Federal Officer for
13 this FACA Committee.

14 MS. STAHLMAN: And I'm Mary Ellen Stahlman, also
15 with the Assistant Secretary for Planning and Evaluation.
16 I'm the staff director for the PTAC staff supporting the
17 Committee.

18 CHAIR BAILET: Thank you.

19 We are now going to turn the meeting over to Len
20 Nichols, who is the lead for the PRT for the COPD and
21 Asthma Monitoring Project.

22 DR. NICHOLS: Thanks, Jeff.

23 I would like to call attention to the lead slide

1 there and remind everybody I stand on the shoulders of
2 giants with Dr. Tim Ferris and Dr. Grace Terrell. I don't
3 know how an economist got in charge of this, but, hey, it's
4 America. It's an interesting country. We'll do the best
5 we can.

6 And maybe even this will work. I'm supposed to
7 click to the right. Do I point this to the sky? See, I
8 told you we should have had a doc in charge of this, so it
9 would work better. We could probably find a human to do it
10 by hand, if we had to, I would guess.

11 CHAIR BAILET: We could. That's why they have
12 "technical" in our name. Right?

13 DR. NICHOLS: Oh, looky here. Progress is being
14 made. Thank you so much.

15 So I'm going to briefly review the PRT's role.
16 I'm going to talk about the proposal in general, the
17 summary of our review and some of the key issues, and we'll
18 talk through then the evaluation.

19 Basically, the way the process works is a
20 proposal comes in after a letter of intent has indicated a
21 proposal is coming. The Chair and Vice Chair of PTAC will
22 assign three members to serve as a preliminary review team,
23 and one of those members is tapped to serve as lead

1 reviewer.

2 Basically, the first thing we do is read the
3 proposal and make sure that we have the information we
4 think we need, and that includes both questions to the
5 submitter. And I would like to commend the submitter for
6 the response to our questions, which were quite voluminous,
7 and your answers were very good. And we also turned to
8 ASPE staff and some of their contractors to get more
9 information.

10 After we review the proposal, we get all the
11 information and so forth, and as you probably know, public
12 comments are available at all these stages. They see the
13 LOI. They see the proposal. They see the comments.

14 We prepare a report of our findings to the full
15 PTAC. That report is posted on the website two weeks prior
16 to this Committee meeting, and it's important to
17 reemphasize, as Jeff did at the outset, that PRT report is
18 not binding. PTAC may reach different conclusions. In
19 fact, members of the PRT may reach different conclusion.
20 We're free to do that as we deliberate and discuss things
21 with our colleagues going forward.

22 I will also say since the PTAC report became
23 public, the submitters filed a statement in response to

1 that, which I found insightful, but I think not everybody
2 had a chance to read it before today. But I'm pretty sure
3 my PRT members are reading it as I talk, so we'll keep
4 going here.

5 Okay. The intervention in general is to look for
6 COPD and asthma beneficiaries, and they would receive a
7 Bluetooth peak flow meter and some software tools to permit
8 data to go to a central server, which through monitoring
9 and management could trigger clinical interventions to
10 reduce early exacerbation and respond quickly to infection
11 detection so that we could accomplish improvements in
12 quality of life as well as lower cost.

13 The payment model calls for CMS to pay for the
14 flow meters, to pay an inflation-adjusted per-beneficiary,
15 per-month remote monitoring and management fee, to waive
16 copays for beneficiary access to the services, allow
17 collaborating pharmaceutical and device companies to
18 provide beneficiaries with discount pricing and coupons for
19 drugs or equipment that may be prescribed to control their
20 particular pulmonary conditions.

21 The proposal aims to improve the health of
22 patients, reduce avoidable ED visits and inpatient
23 hospitalizations. Reductions in emergency department and

1 inpatient utilization are expected to offset the costs of
2 the intervention and thereby lower the total cost of care,
3 and the submitter expects to reduce mortality as well.

4 We briefly review our preliminary judgments of
5 each of the 10 criteria as specified by the Secretary in
6 the final rule, and you can see pretty quickly, if you just
7 scan through there, they meet criterion on 8 of the 10. On
8 scope, we definitely think they did.

9 We'll go through these in general.

10 You see there are two where we didn't think it
11 met the criteria. The first, a high-priority item, is the
12 payment methodology specifics, and then integration and
13 care coordination, we didn't think it met criterion.

14 We were unanimous on all decisions, except for
15 one on flexibility. We had two vote one way and one
16 another, but in general, the conclusion was it met the
17 criterion by a majority vote.

18 The key issues that we identified, basically
19 there's no question this is a very high-priority issue for
20 CMS. There are a lot of patients with COPD and asthma, and
21 the framework the submitter has proposed, we think has
22 great merit. And I think it's fair to say we would like
23 this to be a successful payment methodology going forward.

1 We do think, however, there are elements of this
2 proposal that require further development, and that's why
3 we raised the concerns that we did.

4 Our first concern, which was clear from the way
5 the documents were presented, there were no quality
6 performance requirements to earn shared savings. In the
7 letter that I talked about that was submitted after the PRT
8 report became public, the submitter has indicated there are
9 some quality metrics, which I'd be happy to connect, and
10 we'll talk about that today as we go forward.

11 Do all of the PTAC members have that response? I
12 think it was handed out in paper before. Yeah, it was
13 electronically sent, but there were a lot of things sent,
14 so not everybody caught it.

15 The model does not count some real cost, such as
16 Part D spending and waiving of copays, and we can talk
17 about that as well.

18 The risk adjustment was the thing that probably
19 concerned me as an economist the most. The proposal was
20 based upon a number of chronic conditions the patient has.
21 This method has not been tested, and frankly, I think it
22 would be too risky to put a risk adjustment regime in place
23 like this, but we do think we can talk about how to modify

1 that over time.

2 And then the clinical concern was mostly that the
3 model didn't seem to have enough detail about how
4 integration would be achieved. Primary care providers
5 would not share in the financial risk or the incentives of
6 the program, and other providers behind the pulmonary
7 subspecialists were not clearly integrated with the care
8 delivery model as well.

9 So now I'll go through each specific criterion
10 and what our assessment of it was, and where I think it's
11 important, I'll bring in what the response of the submitter
12 was. And then we'll go from there.

13 So the proposal, as I said, aims to care for
14 patients with COPD and asthma to well-defined and
15 clinically important conditions, roughly 5.4 million
16 Medicare beneficiaries with either COPD or asthma or both.
17 The proposal would cover the daily monitoring. It would
18 utilize new technology, have two-sided risk, a lot of good
19 features we want. It would certainly broaden CMS's
20 alternative payment model portfolio by including pulmonary
21 physicians who are not participants in existing APMs, and
22 of course, it would be a large scope because of the size of
23 the Medicare population.

1 The initial proposal is for a 2,000-beneficiary
2 pilot, but it could be scaled up over time. So, in our
3 view, there was no question, this met the scope criterion.

4 The second criterion is quality and high
5 priority, and here, I think it's important to pay attention
6 to specific words. We do believe it meets the criterion,
7 but I think it's fair to say we think it mentally met the
8 criterion.

9 There is considerable literature that investment
10 in programs that enroll well-selected patients with chronic
11 conditions, characterized by frequent exacerbations,
12 resulting in hospitalization can effectively improve
13 quality and cost.

14 However, for this particular kind of
15 intervention, there is really only one study with
16 sufficient end to give us confidence. That study was
17 conducted in Germany, where a few things are different.
18 They have better beer. They also have different prices of
19 devices, and we didn't think that there was enough details
20 specified. And we can go through the details of that, but
21 many of the clinical details remain to be worked out.

22 However, we thought the promise of the
23 intervention and the plan of the submitter was sufficient

1 to say it met the criteria, assuming the other criteria
2 were met. We didn't want this to be the stumbling block to
3 success.

4 The payment methodology is the place where we
5 felt like there were questions that needed to be answered
6 before we would recommend going forward. Just remember the
7 basic approach. There will be a PMPM payment and a shared
8 two-sided risk arrangement, and that certainly seems
9 appropriate for this kind of clinical intervention, but
10 there are too many unspecified or questionable features.

11 I said in the proposal, there were no quality
12 performance requirements linked to earned shared savings.
13 In the response to the PRT report, the submitter identifies
14 a number of quality metrics, which I will leave to my
15 physician colleagues to discuss when we get to that.

16 The model does not count some real cost such as
17 Part D spending, which was a concern. I think we can talk
18 about that. When the submitter gets to talking, we will
19 have a back-and-forth. But one issue that was clear to us
20 at least in the way we interpreted the proposal was that
21 the model would waive the copays for the beneficiaries in
22 the project, and that we were afraid those costs did not
23 count in the way they described the model.

1 In the response to us, they said, "Oh, yes, we
2 meant those costs to count." So I think there was
3 confusion about whether those costs should count against
4 Medicare savings. So, fundamentally, they would have to be
5 made up in order for the submitter to win a bonus, and
6 that's important to understand.

7 Risk adjustment was the bigger issue, at least,
8 again, in my mind and I think in our collective minds
9 because -- and I think it's fair to say, Mr. Chairman, that
10 this group suffers from the same problem everybody else
11 suffers from. They don't have access to the great data
12 that would enable them to develop a more fleshed-out risk
13 adjustment model. So they proposed using number of chronic
14 conditions, which given the data they had was a reasonable
15 first step.

16 Our concern is that that has not been tested.
17 Our concern is there may be much better ways to do it if
18 they had access to good Medicare data, and that's precisely
19 the kind of technical assistance we would like to make sure
20 this submitter and others have access to at some point.

21 The per-beneficiary, per-month amount was not
22 based on the cost to provide these services. It was based
23 upon sort of an adjustment, given a number that had been

1 worked out for, I think, cancer care or something. So that
2 clearly needs a little bit more work.

3 And then the cost structure that would guarantee
4 the savings assumed device prices that were based on
5 European pricing, which is where this thing has been done
6 full speed before, and obviously, in the United States,
7 those prices are likely to be somewhat different than they
8 are over there.

9 And so, for those reasons, we reached unanimous
10 conclusion, this payment methodology does not meet the
11 criteria as laid out by the Secretary.

12 On value over volume, we thought it certainly
13 did. There's no question that it would enable clinicians
14 to efficiently monitor and manage a patient population with
15 great need, and the early detection is precisely the kind
16 of innovation that we want physicians to bring to fruition.

17 Flexibility, here is where we had our one non-
18 unanimous decision. We agree about all the facts. We
19 differ on the judgment about what to do with those facts.
20 The proposal is simultaneously rigid and somewhat vague.
21 There did appear to be a reliance on one specific device
22 and data transmission method.

23 The exact clinical protocols have not been

1 completely worked out, and that was a concern. But I think
2 the larger concern is that the proposal lacks sufficient
3 detail on how the coordination with other providers would
4 occur given the lack of specificity of the clinical
5 protocols. So two of us were willing to give the benefit
6 of the doubt; one of us was not; and that's why the
7 majority as opposed to a unanimous decision was reached
8 here.

9 There's no question this thing is eminently
10 evaluable, and here integration and care coordination,
11 which is somewhat related to the flexibility one, we felt
12 unanimously that it did meet the care coordination
13 criterion, but did not meet integration. It does not
14 describe in sufficient detail how primary care physicians
15 will be made part of this and does not describe really that
16 much about ensuring that the financial benefit will flow to
17 anybody other than the pulmonologist. So we thought there
18 was too much unspecified about integration, and this
19 decision was unanimous.

20 Patient choice, the patient enrollment is
21 optional, so it's kind of hard to argue with that. Patient
22 safety, again, there's a lot of focus on preventing early
23 exacerbations and infections, so we think patient safety is

1 strongly supported.

2 HIT, I think it's fair to say there's a lot of
3 work to do here because the specific software and device
4 interfaces would need to be developed, and for those of us
5 who have banged around these systems, that's not a simple
6 thing. But, again, we thought this is certainly all doable
7 and, therefore, we felt like the judgment was correct that
8 it did meet the criterion of the Secretary.

9 So there you have it.

10 CHAIR BAILET: I want to thank you, Len, and also
11 thank the members, Tim and Grace, for their efforts on this
12 PRT and all the heavy lifting that they did in your
13 analysis and summary. Thank you very much.

14 I'd now like to ask the Committee members if they
15 have any questions for the proposal review team.

16 Seeing -- oh, Bob?

17 DR. BERENSON: Yeah, I was hoping somebody else
18 would go first. In their proposal, they say the following:
19 "Based upon the review with the peak flow meter findings,"
20 et cetera, "any recommendations for medication change will
21 be sent through the primary care provider. Alternatively,
22 if the PCP allows the pulmonary specialist, the CAMP will
23 make these changes, and they will be recorded in the

1 patient's EMR."

2 Did the PRT pursue this at all to determine
3 accountability for the patient's well-being? That's a
4 concern I have. In the questions, I didn't sort of see
5 anything additional to sort of ask -- find out how this
6 would work. I could imagine responsibility falling through
7 the cracks in this kind of a situation.

8 DR. FERRIS: We agree, and that was precisely why
9 we --

10 DR. BERENSON: The integration [off microphone]--

11 DR. FERRIS: The integration. We did not --
12 there was not an explicit plan for the integration of care
13 between multiple providers. Those patients with COPD don't
14 just have COPD, so it's not only the primary care provider
15 for whom this specific question you ask, Bob, but also
16 other specialists. Very frequently have cardiac disease,
17 it's very frequent for COPD patients to have a
18 cardiologist.

19 So the proposal, I think it's fair to
20 characterize the proposal as being fairly robust in the
21 specific area of care for patients with COPD and asthma,
22 but much more limited in its description of how you provide
23 in this model patient-centered care that involves the

1 integration of all the other physicians who are taking care
2 of the patient.

3 DR. BERENSON: I mean, this, I guess I could
4 reserve it for later, but in the clarifying letter, which
5 is a helpful letter, in the current model we envision using
6 medical assistants supported by pulmonary nurses, IT
7 software engineer, two nurse case managers, a behavioral
8 psychologist, a respiratory therapist, a statistician, and
9 a medical director, but no pulmonologists are mentioned.
10 And it seems like it's not a physician-focused payment
11 model. It seems to me it's disease management support.
12 And that's one of my concerns about it. I will mention
13 some others when we get to the later discussion.

14 DR. FERRIS: Can I respond [off microphone]?

15 CHAIR BAILET: Please, go ahead.

16 DR. FERRIS: So because of where the proposal is
17 coming from, I think we gave the proposer the benefit of
18 the doubt that this was pulmonology-focused since that was
19 the ostensible platform on which this is working. And I
20 would say that the team of people identified in that list
21 is precisely the kind of practicing at the top of your
22 license, have the real work done by physicians, and have
23 the constant contact associated with other monitoring

1 systems through IT or outreach to patients that helps stave
2 off remediable exacerbations. That's precisely the kind of
3 team that one might put together to enable that kind of
4 performance. So I think we -- while I agree with you it's
5 not explicit, I think we read it as part of a whole in this
6 setting.

7 CHAIR BAILET: Harold?

8 MR. MILLER: This I guess is somewhat related to
9 the question Bob raised, but the issue that -- this is also
10 related to the proposal yesterday. So we have an applicant
11 who is, in fact, a physician practice who has a particular
12 approach to changing care, in this particular case using or
13 wanting to use Bluetooth monitors and, you know,
14 respiratory techs, et cetera, et cetera, et cetera. But
15 the payment model, if I understand it correctly, is to pay
16 a per-beneficiary, per-month payment. It is not
17 specifically to pay for Bluetooth monitors or to pay for
18 respiratory techs. And if this particular practice would
19 choose to use the PBPM in that way, that would be their
20 choice. But if the payment model is a PBPM, then some
21 other practice could choose differently to be able to do
22 that and would then be accountable for the outcomes.

23 So I just wanted -- and I'll ask the applicant

1 this, too, but was your understanding of the model that it
2 was to give the practice a per-beneficiary, per-month
3 payment, and then they could decide, whoever got it could
4 decide what to do with it? Or was the payment model to pay
5 them specifically for this particular defined technology
6 and intervention?

7 DR. NICHOLS: So part of the payment model was to
8 provide the Bluetooth meter to the patient, so that's a
9 given. The technology is a given. And the PBPM was to
10 provide the resources for the team that Bob just
11 articulated in addition to the pulmonologist to manage
12 those patients.

13 MR. MILLER: Right. There were two pieces --

14 DR. NICHOLS: Certainly -- and there's also a
15 third. There's a shared savings component against the
16 target --

17 MR. MILLER: But the PBPM would not be tied --

18 DR. NICHOLS: No.

19 MR. MILLER: -- to a specific structure of --

20 DR. NICHOLS: That was not my understanding. It
21 would be flexible from the clinician's point.

22 DR. TERRELL: Although there was some -- in the
23 questions, some discussion of particular algorithms that

1 they had developed or would develop with respect to how the
2 management of these patients would proceed with the team
3 that they were involved with. So whether it was a specific
4 algorithm or care pathway or another or some other way,
5 whether there was flexibility in the model, I think your
6 questions, both of you, are getting at how much of this is
7 proscribed is a good one.

8 There was work that was alluded to with respect
9 to the fact that they have some of this fleshed out and
10 have developed algorithms in place that were particularly
11 tied to a care pathway. This gets back to what we talked
12 about a little bit, I think, yesterday with respect to care
13 models versus payment models and the concern that I
14 expressed then that this is going to continue to be the
15 thing that we've got to understand the relationship between
16 the two. So I think your question is a good one.

17 MR. MILLER: Well, and particularly when we have
18 a practice with a particular approach coming in and saying
19 the payment model would allow this, but the payment model
20 then would also potentially allow other things, which is a
21 -- and that's one of the issues on the flexibility is, is
22 there the flexibility to do it differently or does the
23 payment require use of that algorithm and does the payment

1 require this particular staffing structure?

2 DR. TERRELL: And the other side of that from my
3 point of view is you really have to have very robust
4 quality and outcomes measures as part of a payment model if
5 there's flexibility in what it pays for. And the
6 supplementary information that we receive that you all have
7 in front of you on paper today, we're seeing some of those
8 outcomes measures laid out, hospitalization, ED visits and
9 all of that. But the real need in the situation where
10 there is flexibility and some people could potentially use
11 it for other ways of doing care management has to be around
12 very, very vigorous outcomes measures, in my opinion.

13 CHAIR BAILET: Elizabeth, your question links to
14 Harold's?

15 VICE CHAIR MITCHELL: Yes, thank you. I think
16 it's actually very similar, but I just wanted to get a
17 little bit more precise, because we're talking about a
18 specific product. And as we talked about yesterday, that
19 might not always work in some practices.

20 So you say that this same model could work if
21 another product offered the same functionality, so you
22 could endorse the model without endorsing the specific
23 product?

1 DR. NICHOLS: Yeah, that was a concern we had
2 when the proposal came, and, in fact, when the proposal
3 came at that time, the device had not yet received FDA
4 approval, which even made me nervous. But we asked CMS
5 about this notion of having one particular supplier of a
6 given commodity, whether or not it had FDA approval, and
7 they said, "Well, you know, in certain circumstances we
8 could work it out." And they sort of implied it really
9 depends a lot on what kind of price they're going to charge
10 and other things.

11 Since then, in the communication we got after our
12 PRT report was posted on the website, it's clear that the
13 submitter understands and would like us to understand you
14 could use different technologies to do -- you don't have to
15 have that one machine. And, by the way, it has now gotten
16 FDA approval.

17 VICE CHAIR MITCHELL: Thank you.

18 DR. NICHOLS: But yes, you could use different...

19 DR. FERRIS: I'd also respond just to add on to
20 that. I think maybe building on Grace's comments about the
21 care model and the payment model dynamic that I think we
22 saw yesterday and we're going to see more of, you know,
23 it's fairly easy for someone to propose, a physician to

1 propose or a group to propose, just give me a fee and I'll
2 figure it out, put me at risk and I'll figure it out. And
3 that's the payment model, right?

4 Having the submitter specifically explain what
5 they're going to do lends credibility to the proposal, or
6 not, if what they propose to do doesn't seem credible. But
7 having the care model -- so the application appears to
8 present us with very specific -- like we will use this
9 Bluetooth thing. I think when you think about the payment
10 model, I'm reading the application as this is a credible,
11 or not credible, clinical intervention that is going to
12 provide greater outreach for a group of unstable patients,
13 and that's going to reduce their rate of hospitalizations.

14 But once you propose that, I don't feel when I'm
15 evaluating the payment model like I'm tied to the very
16 specific care model that they propose, because that care
17 model works in that practice and in that situation. And so
18 specifics on the care model are important, but not
19 determinative of whether or not the payment model is a
20 viable payment model. That's just sort of the way I'm
21 thinking about it.

22 CHAIR BAILET: Thank you, Tim. Kavita?

23 DR. PATEL: So I'm going to ask questions to the

1 PRT, but I found also that it might be helpful to hear what
2 Jeff and Elizabeth think. I'm struggling a bit what to do
3 because it does seem like the responses clarify some of the
4 issues specifically around the quality metrics, cost
5 metrics, and that may or may not -- I mean, for me at least
6 changes a little bit on kind of how I think about that
7 section on quality, cost, and potentially the value over
8 volume question. So I'm not sure -- kind of I'm out loud
9 kind of questioning, you know, do we kind of take this
10 information and how would you kind of process responding to
11 what I think is clarified? So that's a little bit of a
12 process and substance question.

13 The second question I -- oh, go ahead.

14 DR. NICHOLS: Well, let's just get one at a time.
15 How about that?

16 DR. PATEL: All right. Go ahead.

17 DR. NICHOLS: Because I think that's a very
18 important place to start, because let me just say this is
19 why I'm glad I'm not a doc. I think that Tim and Grace
20 should respond first, but all of you should talk about the
21 proposed quality -- because we saw the absence of that --
22 in the response letter you just saw, they said, "Oops, we
23 meant to include it," you know, whatever. So here we are.

1 So I think you should look at it specifically and draw your
2 own conclusions, and I'd be glad to learn from your
3 thoughts.

4 CHAIR BAILET: Tim.

5 DR. FERRIS: I guess, Kavita, I, too, found their
6 responses very helpful, and they now put us in the realm of
7 plausibility. But they actually don't tie -- there's no
8 formula to tie them, and as we know, tying them to the
9 model is actually a nontrivial exercise. So what I would
10 say is it's very helpful and directionally appropriate.
11 But I'm still not sure that the response constitutes a
12 payment model, at least in a payment model insofar as it is
13 specifically evaluable. Like I still can't say would this
14 work or not because there's no math there to -- there's no
15 formula.

16 CHAIR BAILET: Kavita, also embedded in your
17 question was a process issue.

18 DR. PATEL: Right [off microphone].

19 CHAIR BAILET: We have spent considerable effort
20 lining up the evaluation, communicating with the submitter,
21 working with the proposal review team, drafting the
22 recommendations. A lot of distillation of information has
23 occurred. And, again, we operate transparently, and we

1 want to have the back-and-forth with our submitters and our
2 stakeholders. Everything is put out for public comment.
3 That's the other thing that is digested by the proposal
4 review team.

5 Our challenge -- and this is really not specific
6 to this proposal -- is that as a Committee, when you get a
7 six- or seven-page letter with exactly the kinds of
8 information that will help us sharpen our thinking on this
9 proposal, the timing makes it very challenging for us as a
10 Committee to digest this information thoughtfully and then
11 be able to have a rich deliberation, as you see playing out
12 before you this morning. That's a challenge, that's a
13 process challenge, and I don't profess to be able to solve
14 that today. But that is something that we're going to have
15 to address going forward, because we've had -- you know,
16 it's not just this proposal, but we have a similar
17 circumstance with some of the other proposals as well.

18 Harold, and then Grace.

19 MR. MILLER: I think it would be good just to
20 spend a minute on this, just to build on Jeff's invitation
21 to people who are listening to send us suggestions about
22 how we might improve our process, because it seems to me
23 that there's at least three options one might do to address

1 this.

2 One is that the PRT report, the draft PRT report,
3 needs to come out farther in advance of the meeting, which
4 would then give people an opportunity to respond to it and
5 then to have it potentially revised, but that would delay
6 the process.

7 The second option would be to have a process for
8 tabling something at a meeting and saying we can't make a
9 decision today because the new information that we've
10 gotten is more significant, or to have some kind of a rapid
11 revision, resubmission, and re-review process afterwards so
12 people don't sort of get a no and then have to completely
13 start all over again. And I'm not sure at all which of
14 those is the right approach to use, and it would be, to me,
15 useful to hear from, you know, people who are thinking
16 about this and watching the process kind of what their
17 reactions are so as we consider the options, we could take
18 that into account.

19 CHAIR BAILET: Grace, and then Len.

20 DR. TERRELL: One of the issues, therefore, is,
21 is the process we have of our review adequate or not to
22 where these things could have been put forth earlier? So,
23 I mean, you can question this for any of the reviews -- the

1 one later this afternoon, this one, or the one yesterday --
2 well, why are we getting information at the last minute or
3 later than sort of the process that may be changing our
4 mind or allowing us to have a richer set of things?

5 We set the process up with 20 pages only so that
6 we wouldn't get hundreds of pages of stuff that wouldn't
7 necessarily get us to where we needed to go. And then we
8 have a review of that information, research that we do.
9 And then we have a series of questions back-and-forth. And
10 I've participated in two of these now, and they have been
11 based on some free-form conversation between the members of
12 the PRT saying, well, I've been thinking about this, and
13 you've been thinking about this, and developing a series of
14 questions, some of which were, you know, 39, 40 questions,
15 of which we got very good answers back.

16 But maybe that's not -- maybe that's really a
17 problem in the process right there. That needs to happen,
18 and then there needs to be something much more specified
19 that would get there. I don't know. But it would seem to
20 me that as we're evaluating this one in front of us now, we
21 based our initial assessment and reports on the information
22 that we had after going through that process, and then
23 we've got other information here just like we did yesterday

1 that elaborates on that. I'm not sure that's a bad thing.
2 It could potentially always happen but -- simply because
3 you learn as you go along. But whether this changes the
4 outcome today or not really is going to depend on as we go
5 through the rest of this process.

6 It doesn't, I believe, eliminate the essential
7 problem we saw with this particular proposal, and that is,
8 they needed help that we weren't able to give them because
9 of the constraints we're under. And that is, had they had
10 some ability to under -- had some technical help that would
11 have allowed them to maybe flush through some of the issues
12 with respect to the payment model particulars that we then
13 critiqued them for, it could have made it stronger. That's
14 what we've got to get better at. This is a good example of
15 a proposal that has some very, very, very good things. We
16 desperately need in this country ways of providing better
17 care to COPD patients, that is, probably several types of
18 innovative care models linked to payment methodology that
19 will allow physicians to do that. But the actual details
20 that they needed to get there, as we've talked about
21 earlier this morning, were not part of our process, and we
22 weren't able to help them do that, as you know.

23 CHAIR BAILET: Len.

1 DR. NICHOLS: So I would just pick up on Grace.
2 I think, in fact, this is working. I sort of don't think
3 that we need to necessarily change it. I'm not sure I'm
4 convinced it's broken.

5 What I think has happened is that we got the
6 proposal. We asked a bunch of questions. They answered
7 the questions. We asked questions of professionals who
8 know more about data than we do. We thought about it. We
9 wrote the PRT report.

10 I think the PRT report, if you will, sharpened
11 the mind of the applicant in a way, "Okay. That's what
12 they're worried about." Boom, boom, boom. This thing
13 right here is a good piece of information.

14 I don't think it came too late for us to be able
15 to think about it. It did come in email. It's just that I
16 don't think everybody on the Committee got that
17 email. I think that's where we are.

18 And so, to me, this is the way it should work. I
19 totally agree with Harold. If the information was
20 sufficiently game-changing, I might want to table, but I
21 don't feel like that's required today, given everything
22 else that we've got.

23 So, in some ways, the only thing I would suggest

1 we'd change in the process -- and I think this might have
2 been proposed at one point. I'm looking at Mary Ellen,
3 because you probably thought of it, and we probably nixed
4 it. Maybe we should send the PRT report to the submitter
5 before we go public and have a little more time, one more
6 round of back-and-forth.

7 I think my concern was, oh, my God, that will
8 delay it, but if these guys respond as fast as this man
9 did, I don't think we've got a real problem with delay. So
10 I think maybe we should reconsider that.

11 CHAIR BAILET: I want to make sure, Kavita, you
12 have another section to your question, but I think, Paul,
13 if you're going to respond to the original --

14 DR. CASALE: Yeah, this will be quick. I'm sort
15 of with Len. I mean, I don't think that it's really very
16 broken.

17 I mean, at some point, you put out the report;
18 you're going to get a response. We've seen it. All three,
19 we've gotten responses organically from all three, and I
20 think whether we send it to them earlier, et cetera, but I
21 think we need to receive it earlier as a full Committee, to
22 be honest with you. And I don't think -- you know, if I
23 had it a week ahead would be fine.

1 And I just want to emphasize --

2 DR. NICHOLS: Well, to be fair, it did come in an
3 email.

4 DR. CASALE: Right.

5 DR. NICHOLS: -- and I saw it, and Mary Ellen
6 called my attention to it. And I said, "That's
7 interesting. I'll read that next week when we get there."

8 DR. CASALE: Yeah. Right.

9 And I guess the other point that I'd want is this
10 is the preliminary report, and I think preliminary is okay.
11 Again, it doesn't have to be perfect and have everything
12 when we get here. Just two points.

13 CHAIR BAILET: Thank you, Paul.

14 And Elizabeth.

15 VICE CHAIR MITCHELL: Yeah, just a quick
16 additional comment. I'm associating myself with Len.

17 The entire intent of this public forum is to get
18 additional information, and I think we are genuinely
19 committed to incorporating that to the extent possible. I
20 am relying on my colleagues to help sort of evaluate do
21 these new metrics make a difference in your initial
22 assessment, but -- it might be hard to watch, but we really
23 are deliberating in real time, and I think additional

1 information is really the name of that.

2 CHAIR BAILET: Thank you.

3 Kavita.

4 DR. PATEL: Oh. So the second -- I have kind of
5 a second set of questions around kind of the PRT's
6 reaction, and I know there's some kind of mention to it
7 around the risk adjustment.

8 If I look at your PRT recommendations and even
9 aside from your recommendations kind of go through each of
10 the criteria, thinking through that -- and we'll vote on
11 that -- I still find myself kind of hung up on -- I found
12 myself kind of troubled by the risk adjustment kind of --
13 or the -- it's, on one hand, very novel because we
14 certainly -- they made a very interesting argument about
15 kind of using the number of conditions. We know that using
16 HCC -- we know that there are a lot of flaws in current
17 risk adjustment methodology to explain kind of the clinical
18 variance.

19 But my question to you all is how much of that
20 was a discussion around specifically that section. You
21 reference it in your summary of the PRT kind of section,
22 Len, but I'm just -- and especially now seeing the response
23 from the submitter.

1 And then I will say I agree with -- I just -- and
2 then the -- kind of a related question is how much of this
3 tension of -- you know, this is a very highly -- you know,
4 unlike the conversation we had yesterday, this is an
5 incredibly prevalent disease, an incredible opportunity to
6 reduce hospitalizations, ED visits. We now see that they
7 are actually thinking about those quality metrics as part
8 of the response. So tell me a little bit about the
9 struggle to think about -- or did the kind of sense of
10 prevalence or impact that this could have on a very kind of
11 burdensome condition kind of come up? So -- and then I'm
12 done. Those are the two questions.

13 CHAIR BAILET: Go ahead, Grace.

14 DR. TERRELL: I just have a quick technical
15 point. Because of work that my organization has done in
16 this same area, including developing care models in COPD, I
17 did not feel compelled to have a lot of discussions about
18 that because one of our criteria were Charlson scores or
19 basically identifying people who had five or more chronic
20 diseases as being in and of itself a risk model. So
21 getting the details from them of the stuff that I guess I
22 already assumed was knowledge I had from my own experience,
23 there was not a lot of dialogue back-and-forth. That may

1 well have been an error on my part or our part, but it was
2 the risk adjustment, that there is data out there that you
3 can use number of chronic conditions with an n of 5 being
4 the number that seems to be a cutoff for levels of stronger
5 development of care models.

6 So you can have five stable chronic diseases and
7 one bad one, COPD or whatever, and that in and of itself
8 can be a -- for those that don't have fancy data, EMRs, any
9 other types of things, including registries that many
10 sophisticated groups have, you can do that with a
11 relatively simple practice criteria.

12 To the Secretary's point earlier about smaller
13 practices or rural practices, that's one thing that's a
14 very simple way of sometimes doing some of this.

15 DR. PATEL: So you saw that as a plus? I just
16 want to make sure.

17 DR. TERRELL: I saw it as a plus.

18 DR. PATEL: Because I know that in your
19 submitter's, I couldn't --

20 DR. TERRELL: We didn't have that dialogue.

21 DR. PATEL: -- infer --

22 DR. TERRELL: I had that dialogue in my own head
23 so --

1 DR. PATEL: Okay. Because I couldn't tell from
2 the questioning back-and-forth if you thought those --

3 DR. TERRELL: Yeah. There was not the
4 questioning back-and-forth --

5 DR. PATEL: -- if you felt that was a detractor
6 or a -- okay. All right.

7 DR. TERRELL: -- because I was making so many a
8 priori assumptions.

9 DR. PATEL: So that would actually indicate that
10 this has a novel aspect to it that's not incorporated in
11 any other current payment methodology, just to clarify.
12 Okay.

13 DR. NICHOLS: Oh, I think it's very creative. I
14 think unambiguously in favor of giving them the technical
15 assistance we think they need to get to the Promised Land.

16 I will point out that the letter that came around
17 in email said they agreed with our assessment of the number
18 of chronic conditions. A letter that came more recently
19 did not.

20 DR. PATEL: Right.

21 DR. NICHOLS: Well, I'm confused, too, because I
22 thought this was a printed version of what came in the
23 email, but this is a different letter. Okay.

1 CHAIR BAILET: Yes.

2 DR. NICHOLS: So there are some differences of
3 opinion, and we probably should just table that. I would
4 just say, in my mind, I'm still not in favor of chronic
5 conditions, but go ahead.

6 CHAIR BAILET: Tim.

7 DR. FERRIS: Well, I did want to say that,
8 harkening back to our discussion yesterday about what might
9 work for one group and what one group is willing to do, our
10 job is actually to think about the implications of a model
11 generalized. And, again, it's novel. It's really
12 interesting. There are risk adjustment methods where you
13 can simply count conditions, but in this particular setting
14 and in this particular model, this has not been tested.

15 And I would say to base the financial future of a
16 group of physicians on a risk-adjusted model that there is
17 no empirical experience with is a risky thing to do, and
18 that is where it sort of fell down for me.

19 CHAIR BAILET: Kavita, are you --

20 DR. PATEL: Yeah, I'm done.

21 CHAIR BAILET: Okay. Very good.

22 Any other questions from the Committee?

23 [No response.]

1 CHAIR BAILET: Well, then at this time, I'd like
2 to invite Dr. Ikeda up to the microphone, and please
3 introduce yourself for your remarks, which will be in the
4 10 minutes. Thank you.

5 DR. IKEDA: Thank you very much.

6 CHAIR BAILET: There you go. You're good.

7 DR. IKEDA: Thank you very much.

8 My name is Daniel Ikeda, and I am a physician
9 from Sacramento, California, in private practice.

10 I am boarded in pulmonary medicine, infectious
11 diseases, and critical care medicine. I belong to a multi-
12 pulmonary and infectious disease group in Sacramento in
13 private practice. We have about 25 of us, and we operate
14 both in an office-based practice as well as act as
15 intensivists in multiple hospitals in the Sacramento area.

16 And so when we looked at the changes in MACRA,
17 one of the things that we were anxious to look at is a way
18 to use telemedicine in order to achieve the six goals that
19 Dr. Price had talked about.

20 We have had -- been very experienced in
21 telemedicine in the intensive care unit, where one of the -
22 - probably the beta site for the VISIQ EICU back in 2003,
23 and through that experience really got a feeling as to what

1 telemedicine has to offer medicine in general.

2 Not only are we able to use a single physician to
3 multiple, multiple hospitals for acute interventions, but
4 the data repository developed through this system allowed
5 us to actually look at outcomes to create pilots on various
6 papers or ideas and to see whether or not we can validate
7 these very different things.

8 Early work in sepsis allowed us to reduce
9 mortality from 40 percent to 28 percent in a matter of
10 months, and we're able to use that experience to then apply
11 protocols throughout the city to achieve similar results.

12 And as we come to look at COPD, the problem with
13 COPD in the clinical practice is that it's a difficult
14 disease to manage, and the problem with the expertise in
15 the area is that much of us as pulmonary physicians are
16 really drawn more toward a hospital-based practice.

17 Currently, I spend a week a month in the office
18 because all the priorities for my expertise is in the
19 hospital, and clearly, there is a need out there for better
20 monitoring and management of these sick patient
21 populations.

22 Now, in looking at this project, I mean, I figure
23 when you create a proposal, you ask for everything you

1 want, with the expectation you're going to get pushback,
2 and that's why I'm here.

3 [Laughter.]

4 DR. IKEDA: But I didn't know how else to write
5 the proposal.

6 But, clearly, the one thing I do want to talk
7 about is the risk adjustment methodology.

8 Part of doing risk adjustments, especially when
9 we're willing to take risk, is looking at what are current
10 models of risk-based treatments. As you look at history of
11 capitation, it's all generally based upon a benchmark base,
12 typically on a mean, and the goal is to improve financial
13 outcomes based upon that mean.

14 Now, the problem with that is that in the past,
15 these types of plans are subject to cherry picking. In
16 other words, if you can get a population of low-risk
17 patients and skew your distribution curve to that side,
18 your numbers are going to look great, but you don't
19 necessarily provide the care that you really want to do.

20 So, for instance, in COPD -- and having access to
21 the chronic condition database, which appear to be very
22 robust and stable based upon just looking at averages over
23 years, it provided us at least a thought of an opportunity

1 to see if we can actually develop a capitation model that
2 doesn't reward cherry picking, because if you think about
3 how this would work under a classic condition, as part of
4 the evaluation, somebody created brand-new tables that were
5 great. I wish I had them when I wrote the proposal.

6 And among the comments was a fact that based upon
7 their evaluation of a universe of COPD patients with
8 existing COPD, which had the biggest n, the average cost of
9 care was about \$24,000.

10 Now, when we did our proposal, we specifically
11 removed the low-risk patients, patients with Conditions 1
12 and 2, and by doing so, our average cost of care was
13 \$32,000.

14 Now, it's the same population because we did the
15 calculations both ways, and so that suggests that if this
16 [unintelligible] were to go forward on a classic capitation
17 model, then there is a risk that the whole process would
18 fall apart because of gain-sharing, and that's not what our
19 purpose was.

20 As a critical care physician, I am very
21 comfortable taking care of very sick patients, and it's
22 really this population of patients in the outpatient that
23 needs the case. In a classic capitation model where I'm at

1 risk for losses and wins, for every sick patient I get, I
2 want two or three healthy patients, if that's the model of
3 capitation.

4 But using a model that actually forms separate
5 buckets of risk -- and, in this case, using chronic
6 conditions as that -- informing a mean, a median, knowing
7 what the 99 percent distribution on the high side is for
8 the fat tail, it provides us now a much better ability to
9 skew my distribution curve toward the sickest of the
10 population, which is the population that really needs the
11 service, without the fear that I'm going to screw myself
12 over because I've chosen a [unintelligible] distribution of
13 patients.

14 And so, as we look at the risk to me and to our
15 group, I am far more concerned about a risk-based model
16 that is based upon the universe of COPD patients because,
17 first of all, the annual cost of care is much lower.
18 Therefore, I would have to actually improve care by a much
19 more dramatic amount in order to achieve savings for
20 Medicare.

21 On the other hand, if I had a capitation model
22 that actually looked to capitate the high-risk group at
23 their true cost, then reductions in cost related to

1 reductions in ED visits and hospitalizations will
2 dramatically improve the overall cost in the high-risk
3 group, which will be reflected in the overall cost of care
4 based upon a comparison, an apples-to-apples comparison of
5 distribution of, say, patients with, say, nine chronic
6 conditions or seven to nine chronic conditions. You can
7 probably lump them at that base, because in those tables,
8 Table 1 shows that the distribution of patients from 1 to
9 20 actually formed a pretty good normal distribution, but
10 obviously, the costs associated with the zero percent
11 versus the 99 percent are vastly different.

12 And that's why we developed this proposal,
13 specifically looking for a model that we would be willing
14 to take risk in, and the only model that really works is
15 not taking care of the healthy portion of that population,
16 because that would actually cost money to Medicare as
17 opposed to save money to Medicare.

18 And so that's why we developed this methodology,
19 to really address that question, and based upon that,
20 obviously we have concerns about tail risk in this high-
21 risk population. I don't have an answer to that, except to
22 say that as we did our per-member, per-month fee, we
23 started first with an assumption that, well, what is a

1 reasonable number to start working with as a benchmark, and
2 so we went to the oncology model. And they suggested about
3 a six percent cost increase. Now, whether that is valid or
4 not, at least it gave us a benchmark that we can put aside
5 and say, well, okay, for 2,000 patients, that's a revenue
6 stream of \$4.2 million for our proposal.

7 Then the question is, is this something we can
8 financially do, make it valuable, but more importantly, can
9 we create a model that is then scalable?

10 So setting that aside, we have been working on
11 budgeting as to what we would actually need for this
12 process, and part of that is really in the paper that I
13 sent today, where basically outlining what are beneficiary-
14 to-health care ratios that would be appropriate and safe,
15 what are the supervisions, what type of ancillary help I
16 need, setting up a new office, needing health care
17 consultants to help through this process of the data, which
18 is really critical to this type of project.

19 And our annual budget to maintain the program
20 right now is running about \$3 million, proposed. Plus,
21 there is infrastructure cost that started that we probably
22 will estimate at about 5- to \$800,000. And then that
23 leaves the remainder, which we felt in order for us to have

1 a go at this, we would need at least a 20 percent revenue
2 withhold in order to protect ourselves if the project fell
3 apart. So we're talking \$800,000 to \$1 million that we
4 would basically put in a withhold account in order to cover
5 our downside risk.

6 And with that, we felt we can actually do this
7 project and accept the risks, which are still unknown to us
8 to a great extent, but create a model by which population
9 monitoring can now be financially viable.

10 And that's the key. That's a problem with
11 telemedicine. There is no good financial model to make it
12 a viable product, but if this project works, then all of a
13 sudden, it opens the door for other things.

14 Now, regarding coordination of care, when I did
15 the proposal, I realized that if we are talking about
16 receiving revenue for multiple chronic conditions, at some
17 point we would have to address the other chronic
18 conditions. And the dilemma I had in the proposal was not
19 talking about that because I didn't want to deviate focus
20 from the primary project. So now we're talking about,
21 well, we can do telemonitoring for multiple chronic
22 conditions. And in reality, that's not really what I want
23 to do right now. I need to validate our assumptions first

1 with what I think is the easiest of the chronic conditions
2 to actually save Medicare money. You know, as a 30-year
3 expert in infectious disease in pulmonary, this type of
4 system will recognize infections at early stage. It
5 doesn't have to be pulmonary. It could be something else.
6 It will recognize early exacerbations of COPD. And if we
7 can capture that and, more importantly, train patients on a
8 continuing interaction to recognize these things and know
9 what to do ahead of time, we will go a long way in
10 preventing ED visits and hospitalizations.

11 And so, you know, I find the discussion between
12 the care model and the reimbursement model very interesting
13 because we struggled with that, too. We want the care
14 model, but we have to develop a reimbursement structure
15 that would make it viable, but more importantly, if
16 successful on a limited basis, is it economically feasible
17 to scale up? And that's the input I can give you right
18 now.

19 And I'm open for any other questions.

20 CHAIR BAILET: Thank you, Dr. Ikeda.

21 Tim you had a question, and then Bob.

22 DR. FERRIS: Well, first just a comment. If more
23 physicians in the United States were so focused on the

1 integration of a care model that is proactive and
2 attempting to minimize the utilization of services, at the
3 same time so thoughtful about the payment models that are
4 necessary to undergird and support that kind of care model,
5 then we wouldn't have a reason for existing.

6 [Laughter.]

7 DR. FERRIS: So having said that, I did just want
8 to get your take on a specific concern around -- I'm sorry,
9 this is going to be a little technical, but you seem to be
10 up to it. If you simply count conditions, I'm going to
11 read you five conditions for two different patients,
12 chronic conditions. So the first patient, Patient A, has
13 hypertension, arthritis, gout, psoriasis, and chronic
14 sinusitis. The second patient has heart failure,
15 amyloidosis, stroke, coronary disease, and diabetes. Those
16 two patients are not even remotely similar from either a
17 cost or a care delivery perspective.

18 And so while I am really excited about the
19 novelty of the method you're proposing, I'm not sure, given
20 those two different scenarios, that there is not still an
21 opportunity for a risk adjustment system to either be
22 abused -- which all of them do; we're not letting the
23 perfect be the enemy of the good -- or that through some

1 random chance, the risk adjustment system actually might
2 leave a physician's practice in the lurch due to just the
3 variability in the selection of patients that it was
4 unanticipated and uncontrollable. And so I just wonder if
5 you'd comment on that.

6 DR. IKEDA: So what I will tell you is that,
7 obviously, the two patient examples you gave me, first of
8 all, none of them had COPD, all right? And I think that's
9 critical at least to this proposal.

10 DR. FERRIS: The comorbidities.

11 DR. IKEDA: Right.

12 DR. FERRIS: There was an assumption that they
13 both had --

14 DR. IKEDA: So everybody in my cohort of patients
15 will have COPD or asthma as a defining condition to enter
16 the program, because that's the area where I have the
17 expertise to intervene. You know, and just looking at the
18 new data tables that came out -- and the one I'll reference
19 is Table 2B. So if you look at that particular table, and
20 you look at ED visits, ED visits related to COPD,
21 hospitalizations, hospitalizations related to COPD, there's
22 a validation that in patients with COPD much of their high
23 utilization costs are due to their lung disease and not to

1 their other comorbid diseases. And that's the disease
2 state that I'm targeting to control, and that's why I am
3 proposing I take all this risk to prove it.

4 Does that answer your question?

5 DR. FERRIS: It answers the question in the sense
6 that you, because of who you are and what you're committed
7 to, are willing to take on the risk. But it does not
8 answer the question of whether or not either the system is
9 gameable or that it could result in adverse financial
10 consequences to any specific practice given an
11 uncontrollable risk selection.

12 DR. IKEDA: So I presume we'll be a guinea pig.

13 DR. FERRIS: I'm sorry?

14 DR. IKEDA: I presume we'll be a guinea pig.

15 CHAIR BAILET: Yeah, yeah. Thank you. Bob?

16 DR. BERENSON: So let me start by saying that I'm
17 very sympathetic to what you're trying to accomplish here.
18 I have a family member who wound up on a ventilator two
19 consecutive winters for weeks at a time because early
20 symptoms were ignored, and that's what happens. So I'm all
21 for it. But I have some concerns.

22 Let me ask you this: You're in Sacramento. It
23 is the heart of Medicare Advantage country. Are there

1 Medicare Advantage plans who have been interested, or
2 capitated medical groups -- there's over 200 of them in
3 California -- that would be at risk and presumably would be
4 quite interested in a technology that could reduce
5 hospitalization and morbidity and mortality. So what's
6 been the experience there?

7 DR. IKEDA: Well, the answer is there is a great
8 deal of interest. But the question is: At what cost and
9 what reimbursement? That's unestablished since we really
10 don't have -- this is not a viable program as we sit here
11 today. So, you know, part of this proposal from our minds
12 is to establish what is a pricing model that we can use as
13 a benchmark as we go to a Medicare Advantage plan. And I
14 don't know what the answers are related to that, because I
15 know what our costs are going to be, and it's not
16 inexpensive. And so from that perspective, you know, I
17 have two medical directors that want to talk to me, you
18 know, after we get this process done, and we are anxious to
19 look at that.

20 Down the road, we want to treat asthma in
21 MediCal, or in Medicaid since we're in Washington, DC.
22 And, originally, this project was developed for, I think,
23 the Innovation 2 grants, but I couldn't finish it in time

1 to submit for that. I really wanted to treat a Medicaid
2 population using this model.

3 Obviously, since it was a grant, I didn't know
4 what the payment model would be afterwards and whether it
5 would be sustainable. But that's water under the bridge
6 now. But I think that this type of care is easily
7 replicable for Medicare Advantage plans and capitated
8 plans.

9 Now, whether it's designed to improve care or
10 reduce costs is a different matter because you can --
11 because in each individual Medicare Advantage plan, they
12 may not have the sufficient volume of patients in, say,
13 COPD to make it, you know, worthwhile for us to do and for
14 them to entertain, although it may be very viable for them
15 to choose high-risk patients in general and monitor them
16 that way. But then the goals and outcomes would be
17 different necessarily. It's not necessarily to save money
18 -- it is, in one sense it is, but really to provide better
19 overall care and hopefully through that process reduce the
20 costs to Medicare, which are not as predictable as with
21 patients with COPD.

22 DR. BERENSON: Let me just follow up. My concern
23 basically is that -- well, if I were -- let me just say

1 this: If I were a Medicare Advantage chief medical
2 officer, I would be looking for more than a German study to
3 demonstrate the proof of the concept. This strikes me as
4 quite relevant for clinical research to prove the
5 effectiveness. We do know that disease management has
6 potential negative impacts when one organization is doing
7 the disease management and they are not integrated with the
8 practice that's actually responsible for the patient.
9 Those would be the kinds of questions -- so I guess my
10 question is: Have you attempted or thought about the need
11 for doing clinical research to prove that the intervention
12 actually works to improve quality and decrease cost before
13 trying to get a national payment model in place?

14 DR. IKEDA: The answer is I'm a clinician; not a
15 researcher. And through, you know, our experience with
16 telemedicine as well as in the practice of pulmonary
17 medicine, we strongly believe as a group we will save
18 money. We will prevent people like your relative from
19 hopefully getting sick enough where he ends up intubated.
20 I mean, I see this all the time in the intensive care unit.
21 And when I talk to them after we've hopefully saved their
22 life, I ask them, "Well, how many days of symptoms did you
23 have before you came to the hospital?" And typically

1 there's this window of time, whether it's two to five days,
2 where patients ignore their deteriorating symptoms and come
3 in where it's too late to intervene at a point where they
4 don't need to go to the ICU. If I can capture these
5 patients early, I will prevent their hospitalization. I
6 know that.

7 And so based on the studies that we have read,
8 we've seen enough information so that we are willing to
9 take risks on this because we firmly believe we will
10 achieve the outcomes that will provide the six points that
11 all of you are looking for in all your projects. We have
12 that type of conviction.

13 CHAIR BAILET: Thank you. Harold?

14 MR. MILLER: Thanks. And thank you for doing all
15 this work. I agree with Tim that this is the kind of thing
16 that we hopefully will be encouraging. I had, I guess,
17 three questions.

18 The first one in some ways is related to the
19 question that Bob was raising, which is that, if I
20 understand the proposal correctly, the physicians in your
21 group would not actually ever see the patients in person --
22 you can clarify if I'm wrong about any of this -- and that
23 there would be basically a remote monitoring to support

1 other physicians, primary care physicians or otherwise, who
2 are the primary care managers for the patient. And as Bob
3 was referencing, most of the experiences with care
4 management programs have shown that unless there is some, a
5 direct patient contact, at least for a portion of the time,
6 not totally, and that there is some real involvement of the
7 patient's primary care physician who's managing the
8 condition, that the results are less successful. I have my
9 own personal experience, having run a project like this,
10 which is getting the primary care physician or whoever is
11 managing the patient to be engaged with the patient, to
12 have them accept that this thing that they're participating
13 in is helpful is important.

14 So I wasn't quite sure that I understood exactly
15 in reading the proposal how you envisioned that connection
16 sort of from the patient's perspective working. So someone
17 is helping them manage their COPD or asthma. You're
18 helping them manage that. And how would this appear from
19 the patients' perspective? And how would the patient feel
20 like there was really a team working together to support
21 them?

22 DR. IKEDA: Those are all very good questions.

23 MR. MILLER: Thank you.

1 DR. IKEDA: What I will tell you is that
2 everything we envision looks at these issues. The reality
3 of what we actually are going to do still is in flux, you
4 know, because I don't have a specific answer for you.

5 What we envision, though, is that as patients
6 become linked to us through this daily interaction, what we
7 hope to happen is that they will call us first if they
8 think they're in trouble. And based upon that call, we can
9 intervene, initially remotely, with maybe hourly or daily
10 follow-up to ensure that they're not getting worse. And if
11 they are not getting worse, you know, we will plan to see
12 the patients if they are local.

13 Now, as we go to a more scaled issue, that's
14 going to be much more difficult, but that's why I believe
15 in scaling. It will require a consortium of physicians to
16 really take over that portion, that role. You know, I
17 think that what this continuous interactive monitoring will
18 do behaviorally is really try to reset behavior, to make
19 patients, you know, adherent to a certain time of day doing
20 certain functions, becoming more educated and empowered to
21 recognize their symptoms, to take presumptive action given
22 a specific set of rules, and to call us and let us know
23 what's going on so that we can make sure they've made good

1 decisions; and if they're not doing better, to get them to
2 an appropriate health care provider immediately so that
3 they don't end up in the emergency room. And if that
4 health care provider is us, then that's what we're
5 committed to do.

6 MR. MILLER: That all makes perfect sense to me,
7 and I have seen that in action. The challenge I'm talking
8 about is how to actually get the patient started in that
9 process, to actually be -- because I've seen the problem
10 that patients have had enough of yet another person being
11 involved. So I guess I would just suggest that I think
12 that sort of how you get the patient engaged and how do you
13 have the PCP engage the patient is important.

14 The second question I wanted to ask is: If I
15 understand it correctly, again, you're proposing a flat
16 per-beneficiary, per-month payment, and the risk adjustment
17 would apply to the spending target, even though it would
18 seem to me that the patients who have more needs and more
19 diseases are, in fact, going to take more time. So I
20 wonder if you think there is still a potential for a cherry
21 picking problem with a flat PBPM.

22 DR. IKEDA: I don't know the answer to that. You
23 know, I presume that as patients have many more chronic

1 conditions, that bucket mean cost will be much higher than
2 somebody with three less chronic conditions. Obviously,
3 that sicker patient will have a higher likelihood of going
4 to the ED and being hospitalized. And, yes, they will
5 require more time, but really that's the patient that needs
6 the time. You know, that's why when we look at ratios of
7 providers to patients, we'll get a sense as to who the
8 patient populations are at highest risk of having problems.
9 And, you know, I can't tell you we have processes for that
10 right now, because we don't. But, clearly, you know, if we
11 can identify a cohort, a subset of that patient, that we
12 can say they're going to be in the hospital in the next
13 three months unless we change things, then it's imperative
14 on our part, even if only from a financial point of view,
15 to create a treatment plan designed to attack this in
16 conjunction with the primary care provider, because many of
17 the problems that we may face and I expect to face will be
18 non-pulmonary. And we have to acknowledge that we will
19 play a role in that intervention to get the patient to the
20 right provider.

21 MR. MILLER: But I'm accurate that you're
22 proposing a flat per-beneficiary, per-month payment --

23 DR. IKEDA: That is correct.

1 MR. MILLER: -- and not a risk-adjusted payment.
2 And the third question, which I was convinced that Bob was
3 going to ask but he didn't -- and probably will if I don't
4 -- is COPD and asthma are both underdiagnosed and
5 misdiagnosed conditions. And I wonder what you have
6 thought -- so, again, when a model like this all of a
7 sudden the payment is based on the patient having the
8 condition rather than a particular service being performed.
9 And I wonder if you've thought about particularly, again,
10 given your, in a sense, distance from the patient, that you
11 won't actually, if I understand again correctly, have seen
12 the patient yourselves and diagnosed the patient, whether
13 you've thought about what problems that might create and
14 whether there are ways to address that.

15 DR. IKEDA: Well, I think part of it is patient
16 selection, correct? And that's particularly what you're
17 pointing to. You know, we foresee, starting the project,
18 initially looking at our own patient population to see how
19 many chronic conditions they have and whether or not they
20 would fit a program like this. We envision that many of
21 the patients that we try to enroll into this program will
22 be patients who actually are captured through their ED
23 visit and hospitalization.

1 And so meeting that gold standard of having a
2 disease sick enough to be treated in an ED and hospital
3 kind of skews the population more toward the more at-risk
4 side than to the healthy side.

5 MR. MILLER: Well, potentially, I guess it does
6 get still to the issue of how good the risk adjustment is,
7 but I just want to make sure I am understanding this
8 correctly.

9 I thought when I read your proposal, you were
10 talking about providing this support for a broad regional
11 range of practices. This is not essentially we are a
12 pulmonary medicine practice and we want to have this
13 service for the patients that we manage completely
14 ourselves, sort of a specialty medical home concept.

15 This is the concept where you would be providing
16 a supplemental special service for others who are managing
17 it. So the point is you would not necessarily have been
18 seeing these patients. You would only see them after
19 something bad happened eventually.

20 DR. IKEDA: Correct.

21 MR. MILLER: And even -- I'm not even clear on
22 whether then you would see them, because they might end up
23 at a hospital that you don't staff.

1 DR. IKEDA: That is correct.

2 MR. MILLER: Okay.

3 DR. IKEDA: So I don't know what happens when it
4 scales, when we go beyond areas that we physically can
5 service, and to that extent, I am kind of trusting the
6 database because I figure the database is going to be the
7 same, either way, as patients become more remote to us
8 physically, that people all of a sudden aren't going to
9 come up with new diagnosis of COPD in order to get into the
10 program if they lived 90 miles away, at least that's my
11 assumption.

12 MR. MILLER: Thank you.

13 CHAIR BAILET: Kavita and then Bruce.

14 DR. PATEL: Dr. Ikeda, I first wanted to commend
15 you because I can only imagine -- it seems like your
16 imprint is all over this proposal. I can't imagine how in
17 private practice and what sounds like a very typical busy
18 practice, you actually had the time to pull this together.
19 So I wanted to just tell you that I could never have done
20 that, and I'm impressed.

21 I wanted to ask kind of two -- you've seen now
22 the communication kind of back-and-forth, and it seems like
23 there is some kind of questions about how -- even with your

1 thoughtful response about the quality metrics, kind of how
2 you're thinking about maybe tying that to the payment
3 model. I respect that your day job is to actually take
4 care of patients, so you don't study payment models on a
5 daily basis.

6 But do you mind -- just having heard that
7 critique, can you articulate how you may have thought about
8 the linkage in quality with what you're proposing?

9 And then my second question -- that was just the
10 first one.

11 DR. IKEDA: Okay.

12 DR. PATEL: The second question ties to what
13 Harold mentioned about the diagnosis issue --

14 DR. IKEDA: Right.

15 DR. PATEL: -- because, as an internist, we know
16 that so many people are misdiagnosed probably by my own
17 hands, and so there's reliance on your ability to do kind
18 of thoughtful pulmonary function testing, et cetera. In
19 whether it's the German study or other studies, have you
20 seen some kind of requirement or criteria that has like a
21 documented basis for the diagnosis?

22 DR. IKEDA: Well, most of the studies don't talk
23 about chronic conditions, number one.

1 DR. PATEL: Right.

2 DR. IKEDA: They talk about COPD.

3 DR. PATEL: Right.

4 DR. IKEDA: And most of their entry criteria are
5 based upon spirometry data.

6 Now, as it turns out, these new peak flow meters
7 actually have spirometry capabilities, and so looking --
8 and that's why we chose that, because, number one, it would
9 meet PQRS standards daily, and we'd be able to evaluate
10 that to determine if, in fact, we thought patients were
11 misdiagnosed based upon that data. That's not great, but
12 at least it gives us more information to deal with. That's
13 that question.

14 Regarding the first question, as providers of
15 care in our telemedicine unit in the ICU, we have been
16 dealing with quality standards and metrics for the past 13
17 years, and typically, our reimbursement for our services
18 are tied to meeting certain benchmarks in those quality
19 standards. So we don't have a problem being benchmarked to
20 quality standards and attempting to meet those goals.

21 I guess the question is, What are the important
22 quality standards of the person paying me, and what do they
23 want? Because I can propose a list of different quality

1 standards, and they may not have an interest in those,
2 maybe because I can achieve them so readily. And I'm more
3 than happy to ask the payer, "What are your quality
4 standards, and what benchmarks do you want to hold us to?"
5 And I'm perfectly happy doing that. We're very comfortable
6 with that process.

7 DR. PATEL: In one of your letters of support --
8 I want to make sure; I was trying to flip through to find
9 it -- it looked like it was the State of California or DHS,
10 perhaps.

11 DR. IKEDA: Yeah.

12 DR. PATEL: So you mentioned Medicaid.

13 DR. IKEDA: We mentioned Medicaid.

14 DR. PATEL: We have a letter of support from the
15 state. California enjoys one of the broadest delivery
16 system reform waivers. Was there ever a question or
17 potential for like a State of California Medicaid-level
18 pilot or kind of building a -- Bob talked about MA. I'm
19 just curious --

20 DR. IKEDA: Right.

21 DR. PATEL: -- if that came up in --

22 DR. IKEDA: Well, they were really interested in
23 us getting the grant.

1 DR. PATEL: You mean getting this to work?

2 DR. IKEDA: Getting the grant in order to do the
3 pilot.

4 DR. PATEL: You mean the original CMMI grant that
5 you had applied for?

6 DR. IKEDA: No. For the Innovation II grant.

7 DR. PATEL: Innovation II, okay.

8 CHAIR BAILET: Yes. Right.

9 DR. IKEDA: And so when that fell through, they
10 were not necessarily interested in creating a funding model
11 for it.

12 DR. PATEL: Okay. Thank you.

13 CHAIR BAILET: Bruce.

14 MR. STEINWALD: I would like to follow up on one
15 of your responses to the question raised by Dr. Ferris on
16 risk adjustment. Clearly, that was an important issue for
17 the Preliminary Review Team.

18 I want to make sure I got this right. When Dr.
19 Ferris identified these two very disparate patients with
20 five chronic comorbidities and you agreed that they were
21 very different -- but I think you said because they all
22 have COPD and COPD tends to dominate the costliness of the
23 patient, you weren't so concerned that those comorbidities

1 were very different from each other.

2 Do I have that right, and if I do, could you
3 remind us on why -- on what basis do you make that
4 assertion that it's the lung disease that really dominates
5 the patient's costliness?

6 DR. IKEDA: Well, I have to look at the data. I
7 mean, the data with COPD as a primary or secondary
8 condition dominates ED and hospital admissions, at least
9 looking at the data that was provided to the team. That
10 was our initial assumption, quite honestly, is that in
11 patients with multiple comorbid diseases, inability to
12 breathe is probably the single most frequent symptom
13 forcing people to go to the emergency room.

14 Now, inability to breathe may not be due to COPD.
15 It may be due to heart failure, but clearly that plus
16 infection. So, based upon that, I don't really know how to
17 control a lot of these other chronic conditions like
18 arthritis. Clearly, I know that control of hypertension is
19 good, but it won't necessarily be reflected in any
20 immediate outcome benefit.

21 So based upon lack of information that control of
22 other chronic diseases adversely impacts the overall cost
23 and utilization, as long as they have COPD, that's the one

1 variable that I propose to control.

2 Does that make sense? Does that answer your
3 question, I guess?

4 MR. STEINWALD: Let me follow up just for a
5 moment. Yes, it's the one intervention that you hope to
6 control, but it also -- as I understood your response to
7 Dr. Ferris, it also makes you more comfortable that the
8 differences in comorbidities of different patients with
9 COPD don't concern you that much because the COPD lung
10 disease dominates, in your view, the costliness of the
11 patient.

12 DR. IKEDA: I guess the real answer is I don't
13 know.

14 MR. STEINWALD: Okay.

15 DR. IKEDA: But I am willing to find out.

16 MR. STEINWALD: Thanks.

17 CHAIR BAILET: Grace.

18 DR. TERRELL: Just a series of questions, some of
19 which are just very quick answers. First one is there's
20 chronic care management codes that are part of the fee-for-
21 service system now. Did you all look at those? Have you
22 used them? If not, why not? Has there been an opportunity
23 to think about that with respect to the processes that

1 you're doing?

2 DR. IKEDA: Well, I don't see that code as
3 necessarily being applicable to telemedicine --

4 DR. TERRELL: Okay.

5 DR. IKEDA: -- because the proposal, as written,
6 is not really designed to be a chronic disease management
7 skill, although that's incorporated into the process.

8 If we're being paid a per-member, per-month
9 benefit and taking risk, I don't see why I should be
10 charging an additional charge for chronic care management.
11 I mean, that seems to be double dipping.

12 DR. TERRELL: I was just looking at in lieu of
13 that. In other words, right now, without this payment
14 model, there were some other things that are out there.
15 Are you utilizing them, and if not, why not?

16 DR. IKEDA: Obviously, the whole impetus for us
17 wanting to do this project is to look at MACRA and how as
18 specialists we can participate in some form of advanced
19 payment methodology that would basically allow us to get a
20 five percent increase in our Medicare payment.

21 DR. TERRELL: Okay.

22 DR. IKEDA: And that's a very big incentive for
23 us, as it would be for any other provider that enters this

1 program.

2 I don't see how using the chronic care management
3 codes achieves that goal, unless you can tell me.

4 DR. TERRELL: Okay. My next question is, if you
5 were wildly successful with this -- you've sort of alluded
6 to this with some of your answers to some others, and we
7 just were able to really work this out for your group and
8 your region. What steps would you see that we would take
9 to make this a national payment model, given the
10 specificity of your particular situation with your practice
11 resources, versus sort of the Wild Wild West of the entire
12 U.S. health system?

13 And the reason I'm getting to this, you alluded
14 to it earlier. You wrote, I think, initially a grant
15 proposal that you didn't get in on time --

16 DR. IKEDA: Right.

17 DR. TERRELL: -- and used that thought process to
18 actually write a proposal for a payment model, and one of
19 the tensions, I believe, that's going to continue to happen
20 at the level of PTAC are folks who are thinking about their
21 own circumstances and saying, "You know, if I had this
22 particular thing, I could really practice better medicine
23 and achieve things that I can't in the current system,"

1 versus if we looked at that, how could we roll that out
2 above and beyond just an individual practice? As we are
3 thinking about that at the level of PTAC, that's one of the
4 things that we are really working on.

5 So any wisdom you have or any thoughts you have
6 as to how we could go from your specific circumstance to a
7 wider policy approach, I would be interested in hearing
8 your thoughts.

9 DR. IKEDA: Well, what we assumed is that if we
10 were wildly successful, people would find out and re-create
11 the model --

12 DR. TERRELL: Okay.

13 DR. IKEDA: -- because the payment methodology
14 would be there, and that's part of the intent.

15 Do I think I could provide services nationwide?
16 No, I don't think so.

17 DR. TERRELL: Okay.

18 DR. IKEDA: I mean, if I can just provide a
19 region-wide, that would be a start, and maybe we'd have
20 some expertise at the end of this to scale up and down
21 California and maybe some of the local states. But my
22 expectation is the economic benefit related to this and the
23 ability to be designated as an advanced payment methodology

1 will attract other people once they figure out that the
2 real risks in doing this right are small.

3 Right now, people think I'm crazy to propose a
4 capitation model that's based upon treating the sickest of
5 the sick, but I do believe -- and as a group, we believe --
6 that we can accomplish this goal. So I hope from that
7 standpoint, we're successful because, if we're successful,
8 the proposed payment model is economically robust enough so
9 that it should withstand, hopefully, the bad fat tail risk
10 that is always going to be out there or ultimately will
11 come to agreement with CMS assuming -- that's one of my
12 questions, actually, is if the proposal gets approved to
13 pass on to the Secretary, it's really my assumption that
14 CMS will look at the proposal and at that point start
15 making changes to the actual implementation of the concept
16 to an entirely different plan, and I was kind of preparing
17 for that discussion at some point in time to see how that
18 works.

19 Once those particulars are worked out, then the
20 model is then out there for other people to duplicate.

21 DR. TERRELL: Okay.

22 DR. IKEDA: And I think that's the answer I will
23 give you.

1 DR. TERRELL: All right.

2 DR. IKEDA: But I think if I am wildly
3 successful, this will scale rapidly because it has all the
4 advantages that we all seek in terms of patient care
5 outcomes, and it's financially viable for whether it's a
6 system-wide health care plan to incorporate and then start
7 using those revenues to treat their Medicaid patients in
8 addition, because if I am correct and we are wildly
9 successful, that's the population I really want to treat,
10 because there is no good payment model for that. And
11 providing the service individually is very expensive.

12 DR. TERRELL: A couple more questions. One of
13 the things that's interesting about a model that's taking
14 care of the sickest of the sick and doing it in a capitated
15 risk point of view is related to end-of-life issues, and
16 there's a point where integration with palliative care and
17 not doing everything, it sometimes prevents the patients on
18 a ventilator.

19 How much of the model that you have here --

20 DR. IKEDA: Envisions --

21 DR. TERRELL: -- can address that?

22 DR. IKEDA: Envisions that possibility?

23 DR. TERRELL: Yeah.

1 DR. IKEDA: Well, it's interesting that you
2 mention that. One of the Innovation I projects that was
3 completed was a project called AIM, which deals with the
4 last life of care, and that project was performed by Sutter
5 Health, which I'm affiliated with. So I'm well aware of
6 that process. One of my partners is certified in
7 palliative care, and so we've talked about, to some extent,
8 how to incorporate these concepts.

9 Obviously, in doing so, it will increase our
10 mortality --

11 DR. TERRELL: Right.

12 DR. IKEDA: -- since in planning for end of life,
13 we have to assume that we're actually increasing mortality
14 over the short term, as documented by the successful study
15 by Sutter, where they did save Medicare in that program a
16 large sum of money.

17 So, obviously, we're not going to reinvent the
18 wheel there but intend to work with Sutter in this process.

19 DR. TERRELL: Okay. The final question I have is
20 respect to the quality stuff that initially we felt that
21 your application didn't address adequately. What you've
22 brought back to us today are quality measures that are
23 related to utilization of services. It's hospitalization

1 and ER and all that. But one thing that's true about the
2 pulmonary and the chest specialist is they've got very
3 specific, more traditional guidelines with respect to
4 quality that have to do with utilization of certain types
5 of pharmacotherapy, long-acting beta-agonist vaccine, many,
6 many other things, when to use pulmonary rehab.

7 Is there a reason why you did not think about
8 those as being something that should be part of this
9 measure with respect to quality and outcomes? Is that
10 something that you're just already doing? Is that
11 something that the care model itself would or would not be
12 part of? I'm just curious about that because those, I
13 presume, are the things that, at least as far as we know
14 right now, have some impact on long-term management of COPD
15 exacerbations.

16 DR. IKEDA: Well, you are absolutely correct, and
17 in fact, in the proposal, I listed that we would be using
18 guidelines from these models.

19 Now, whether or not Medicare would want to
20 benchmark on compliance with these, we're perfectly open
21 for that, because really benchmarking to quality goals is,
22 in our minds, primarily the desire of the person paying us,
23 because we want to be benchmarked to the goals they want to

1 measure versus the goals necessarily that we want to
2 measure.

3 DR. TERRELL: Thank you.

4 CHAIR BAILET: Dr. Ikeda, I share Dr. Patel's
5 earlier comments and applaud your efforts, given that
6 you're a busy critical care physician.

7 I have a couple of questions. I don't want to
8 get, necessarily, into the weeds, but you made an earlier
9 comment about your experience with the eICU. You were one
10 of the early adopters or worked in a system that had
11 adopted that. Having placed that system within a 2,000
12 employed-physician group and 15 hospitals, I want to
13 understand that. These initial 2,000 patients, are these
14 your patients specifically, or is this a population of
15 patients that you are going to be monitoring, much like the
16 eICU methodology?

17 DR. IKEDA: Well, I think for this initial
18 recruitment, it would have to be locally. For the pilot we
19 would have to look into Sacramento County residents. Now,
20 in Sacramento County, based upon the latest data, there are
21 18,000 people, Medicare, with a diagnosis of COPD.

22 CHAIR BAILET: Okay.

23 DR. IKEDA: So the population is there. And so,

1 you know, we, in our office, see just the tip of the
2 iceberg, which are typically the sicker of the sick, and
3 obviously a number of my patients, in my practice, would
4 benefit from something like this. But we also see many
5 patients that are not as well monitored or cared for,
6 through the emergency rooms at various hospitals, that get
7 admitted, and we envision trying to create a program to
8 recruit and enroll those individuals into the program, and
9 we'll find out how successful that is once the program is
10 running, assuming it's approved.

11 CHAIR BAILET: Right.

12 DR. IKEDA: But that's what we envision first, is
13 really, it's that high-risk population where the capture
14 point typically is going to be in the hospital-based
15 setting.

16 The other component will be an outreach to the
17 varying groups in town, as well as to competing
18 organizations, such as, in Sacramento there is Kaiser and
19 UC Davis.

20 CHAIR BAILET: Right.

21 DR. IKEDA: And we want to be open with them as
22 well, to offer the services and allow them to participate
23 in this as well. But I think before I can go to that next

1 step, I need an actual payment model that I can say, you
2 know, we're going to pilot this. Dr. Louie, you know, at
3 UC Davis, you know, can you -- are you interested in, you
4 know, in doing the research and seeing how this works as an
5 independent provider?

6 And so I think, you know, we'll be able to
7 achieve that 2,000 through a variety of means, although I
8 clearly don't have an actual number of distribution as to
9 how that's going to happen.

10 CHAIR BAILET: So, thank you for that
11 clarification, and here is directly what I have a question
12 about. This is new, and I was on the ground when eICU
13 concept came to the fore, and the challenge that we had,
14 which was not necessarily just the challenge within my own
15 practice, was that these patients, if they're not your
16 patients, have very strong relationships, because of their
17 comorbidities and just their sort of genetic makeup, if you
18 will, they are very sticky to other physicians.

19 DR. IKEDA: Exactly.

20 CHAIR BAILET: And the other physicians have a
21 very significant influence over what happens with these
22 patients, and what happened in the eICU environment were
23 that you had this cohort of physicians who were not their

1 physicians but they, by chance -- by just the nature of the
2 program, were monitoring these patients. And there was a
3 lot of tension between the monitoring physician and the
4 physician cohort that actually had a very strong bond, and
5 patients were -- there was a lot of tension. There was a
6 lot of opt-out. There was a lot of challenges in the early
7 adoption.

8 And so I guess I'm curious, have you thought
9 through -- have you had that experience? You've thought
10 through those challenges, having been in the trenches?

11 DR. IKEDA: Well, I was the medical director
12 during the time.

13 CHAIR BAILET: And you're still here to talk to
14 us.

15 DR. IKEDA: And so I had to talk about the fact
16 that we weren't big brother, and we're not trying to take
17 over the care of their patients. And it took a long time,
18 in some instances. You know, obviously, you know, whenever
19 we did write an order on such a patient we certainly
20 contacted the physician, indicating the reason why we
21 intervened. But over time it worked out. You know, they
22 lost fear.

23 But regarding this project, you know, clearly,

1 you know, if we get the green light, one of the first
2 projects is really a physician outreach, town hall if you
3 wish, to find out how do they feel about entering their
4 high-risk patients. What do they get in return? Obviously
5 we want to make sure that any patient that's entered into
6 the program meets their MIPS PQRS standards, so that they
7 can report that. Clearly, we want to be a lifeguard and a
8 safety net for their high-risk patient population, similar
9 to what we do in the eICU. And, clearly, we want to figure
10 out how coordination of care should occur without the
11 physician on the other end feeling we're usurping their
12 responsibility and their patient population.

13 So those are all issues that, you know, we look
14 at, and that's why, in part, with the coordination of care
15 I kind of didn't know what to do with that question.

16 CHAIR BAILET: Yeah, well, and that's something
17 that we'll discuss when that metric comes up a little
18 later. Elizabeth?

19 VICE CHAIR MITCHELL: Thank you, and thank you
20 very much for the proposal. I have two questions and a
21 comment.

22 My comment, first, was just to sort of recognize
23 and applaud your statement that said you were ready to be

1 held accountable for the priorities for whoever is paying
2 you. Having worked with public and private employers, that
3 is not always something that people are so bold about, so I
4 just wanted to recognize that.

5 My question, one is on sort of the HIT aspect of
6 this. I think the PRT -- and you said that there is
7 clearly a technology component that people are comfortable
8 with. I'm more interested in the information-sharing
9 aspect of that criteria. And you've acknowledged some
10 potential barriers created by the, perhaps, lack of
11 interoperability across the EHRs.

12 So can you comment on how much of a barrier you
13 think that will be, and some of your thoughts on how that
14 will be addressed?

15 DR. IKEDA: Locally, it shouldn't be that big a
16 problem. You know, right now, you know, in our private
17 practice we use an EMR called Athena, which has no
18 connectivity at all with any of the EHRs from the groups,
19 so currently we end up faxing and scanning a lot of stuff.
20 But at least within our region we are now -- it is starting
21 to coalesce around Epic. You know, the Sutter system has
22 it. It looks like the Mercy outpatient system is going to
23 -- or Dignity now -- outpatient system is going to evolve

1 to it. Kaiser has it. UC Davis has it.

2 And so for the purpose of this project, we would
3 probably use Epic as our platform, which allows
4 connectivity to the varying providers city-wide. So
5 locally, that's easy.

6 You know, as we think about scaling it, it does
7 become an issue, and I don't have good answers to how we're
8 going to -- how we would approach and overcome those
9 issues. That's what I think I need an IT, you know, person
10 to talk to, other IT people, about how we can make that
11 happen.

12 VICE CHAIR MITCHELL: Well, thank you. That
13 actually segues to my other question, which is very similar
14 to, I think, Grace's question about scale, because,
15 obviously, scalability is a key -- well, key part of our
16 thinking. But my question was more focused on readiness.
17 You have been, I think, extremely candid and open about the
18 unknowns of this model, which is entirely appropriate.
19 That's why you're here. But do you have a sense -- and
20 this may not even be fair -- sort of the readiness of
21 others in the field to test this, or how much needs to be
22 learned before it is scalable?

23 DR. IKEDA: I think a lot depends upon whether or

1 not we're as successful as we hope we can be. You know,
2 success breeds a lot of interest and taking people off the
3 inertia step. You know, clearly, if we see signs that this
4 is working very well, you know, we can start contacting
5 other major groups in different cities to see if they have
6 an interest.

7 I mean, you know, as pulmonary specialists we do
8 have a network, and we can utilize that network,
9 potentially, to scale people into their own communities if
10 they have the interest. But everybody is going to be
11 scared in the beginning, because the risk-sharing model I'm
12 proposing is obviously unique. You have concerns about
13 them. They are going to have even more concerns, since it
14 would be their money on the line. And so the answer is, if
15 we are wildly successful then scaling becomes a slam-dunk.
16 If we're not successful, it goes nowhere.

17 VICE CHAIR MITCHELL: Fair enough. Thank you.

18 CHAIR BAILET: Paul.

19 DR. CASALE: Yeah. I will just add my gratitude
20 for bringing this forward. Thank you. Clearly a lot of
21 work has been put into this.

22 Just a quick question. You know, in the BPCI
23 model, one of the clinical conditions is COPD, asthma. Did

1 you ever have a conversation or think about, again, within
2 the physician community that you work in, to participate in
3 that, and maybe leverage this as part of that?

4 DR. IKEDA: No, we did not. I mean, we're not
5 that familiar with that model, to be honest. I mean, most
6 times I'm in the intensive care unit, and so, you know, I
7 used to have a big outpatient practice but I don't now, and
8 from time to time my interests, you know, aren't
9 necessarily, you know, over there, because I can't -- don't
10 have the time to spend on it. But since this particular
11 project is one I created previously, it was easy to dust
12 off the shelf, honestly, and certainly I could commit to
13 this to the point where I already told my senior partner --
14 actually, I'm pretty senior myself --

15 [Laughter.]

16 DR. IKEDA: -- my boss, that I'm willing to give
17 the ICU back to the youngsters and devote time to this to
18 make it successful.

19 CHAIR BAILET: That's very noble of you.

20 We have no more questions within the committee.

21 DR. IKEDA: Okay.

22 CHAIR BAILET: Seeing none, I want to thank you
23 again for your attention and the detail and the effort that

1 you put in interacting with us and being extremely specific
2 and helpful in answering our questions, as we consider your
3 proposal. So that is very kind.

4 DR. IKEDA: Well, honestly, I found this to be a
5 very fascinating project. It kind of enlivened my
6 intellectual side, after just seeing patients day-in and
7 day-out. And so I appreciate the opportunity to have a
8 chance to bring this proposal forward and sit before you.
9 And if Blue Shield is interested, I'm willing to talk.

10 [Laughter.]

11 CHAIR BAILET: So, yeah, we'll talk a little
12 later about that, but again, thank you very much.

13 DR. IKEDA: Okay. Thank you.

14 CHAIR BAILET: All right. So our next section of
15 the meeting is, as we said, being transparent and working
16 with the stakeholder community, we have opened up the floor
17 for public comment. We had some folks on the phone who
18 have been listening in to the entire session, but I'd like
19 to have James Gajewski step up forward, if he is here, to
20 present. I think I got that right. You'll thank me for
21 that.

22 DR. GAJEWSKI: I do thank you, but you're only
23 close. It's Gayeski [phonetic.]

1 CHAIR BAILET: Oh, my goodness. Okay. Well,
2 maybe another couple sessions we'll get it worked out.

3 DR. NICHOLS: It worked out yesterday.

4 CHAIR BAILET: Yes. Absolutely. Yes.

5 DR. GAJEWSKI: Yes. Anyway, I again want to
6 thank the panel for the opportunity to speak. As I stated
7 yesterday, I represent the American Society for Blood and
8 Marrow Transplant. I actually deal with a lot of pulmonary
9 disease, primarily bronchiolitis obliterans, but I take
10 care of my COPD and my asthma patients because, as I noted
11 yesterday, I, for six months to one year, to two years,
12 sometimes, am the primary care physician for this.

13 Yesterday I made lots of comments about the
14 issues of cherry picking and patient access, and I just
15 want to remind the panel, bone marrow transplant has lived
16 under case rates since 1991. We have some outlier clauses
17 but we live under case rates. We also, since 2005, have
18 had our one-year survivals published by center, and we now
19 are having physicians and groups having to say no to
20 patients, either because we can't get proper compensation
21 or we have to worry about our acuity adjustments issues and
22 our survival.

23 I have been on the front line to say no to the

1 patients for therapy when the therapy is their only chance
2 for living. I have also been on the front line for
3 stopping ventilators, many times in my life, in my career
4 as a physician. So these issues are very personal to me,
5 because of the type of practice I have, because I take care
6 of transplants in acute leukemia patients.

7 So acuity adjustors -- and I appreciate all the
8 comments about risk adjustment and I agree, perfection will
9 be the enemy of the good, and yet we have to preserve
10 access for these patients.

11 So one of the issues with acuity adjustment is
12 data collection, and everybody here has talked about the
13 robustness of Medicare data and yet many of us, in other
14 settings and venues, will say that the claims data for ICD-
15 10 and ICD-9 is very specious.

16 One of the issues for these complex patients is
17 that all of us who are cognitive care providers with these
18 complex patients are billing Level 3 inpatient, we're
19 billing Level 5 outpatient. Sometimes we get to bill
20 critical care with these patients, but if I do team-based
21 care I can't bill critical care because those codes were
22 never designed by CPT and RUC for those.

23 The answer for some of Grace's questions, which

1 is not the chronic care management codes but maybe
2 something that was approved this year, is prolonged
3 service, non-face-to-face time that may capture some of
4 this work effort. But it is also very hard for us, as
5 cognitive care providers, to get that problem list into any
6 sort of claims software to be as robust as it should.

7 And so as I think about COPD and asthma, and many
8 of the people at this table, I know, have treated COPD and
9 asthma, but how many of you have put in chronic hypoxia?
10 How many of you have put in CO2 retention or mixed acid-
11 base disorder with primary hypercapnia, because these are
12 the patients with COPD who are the most brittle, the worst,
13 the highest complication rate.

14 Also, as we deal with these COPD-ers, they are
15 also, like my patients, they have ischemic heart disease,
16 and there is an interrelationship. Many of them have
17 diabetes. They also have peripheral vascular disease,
18 cerebrovascular disease, all of these things.

19 One of the sad lessons, having negotiated
20 transplant contracts, both with my honorable colleagues
21 from Blue Cross but with every major payer in the country -
22 - I have lived under case rates for commercial payers since
23 1991. When I was a young man doing those sort of

1 negotiations, without all these gray highlights in my hair,
2 I tried to write a contract where we would just deal with
3 the disease and any comorbidity we would get a supplemental
4 payment for. The problem is, when you're looking at a
5 three- or six-month payment time period to say that the
6 creatinine is due to the hypertension or the diabetes
7 versus the immunosuppressant drugs I prescribe, you can't
8 do that, and that's why we've had to live with outlier
9 clauses.

10 But the issue of these comorbidities -- and I
11 applaud the presenters for coming up with an idea, but
12 there is going to be risk stratification with it and it's
13 not just going to be those five comorbidities. The patient
14 with ischemic heart disease who also has an ejection
15 fraction of 30 percent and has COPD is a very different
16 patient than some of the others with five comorbidities,
17 and we are going to have to think about this or there will
18 be this cherry picking, and the patients most in need of
19 care will be denied access of care.

20 The other issue with a lot of these patients is
21 going to be cognitive decline, and all these new, wonderful
22 systems we're talking about require in-home sort of
23 monitoring with electronic sophistication and usually a

1 home caregiver. Well, not everybody has that. Not all
2 these patients, when you hit 65, 70, 75, have a lot of
3 sophistication, and these are patients on 20 meds a day.
4 We can't get a visiting home nurse there every day to help
5 them with medication management. We all try very hard to
6 do that.

7 I also would say that some of the other issues
8 that I, who takes care of these critically ill patients,
9 struggle with is some of the other requirements under MACRA
10 and some of the things for electronic health care, having
11 patients have immediate access to my notes. My friends who
12 are mental health providers get some protected space of
13 access for their notes, where they can make comments, but
14 anything that affects a patient outcome should be
15 documented in my note.

16 So as I deal with patients going through divorce,
17 that hurts. As I deal with cognitive decline, patients
18 with what I feel are personality disorders that is
19 affecting their compliance, where they're actually
20 sabotaging their care, I put those into my notes. They
21 have immediate access to them. I get comments back. It is
22 a huge issue.

23 And so if we are going to do any of these complex

1 patients correctly, how we do this documentation of the
2 complexity is going to be important. How we pay the
3 providers to do this complexity of documentation is
4 important, because the claims data is not as robust as we
5 would like it to be, and to do this well, to preserve
6 access, it will have to be.

7 The final issue, as I think about this model, you
8 really do have a dimorphic patient population between COPD,
9 and if you think about the Medicaid patients with asthma,
10 which will primarily be children and adolescents and you
11 have to deal with things of dysfunctional home situations,
12 you have to deal with the inability to get homes cleaned
13 because parents are working or there's family dysfunction
14 and disaccord. All these things, and the emotional health
15 of the environment, will drive a lot of the issues. That's
16 data that's never been coded in claims data, number one.
17 Number two, how are we actually going to have some control
18 or do acuity adjustment for that, and yet we must.

19 And so, you know, I commend the presenter for all
20 they have done, but I also need to have this panel to think
21 and deliberate about all these complexities, because these
22 are not easy. But this is what it's like taking care of
23 patients in real-life situations.

1 CHAIR BAILET: Thank you, doctor.

2 Any other folks in the audience who may want to
3 come forward and provide public comment?

4 [No response.]

5 CHAIR BAILET: We are now going to ask the
6 operator to open the lines. I believe there's potentially
7 some folks who may have registered to comment.

8 OPERATOR: At this time, if you would like to ask
9 a question, please press star and the number 1 on your
10 telephone keypad. We will pause for just a moment to
11 compile the Q&A roster.

12 Please press star and the number 1 if you would
13 like to ask a question.

14 And there are no questions on this end.

15 CHAIR BAILET: Thank you very much. Before we
16 start deliberating we are going to take a 10-minute recess.
17 Thank you.

18 [Recess.]

19 CHAIR BAILET: We're going to go ahead and please
20 take your seats. Thank you.

21 We're now at that moment in time when we're
22 actually going to start our deliberations. What we are
23 going to do is we have an electronic voting system for us,

1 and as we walk through all of the Secretary's criteria and
2 as the PRT shared the report shared earlier, we're going to
3 look at each criteria individually, and we are going to
4 score them as a Committee to help sharpen our thinking, and
5 ultimately we're going to make a recommendation to the
6 Secretary.

7 Also, I'm asking our DFO, Ann, to read -- because
8 there are people on the phone who will not be able to see
9 the screen. As we go through each criteria, she will read
10 the results as we move through the process.

11 Are there any other comments from folks before we
12 start deliberating? Is the Committee prepared to begin
13 deliberating at this point?

14 [No response.]

15 CHAIR BAILET: I think we're ready to go then.
16 So let's start with the first criteria, Scope of the
17 Proposed PFPM, one of the three designated high-priority
18 criteria. The proposal aims to broaden or expand CMS's
19 alternative payment model portfolio by either: one,
20 addressing an issue in payment policy in a new way; or,
21 two, including alternative payment model entities whose
22 opportunities to participate in APMs have been limited.

23 So a score of 1 to 2, Does Not Meet; a score of 3

1 to 4, Meets; a score of 5 to 6, Meets and Deserves Priority
2 Consideration. And for the purposes of this portion of our
3 deliberation, this is a simple majority?

4 MS. STAHLMAN: Yes.

5 MS. PAGE: Yes.

6 CHAIR BAILET: So we are ready to vote. Yes,
7 please, Paul?

8 DR. CASALE: Just a question. On the opportunity
9 to participate in other APMS -- and I brought up the
10 question about BPCI -- did the PRT think about whether this
11 could be incorporated into the BPCI with COPD/asthma, you
12 know, condition?

13 DR. NICHOLS: We didn't think so much about BPCI
14 for the reasons anticipated, but we did talk about another
15 payment model, fee-at-risk. But we talked about it, and
16 it's an idea that would be on the table going forward.

17 CHAIR BAILET: I want to make one other comment
18 before we vote. Folks who are looking at the screen will
19 see that there are 11. Although there are 10 of us voting,
20 the 11th person is the person behind the curtain
21 controlling the electronics, and they are doing a good job.
22 I'm sure that was just a fat finger.

23 MS. STAHLMAN: Somebody voted.

1 CHAIR BAILET: All right. So we're going to go
2 ahead and start over. Ready to go.

3 Ann?

4 MS. PAGE: We have zero members voting 1, Does
5 Not Meet. We have one member voting 2, Does Not Meet. We
6 have zero members voting 3, Meets. We have four Committee
7 members voting 4, Meets. We have five Committee members
8 voting Meets and Deserves Priority Consideration, and zero
9 members voting 6, Meets and Deserves Priority
10 Consideration.

11 According to the rules of the Committee, if a
12 proposal is found to meet a criterion, it rolls down to
13 when we have a majority of six votes, so this would be
14 found to meet the first criterion, Scope of Proposed PFPM.

15 CHAIR BAILET: Thank you, Ann.

16 Any comments from the Committee based on the
17 results? We're going to go ahead to the second criterion,
18 Quality and Cost, which is -- oh, Bob?

19 DR. BERENSON: We can do comments, right [off
20 microphone]?

21 CHAIR BAILET: Yeah, that's right.

22 DR. BERENSON: I thought we were deliberating. I
23 have great concerns about the diffusion, potential

1 diffusion of accountability in abnormal disease management
2 finding. And I know the Committee -- the PRT has
3 identified that issue and put it down under lack of
4 integration. But I think this is fundamental to the model.

5 In some places, the model is a disease management
6 intervention with little role, frankly, for pulmonary
7 physicians. I even had -- I still have concerns that it's
8 not really a physician-focused payment model. But assuming
9 it is, then I think the lack of attention to that
10 interaction and who's really responsible and what happens
11 when a pulmonary physician gets a seriously abnormal result
12 but doesn't have the patient's medical records, et cetera,
13 et cetera, needed more attention. And so that's why I
14 would elevate that concern from whatever, number 7 or
15 number 8, into a fundamental concern that I would have.

16 CHAIR BAILET: Harold?

17 MR. MILLER: One of the things I'm struggling
18 with, and I think we were struggling with partly yesterday
19 on all of these, is that whatever the issue may be actually
20 cuts across multiple criteria, and it's kind of hard to
21 figure out whether you -- where you put that. And I was
22 trying to do this yesterday, having reflected on all that,
23 was to try to go back to what the criterion says. And the

1 criterion says it anticipated to be able to improve quality
2 and reduce costs. And my conclusion from that is that this
3 is clearly anticipated to do that. There's an intervention
4 that it's supposed to support that will do that. There is
5 varying degrees of experience that it can, in fact, do that
6 because we know that this population does get hospitalized
7 a lot. And we know that efforts to try to contact them to
8 encourage them to identify problems early does work.

9 So, to me, I find that it meets this because it's
10 anticipated to do that. And I think that the quality
11 aspect, it seems to me, is addressed. This issue came up
12 yesterday. I think that if you're focusing on trying to
13 keep people out of the hospital, that that is a quality
14 improvement. It may not be the full set of measures that
15 are needed to be able to do that.

16 And so I just wanted to say at least the way I'm
17 thinking about this, because I think we ultimately will
18 have to figure out exactly in the future how we apply all
19 these criteria, is that's how I'm thinking about the
20 criteria. My concerns about some of the other issues
21 really I'm sort of going to put into the second -- the
22 third bucket, which is how well is the payment methodology
23 structured to try to protect against potential problems of

1 some kind, et cetera.

2 CHAIR BAILET: Thank you. Bob, your card is up,
3 but you're done, right?

4 Any other comments?

5 [No response.]

6 CHAIR BAILET: So this is the second criteria.
7 The proposal's anticipated to improve health care quality
8 at no additional cost, maintain health care quality while
9 decreasing cost, or do both, which would be improving
10 health care quality and decreasing cost. Again, a high
11 priority, and we are ready to vote.

12 Ann?

13 MS. PAGE: Zero committee members have voted 1,
14 Does Not Meet. Two Committee members voted 2, Does Not
15 Meet. Five Committee members voted 3, Meets. Three
16 Committee members vote 4, Meets. And zero Committee
17 members voted for 5 or 6, Meets and Deserves Priority
18 Consideration. So the majority has determined that this
19 proposal meets Criterion 2.

20 CHAIR BAILET: Thank you, Ann.

21 Any additional comments from the Committee based
22 on the results?

23 [No response.]

1 CHAIR BAILET: We'll go ahead and move to
2 Criterion 3, Payment Methodology, which is also high
3 priority. Pay alternative payment models entities with a
4 payment methodology designed to achieve the goals of the
5 PFPM Criteria. Addresses in detail through this
6 methodology how Medicare, and other payers if applicable,
7 pay APM entities, how the payment methodology differs from
8 current payment methodologies, and why the PFPM cannot be
9 tested under current payment methodologies.

10 We're ready to vote. Oh, Harold. I'm sorry.
11 Harold has a comment before we vote.

12 MR. MILLER: I'm sorry to disrupt the rapid flow
13 to voting. I wanted to make the observation that I think
14 this risk adjustment issue is going to come up frequently
15 with a lot of models, and we, I think, probably would all
16 agree that the risk adjustment systems that exist today
17 don't work very well, which means that in almost any case
18 it's going to be difficult to say that somebody can bring
19 in something that we know will work.

20 This one, I was struck particularly with the
21 follow-on letter that we got today. I was originally sort
22 of in the camp that said that -- that is not a pun, "camp"
23 -- in the camp that said that COPD we ought to be risk-

1 adjusting based on the severity of COPD, not the other
2 things that they have. But I was struck by the argument
3 from the applicant, and I'm recalling my own experience in
4 having run a project focused on COPD, that it was, A, very
5 difficult to measure the severity of COPD. There is no
6 code for that. And, moreover, what we tend to define was
7 that the patients who were the easiest to keep out of the
8 hospital, were, in fact, the patients who sort of just had
9 COPD, and it was the others who had other problems that
10 were the most difficult to keep out.

11 And so it struck me that it becomes an
12 interesting thing when the criteria applies to couldn't be
13 tested otherwise, is that if, in fact, it's a different
14 approach to risk adjustment, that it merits testing in some
15 fashion, and it's difficult to figure out whether it will
16 work without actually testing it. But I do think that some
17 of the other questions that came up yesterday about a total
18 cost model become more problematic whenever you have a risk
19 adjustment structure based on number of chronic conditions,
20 because if all of a sudden one of those chronic conditions
21 is rheumatoid arthritis and you suddenly have biologic
22 drugs coming in or inflammatory bowel disease or whatever,
23 that's a very different issue than saying the goal is to

1 try to keep people out of the hospital regardless of what
2 their conditions are.

3 So I do think that there is going to have to be
4 some -- if the risk adjustment structure is going to be
5 different, there's also going to be a different way of
6 measuring the accountability, the total cost or whatever
7 measure, to be attached to that. Otherwise, it could
8 potentially lead to some patient problems and require more
9 quality measures, et cetera, to go along with it.

10 CHAIR BAILET: Thank you, Harold. Len.

11 DR. NICHOLS: So I agree with Harold that the
12 risk adjustment is novel and the proposal is novel and it
13 needs work. And I think the fundamental question we have
14 is: Do we want to do the work before we start running
15 money through it, or do we want to do the work maybe after?
16 And I must say I come down on the side of I think there's
17 enough creativity here, this is worth investing resources
18 in. I don't think it's ready to run money through it. I
19 just feel too queasy about the variation that would go with
20 using this system as it is without it having been run
21 through a lot more testing and alternative ways of
22 capturing that severity, including combining electronic
23 health record data with the claims, if we can get that far,

1 at least for a pilot. So that's kind of where I come out.

2 MR. MILLER: If I could ask, what is in your mind
3 about what would be the next steps then? There would be
4 more work on the model done before it would be appropriate
5 for actual testing?

6 DR. NICHOLS: So we have this letter to the
7 Secretary, and I think what we put in a letter to the
8 Secretary -- I mean, to me, the most surprising thing in
9 the last four hours is that somebody said it didn't meet
10 the scope test. To me, this is big -- five or six of us
11 had it way over here to very high scope, merit,
12 preponderance of evidence for quality. But I think there's
13 concern about lining up and having this very willing
14 gentleman bear this risk without having kicked the tires a
15 great deal more. And so what I think we do first is we
16 give the task of designing a risk adjuster to CMS. That
17 would be my suggestion for the letter. And in the
18 meantime, we work out more of the accountability details
19 with the submitter, and in a sense we start the process of
20 modifying the proposal, but let's come back to that second
21 conversation with a much more robust risk adjuster
22 proposal. There may be two or three, by the way, that we
23 might test.

1 MR. MILLER: So if I may, again, the point I made
2 yesterday is I'm trying to think about whether or not the
3 revision to the model could be done without actually trying
4 it somewhere. And I'm not convinced in this particular
5 case that it could because it would in many cases rely on
6 clinical data that would be hard to get without actually
7 doing it.

8 I think the issue about putting the applicant at
9 excessive risk it seems to me could be dealt with by
10 structuring a limited test with a fairly narrow risk order
11 around it, to say we're not quite sure yet and we want to
12 try this initially, anyway, to see how it goes before
13 adjusting that, because, I mean, that would be the way most
14 models, in fact, do start, is kind of with a narrower risk
15 band and then expanding it over time once one is more
16 confident.

17 So it doesn't seem to me that we should not
18 propose something because of that, because I think the
19 initial phase of a model could be structured, particularly
20 in a limited testing phase, to be able to protect the
21 applicant from that as a limited tester.

22 CHAIR BAILET: Kavita.

23 DR. PATEL: So the great thing about this is that

1 we're all doing this like live, and we've never done this
2 before, so it's like someone has a camera on one of our
3 family dinners and we're all starting to talk about things
4 that you didn't actually realize we would talk about.

5 My issue with that, Harold, is that I feel like
6 then -- this goes back to something Paul and I and Rhonda
7 struggled with in our PRT. We had to walk the line of kind
8 of doing what was right in front of us. So I kind of read
9 this myself, the black and white. I will say that the
10 additional information helped to change a little bit of my
11 thinking. But I read what was written in front of me, and
12 I feel like what you just said, Harold, is not what was
13 written in front of me. So I don't know how to -- I'm
14 struggling a bit with how much can we do to do what I think
15 Len is suggesting, which is right in my mind, you know, if
16 there was a little more technical -- if there was some
17 vehicle by which there were other people to kind of help
18 with thinking through risk adjustment or a refinement of
19 the payment methodology, that would impact my -- you know,
20 maybe a later decision. But today I have what's in front
21 of me, and I feel like what you articulated is not what's
22 in the proposal.

23 But I also don't want to be so over-interpretive

1 and punitive that we're limited to this 20 pages and not to
2 something else. And I just don't know how to react to
3 that.

4 CHAIR BAILET: Harold?

5 MR. MILLER: So if I can respond to that, because
6 I think that's an excellent point. What I guess I was
7 looking at is saying the applicant has proposed a risk
8 adjustment model. We are concerned about how it would
9 work. It's not -- we were originally saying we think it
10 needs to be changed. Now I'm saying, well, maybe it
11 doesn't need to be changed. But the problem is there's
12 risks associated with a risk adjustment model, and what I
13 was trying to think through was, well, could you actually
14 figure out what those risks of the risk adjustment model
15 are without actually putting it in place and trying it in
16 some fashion?

17 I'm on the fence about that, but what I was
18 saying was it seems to me that if, in fact, one leaned
19 toward the basic concept here needs to be tried, that we
20 could -- and the concern is simply that the applicant would
21 be at very high financial risk, we could protect them
22 against that if we felt that the model should be tried.

23 I was sort of making that statement independent

1 of whether one agrees with this specific proposal that they
2 have made, but it does seem that in a case like that, if --
3 but you're absolutely right, it wouldn't be go invent a
4 whole new risk adjustment model and then try it. My
5 argument was if, in fact, something like this -- if our
6 concern about it is not that the proposal is bad but that
7 because it has never been tried, we have no idea whether
8 it's going to send them into bankruptcy. We could protect
9 them against that in a trial. That was my point.

10 So thank you for that clarification.

11 CHAIR BAILET: Elizabeth?

12 VICE CHAIR MITCHELL: Along the lines of health
13 policy reality TV --

14 [Laughter.]

15 DR. PATEL: [Off microphone].

16 VICE CHAIR MITCHELL: -- we are sort of exploring
17 this out loud. And I was going to save these comments for
18 later, but I have a very similar dilemma. I have no doubt
19 that your practice could test this and probably be very
20 successful. I have not been convinced that others could or
21 would, and we are limited in what we can recommend, our
22 options. So I'm leaning more towards very strong comments
23 to the Secretary that this has a lot of merit, but the

1 readiness question to me is really significant. So I just
2 -- I'm struggling with the same thing, but I really worry
3 about our range of options.

4 CHAIR BAILET: Tim.

5 DR. FERRIS: I think to address Harold's point
6 about whether or not this requires testing to be improved,
7 from my perspective it is very clear that one could do
8 computer simulations of lots of different risk codes at the
9 practice level. We do it all the time, health policy
10 researchers do it all the time. There's no question that
11 you could get an enormous amount of information without
12 actually going through the testing process in this
13 particular case. It may end up in the same place, but
14 that's not a question in my mind.

15 CHAIR BAILET: Len?

16 DR. NICHOLS: Ditto, and I think my point would
17 be, Harold, while, yes, we could protect this applicant
18 from the risk, I don't think there's enough confidence that
19 that particular model is going to be the end game that we
20 should do that. I think we should do the simulations, do
21 the experiments, find different ways to calibrate these
22 different variances, not just the means, and then come back
23 with a very stratified structure in order to deal with the

1 exact patients Dr. Ikeda has focused on. And that's what I
2 think would serve us all much better than starting before
3 we're ready.

4 CHAIR BAILET: Bob.

5 DR. BERENSON: This, I guess, is going to be most
6 useful just as a process point, because it's a little late
7 in the game, but one of the Medicare MAPCP -- what does
8 MAPCP stand for? Multi-Payer Advanced Primary Care demos
9 use a number of chronic conditions as their risk adjustor,
10 and there is experience at least there. I don't believe --
11 well, I won't say what I believe, because I don't -- I
12 might be wrong, but there is some experience, and the
13 process point is that I think we need to do more
14 surveillance when we have issues like this that come up and
15 we just assume that nobody has ever tested this before. I
16 think it has been tested, and so I would just throw that
17 out.

18 CHAIR BAILET: Len, did you have an additional
19 comment?

20 DR. NICHOLS: In a primary care setting?

21 DR. BERENSON: In a primary care setting.

22 CHAIR BAILET: Okay. Seeing no other comments
23 from the Committee, we will go ahead and vote on Criterion

1 No. 3.

2 Ann.

3 MS. PAGE: Three Committee members have voted 1,
4 that the proposal Does Not Meet the criteria. Five
5 Committee members voted 2, proposal Does Not Meet criteria.
6 Two Committee members voted 3, Meets the Criteria, and zero
7 Committee members voted for 4, and zero voted for 5, and
8 zero voted for 6. So the majority of the Committee has
9 determined that the proposal Does Not Meet Criterion 3.

10 CHAIR BAILET: Any other comments from the
11 Committee on this criterion based on the outcome?

12 [No response.]

13 CHAIR BAILET: Seeing none, we are going to move
14 forward with Criterion No. 4, Value over Volume. The
15 proposal is anticipated to provide incentives to
16 practitioners to deliver high-quality health care.

17 Comments from the Committee? Deliberations
18 before we vote?

19 [No response.]

20 CHAIR BAILET: Let's go ahead and vote, then.

21 Ann?

22 MS. PAGE: Zero Committee members have voted 1,
23 Does Not Meet. Zero Committee members have voted 2, Does

1 Not meet. Four Committee members voted 3, Meets. Six
2 Committee members voted 4, Meets, and zero Committee
3 members voted 5, and zero Committee members voted 6, Meets
4 and Deserves Priority Consideration. So the majority of
5 the Committee has found that the proposal Does Meet
6 Criterion 4.

7 CHAIR BAILET: Any comments based on the results?

8 [No response.]

9 CHAIR BAILET: We're going to move forward with
10 Criterion No. 5, Flexibility. Provide the flexibility
11 needed for practitioners to deliver high-quality health
12 care. Any comments before we vote?

13 [No response.]

14 CHAIR BAILET: Let's move forward. Ann?

15 MS. PAGE: Zero Committee members have voted 1,
16 Does Not Meet. One Committee member voted 2, Does Not
17 Meet. Seven Committee members voted 3, Meets. Two
18 Committee members voted 4, Meets; and zero Committee
19 members voted 5 or 6 for Meets and Deserves Priority
20 Consideration. So the majority of the Committee has found
21 that the proposal Meets Criterion 5 for Flexibility.

22 CHAIR BAILET: Thank you, Ann.

23 Any comments from the Committee based on the

1 results?

2 [No response.]

3 CHAIR BAILET: We're going to move forward with
4 Criterion No. 6, Ability to Be Evaluated, have valuable
5 goals for quality of care cost and other goals of the PFPM.

6 Any comments?

7 [No response.]

8 CHAIR BAILET: Ready to vote. Ann?

9 MS. PAGE: Zero Committee members have voted 1 or
10 2, Does Not Meet. Four Committee members voted 3, Meets
11 the criterion. Six Committee members voted 4, Meets the
12 criterion, and zero Committee members voted 5 or 6, Meets
13 and Deserves Priority Consideration. So the majority of
14 the Committee has determined that the proposal Meets
15 Criterion 6.

16 CHAIR BAILET: Thank you.

17 Any comments from the Committee?

18 [No response.]

19 CHAIR BAILET: We're going to move forward then
20 with Criterion No. 7, Integration and Care Coordination,
21 encourage greater integration and care coordination among
22 practitioners and across settings where multiple
23 practitioners or settings are relevant to delivering care

1 to the populated treated under the PFPM.

2 Any Committee members? Harold and then Grace.

3 MR. MILLER: I just wanted to comment on this
4 because, again, I think some of this is going to be
5 relevant for future things, but the criterion says
6 encourage and not require. So an interesting question, it
7 seems to me, is that this, if it was structured the way it
8 was structured, would certainly encourage it because it
9 might be very difficult for anyone to be successful unless
10 they, in fact, integrated and coordinated care, which I
11 think is sort of where the PRT came down in terms of
12 encouraging it without saying exactly how it would be
13 achieved, which in some sense is okay for a payment model
14 if, in fact, you believe that that can be done.

15 DR. TERRELL: One of the things that we need to
16 be thinking about is the ambiguity of the word "care
17 coordination" with respect to this criterion. So it can be
18 thought about within the context of the care coordination
19 for an individual patient with all the resources that a
20 nurse navigator or other type or telemedicine or any of
21 these types of things can potentially do this, basically,
22 coordinating resources versus care coordination between
23 providers, which I believe we're using within the context

1 of integration here. But this is just an acknowledgement
2 or something for the PRT to be thinking about, because
3 we're now seeing two proposals in a row that I think are
4 very much focused on care coordination for the patient in
5 their model that they're proposing, but not necessarily as
6 focused upon the whole integration of care.

7 So, as we're thinking through this in the future,
8 we may want to either make a distinction in our own
9 criteria or at least be more explicit with that for the
10 applicants, so they can comment on both aspects of it.

11 CHAIR BAILET: And I guess, Grace, adding to that
12 comment, in this particular condition with the
13 comorbidities being high touch and requiring expertise from
14 a multiple set of disciplines, I do think that while I do
15 acknowledge the patient coordination, which is extremely
16 heavy here, to really maximize the benefit of this model,
17 it is that integration with the other clinical teammates
18 who would be taking care of these patients, so I do think
19 that's important.

20 Kavita.

21 DR. PATEL: So, again, I'll just verbalize the
22 things I'm struggling with. When I read what was
23 originally kind of proposed, I arrived at the same --

1 independently the same conclusion the PRT did.

2 I think when I hear Dr. Ikeda and kind of any
3 colleagues that work with him on this putting into the kind
4 of paper response that we have -- and I'll read it: We've
5 decided that this concern about the coordination is a valid
6 argument and in our evolving care plan will expand
7 monitoring to other chronic conditions, et cetera. We will
8 consult with other and offer care coordination of other
9 chronic diseases in our population of patients with COPD
10 and asthma.

11 So I'm trying to kind of read to the letter of we
12 don't know what care coordination is, or at least we think
13 we do, but it's not specified in the Secretary's criterion
14 how maybe the PRT might respond to that, or I'll say my
15 response to that is that he is -- or at least the proposal
16 is trying to encourage, even though the intentionality was
17 expressed in this kind of late-breaking document, that
18 there is actually an encouragement of this coordination,
19 although the details have to be fleshed out.

20 So I would almost just put forward that this
21 could potentially meet the criterion just based on this
22 added inclusion.

23 CHAIR BAILET: Bob and then Paul.

1 DR. BERENSON: Well, I'm going to disagree with
2 Kavita. I think that added inclusion gives me more
3 concerns. We're going to have a pulmonary practice
4 essentially coordinating care for a patient's diabetes and
5 heart failure when the patient is being cared for by a
6 different physician. The whole thing doesn't hang
7 together.

8 I mean, I think this is added to recognize the
9 need for care coordination, but again, I'll just say a
10 separate disease management program, which is what this is,
11 with perhaps some pulmonary physician involvement to deal
12 with COPD exacerbations is not the place to be doing
13 overall care coordination divorced from the patient's
14 regular source of care.

15 DR. CASALE: Yeah. Just to comment again, as you
16 pointed out, this Criterion 7 is specifically around
17 coordination among practitioners, so I understand
18 coordination -- care coordination for the patient is
19 critical, but this criterion is around practitioners.

20 And although in that add-on statement, there is
21 encouragement that there would be more, as Dr. Ikeda said,
22 right now it's relying on faxing. Again, I think you need
23 more detail to try to understand how this would -- or

1 experience on how this would actually work other than the
2 traditional methods which are currently being used, which
3 we know are ineffective.

4 CHAIR BAILET: Thank you, Paul.

5 Len and then Harold.

6 DR. NICHOLS: So a great thing about being a non-
7 physician is you get to learn from physicians on the PRT,
8 and what we talked about in more detail than anything else
9 on this criterion was a distinction between care
10 coordination and care integration. And, actually, it was
11 integration that we unanimously concluded it was lacking.

12 Care coordination definitely is encouraged in all
13 kinds of ways, but I think it's integration that we were
14 worried about.

15 CHAIR BAILET: Harold.

16 MR. MILLER: So the fact that this applicant said
17 that they were planning to coordinate care does not
18 necessarily mean anything about the model. It's sort of
19 that this applicant was saying that they would do it.

20 But what it does seem to me to indicate is that,
21 in fact, they felt that the model would, in fact, sort of
22 push them in that direction.

23 I would distinguish, I guess, if the model was

1 saying, "We are going to prevent COPD hospitalizations, and
2 that's all. We don't care about anything else. And if the
3 patient is going in for something else, not our problem,"
4 and you would have the ordinary food fight that goes on in
5 trying to figure out, so why did that patient get
6 hospitalized, then I would be worried about it. But the
7 fact that they are saying, "It doesn't matter. Whatever
8 they end up in the hospital for, we're going to be
9 accountable for that," certainly to me says you're going to
10 have to figure out somehow how to coordinate care with all
11 those other physicians that are taking care of those things
12 because the pulmonologists aren't going to be terribly
13 expert at managing all that.

14 So, to me, if it's encouraged, does the model
15 encourage it? Yes. And the fact that the applicant said,
16 "You're right. We're going to have to do that," sort of
17 reinforces that notion for me.

18 CHAIR BAILET: Tim.

19 DR. FERRIS: I guess I would ask Harold. We
20 heard from the applicant that they would do it because they
21 think it's the right thing to do. What specifically about
22 the model encourages that behavior?

23 MR. MILLER: Well, what I just said was that, in

1 fact, if they -- if the patient is hospitalized for an
2 exacerbation of their heart failure, of their rheumatoid
3 arthritis, of their whatever, they will be accountable for
4 that. So if they're not figuring out how to manage that,
5 then they are going to be at significant financial risk.
6 That seems to me to encourage that. That's at least my
7 interpretation of it.

8 That's why I was trying to distinguish it that I
9 don't think that a model that said we are only going to be
10 accountable for COPD- or asthma-related things would, in
11 fact, have that same level of encouragement. In fact, it
12 could encourage the opposite, which is finger-pointing to
13 say, "No, it wasn't my problem."

14 CHAIR BAILET: Paul.

15 DR. CASALE: As I think about it, just because
16 somebody is willing to accept the risk doesn't guarantee
17 that there is going to be integration or coordination of
18 care, in my mind, without at least seeing some ideas on how
19 that would actually happen in the model, not just "We'll
20 take the risk." To me, that doesn't guarantee. I think
21 the model should describe a little more fully around how
22 all that would work for me to feel comfortable with this.

23 CHAIR BAILET: Grace.

1 DR. TERRELL: So that's going to be a crucial
2 question, I believe, this afternoon, is a crucial question
3 in this one as well, which is, is a payment model itself
4 going to, therefore, naturally lead to certain behaviors or
5 a priori are we going to expect certain aspects of the
6 Secretary's criteria to be explicit in the models?

7 What I just heard you say is that you don't
8 believe that one payment model methodology naturally leads
9 to the other, and it does need to be explicit.

10 We need to be thinking as a committee about that,
11 not only for this model, but for others that are going to
12 come forth. That's one of the crucial things that we need
13 to understand, each of us individually, what is the
14 relationship between the payment model and the Secretary's
15 criteria for all these other things. Does it naturally
16 lead to it, or are we going to insist, as we make a
17 recommendation going forward that are being explicit, you
18 know, tie, if you will, to that?

19 So I think that, Paul, your comments are actually
20 extremely relevant to our broader issues that we're going
21 to be struggling with.

22 CHAIR BAILET: Thank you, Grace.

23 Any other comments from the Committee before we

1 vote?

2 [No response.]

3 CHAIR BAILET: Then let's go ahead and vote.

4 Ann.

5 MS. PAGE: Four Committee members have voted 1
6 that the proposal Does Not Meet the criteria. Another four
7 members have voted 2, the proposal Does Not Meet the
8 criteria. One Committee member voted 3; it Meets the
9 criteria. Zero Committee members voted 4, Meets the
10 criteria. One Committee member voted 5, Meets and Deserves
11 Priority Consideration, and zero Committee members voted 6,
12 Meets and Deserves Priority Consideration. The majority of
13 the Committee has voted that the proposal Does Not Meet
14 Criterion 7.

15 CHAIR BAILET: Thank you, Ann.

16 Any comments from the Committee based on the
17 results?

18 [No response.]

19 CHAIR BAILET: We are going to move forward,
20 then, with Criterion No. 8, Patient Choice. Encourage
21 greater attention to the health of the population served
22 while also supporting the unique needs and preferences of
23 individual patients.

1 Any comments before a vote from the Committee?

2 [No response.]

3 CHAIR BAILET: Let's go ahead and vote.

4 Ann?

5 MS. PAGE: Zero Committee members have voted 1.
6 Zero Committee members have voted 2, Does Not Meet. Four
7 Committee members vote 3, Meets the criterion. Five
8 Committee members voted 4, Meets the criterion. One
9 Committee member voted 5, Meets and Deserves Priority
10 Consideration, and zero Committee members voted Meets and
11 Deserves Priority Consideration. The majority has voted
12 that the proposal Meets Criterion 8, Patient Choice.

13 CHAIR BAILET: Any comments from the Committee
14 based on the results?

15 [No response.]

16 CHAIR BAILET: We'll move to Criterion No. 9,
17 Patient Safety. How well does the proposal aim to maintain
18 or improve standards of patient safety?

19 Any comments from the Committee before we vote?

20 Bob.

21 DR. BERENSON: Yeah. This is the place, I guess,
22 I get to say what my fundamental problem is, which is that
23 we have an intervention, which I would love it to work, but

1 it hasn't been proved effective, except in one German
2 study.

3 So I do not know whether it would achieve its
4 aim. I mean, the thing says to aim. It certainly aims to
5 do the right thing, and it could do the right thing, or it
6 could result in diffusion of accountability with primary
7 care physicians no longer -- I mean, I've got a pulmonary
8 doc who is going to deal with this, and I don't have to
9 worry about it, and a pulmonary doc who doesn't have the
10 relevant information. I want to know that the intervention
11 works, and then I can worry about a payment model. And I
12 don't think we're at the stage. I don't think we should be
13 using the PTAC offices to do basic clinical research, I
14 guess is what I would say, and that's my concern.

15 So I have difficulty. The aim is exactly right,
16 but I don't have any confidence that it will be achieved or
17 not achieved.

18 CHAIR BAILET: Thank you, Bob.

19 Harold?

20 MR. MILLER: I think an interesting aspect of
21 this proposal is I don't think we can sort of criticize
22 them on both sides. They actually are not taking
23 accountability and payment for all of the payment

1 associated with the patient. So there are going to be
2 other clinicians still responsible for those patients under
3 whatever payment model applies to those other patients.

4 This model, at least as I understand it, is
5 designed to try to provide an extra overlay layer of help
6 to the patient beyond what they can get today. It is
7 possible, as you say, that that might lead other people to
8 sort of pass the blame or the responsibility on to these
9 folks, but it doesn't seem to me that that is inherent in
10 the model. That adding an extra layer of protection on top
11 would seem to me to be a good thing to do rather than
12 otherwise.

13 I mean, the converse would be to say that
14 everybody who is responsible for the patient is suddenly in
15 this risk-based model that we're a bit uncomfortable with
16 would be, to me, a higher level of concern about patient
17 safety.

18 CHAIR BAILET: Bob.

19 DR. BERENSON: So I would just respond. So why
20 don't we find out by doing a clinical -- doing some
21 clinical research and what the impact is before we decide
22 to do a national payment model?

23 MR. MILLER: Well, I would just say, I think you

1 keep referring to national payment models. That's why we
2 are talking about limited scale testing, and I think the
3 issue ends being, in some cases, what does clinical
4 research mean? We've seen that some of the grant programs,
5 to simply fund an intervention, don't really get at the
6 issue very effectively of how do you structure a payment
7 model to support them.

8 So I do think we have to figure out how to create
9 the bridge between the health care innovation award
10 approach and payment models. And I would respectfully
11 disagree with my colleague, Tim, that you cannot do all
12 this stuff through simulations, because the whole problem
13 is that if you are running simulations you are running
14 simulations against past existing behavior, not how care
15 would change under a different model, and that is one of
16 the fundamental problems in recalibrating risk adjustment
17 models, is because you can only calibrate them against the
18 behavior you're trying to change, which is not a good thing
19 to do.

20 DR. BERENSON: I didn't think we were talking
21 about limited scale testing, necessarily. I thought that
22 was one of the options we had, and maybe that is where this
23 fits. But I do think one of our options is to even give it

1 high priority for broad testing. So maybe we can -- we
2 will agree -- I don't know; we haven't voted yet -- but
3 your point is what we're talking about is limited-scale
4 testing. I didn't think that is what we were talking
5 about.

6 CHAIR BAILET: Thank you, Bob. Tim.

7 DR. FERRIS: Harold, once again you've
8 mischaracterized my comments, and so I just want to point
9 out that what I said was that we could improve the
10 understanding of the variance associated with the practice
11 level. I stand by that statement. Thanks.

12 MR. MILLER: With that clarification, I would
13 agree with that. Thank you.

14 CHAIR BAILET: All righty then. We're going to
15 go ahead and vote.

16 Ann.

17 MS. PAGE: Zero Committee members have voted 1,
18 Does Not Meet; two Committee members have voted 2, Does Not
19 Meet; seven Committee members have voted 3, Meets the
20 criterion; one Committee member voted 4, Meets the
21 criterion; and zero Committee members voted for 5 or 6,
22 Meets and Deserves Priority Consideration. The majority of
23 the Committee has voted that this proposal Meets Criterion

1 9.

2 CHAIR BAILET: Thank you, Ann. Any additional
3 comments from the Committee? I see Grace.

4 DR. TERRELL: For the next one.

5 CHAIR BAILET: Oh, for the next one. Okay. Then
6 we're going to move forward, for Criterion 10 -- you guys
7 are rushing me here -- Health Information Technology.
8 Encourage use of health information technology to inform
9 care.

10 Grace.

11 DR. TERRELL: This issue came up yesterday, when
12 we were talking about this criterion of encouraging the use
13 of health information technology. Everybody went off on
14 interoperability in electronic health records and that
15 aspect of technology. But I think that this particular
16 proposal really talks about other ways of thinking about
17 health care technology. In this case a Bluetooth device
18 that is providing the information back to providers is not
19 integrated across some Epic system, although this was
20 discussed as something that might need to be planned for.

21 And as we're thinking about this particular
22 criteria in the future, I suspect that we're going to get
23 far more types of beta and innovative new types of

1 technology that are going to be coming as part of these
2 models, that are not going to be mature, they are not going
3 to necessarily have anything except a study from Germany,
4 because that's the nature of innovation. And so much of
5 the innovation that's happening right now is happening in
6 health care within the context of care delivery at the
7 individual patient level and how to enable their
8 experience, particularly, to not be so facility-based and
9 to be based much more on chronic care management type of
10 enablement tools.

11 So this particular criterion, over time, we may
12 find ends up being one that we spend more time thinking
13 through, as a committee, than some of the others. I may be
14 wrong about that but we've now had two in a row that are
15 very much in the same mode of a technology that's important
16 in it. And with this particular one, it's right there on
17 the edge of the way a lot of the investment in technology
18 is going.

19 So we just need to make sure that as we are
20 talking about our own thought processes, that we don't get
21 trapped in today's technology and the health systems and
22 the population tools that are out there now. It may or may
23 not be mature but it's going to be something that, I think,

1 is going to continue to come up.

2 CHAIR BAILET: Elizabeth.

3 VICE CHAIR MITCHELL: Thank you. I actually am
4 impressed and like the innovative technology aspect of this
5 proposal, but the more we've talked about integration
6 across specialists and others, the more concerned I am
7 about the information-sharing aspect of this, which, I
8 mean, we're talking about HIT to inform care. And, again,
9 through no fault of the applicant, I don't think the answer
10 can be just universal adoption of Epic, because we've got
11 to find ways to get information shared across practices,
12 particularly for something that assumes coordination across
13 multiple practices and specialties. So I'm actually more
14 concerned about this than I was.

15 CHAIR BAILET: Len.

16 DR. NICHOLS: So I'll pick upon Elizabeth's point
17 about Epic. I know quite a few systems in Virginia that
18 all have Epic and they can't talk to each other, so trust
19 me, that ain't going to be the solution.

20 What needs to be worked out, therefore, is a way
21 to parallel track the development of the risk adjust or the
22 development of the interfaces that are going to make this
23 kind of creative technology actually operational across a

1 wide range, and we need to be working on that
2 simultaneously.

3 CHAIR BAILET: Thank you. Grace, do you have
4 another comment? Your card is up.

5 DR. TERRELL: Sorry, no.

6 CHAIR BAILET: So we're going to go ahead and
7 vote.

8 If you think you voted, you may not have, so you
9 may want to push your button again. There we go. Ann?

10 MS. PAGE: Zero Committee members have voted 1,
11 Does Not Meet; two Committee members voted 2, Does Not
12 Meet; three Committee members voted 3, Meets; five
13 Committee members voted 4, Meets; and zero Committee
14 members voted for 5 or 6, Meets and Deserves Priority
15 Consideration. The majority of the Committee has voted
16 that this proposal Meets Criterion 10, Health Information
17 Technology.

18 CHAIR BAILET: Thank you, Ann. Any comments on
19 this criterion? Any additional comments, based on the
20 results?

21 [No response.]

22 CHAIR BAILET: So what we're going to do now is
23 the folks on the information technology side for us are

1 going to provide a summary slide, which we'll review in a
2 minute, which summates the voting through these 10
3 criteria, and while we're doing that, if there's any other
4 committee comments, in general, about this proposal, before
5 we actually begin deliberations and vote relative to the
6 recommendation to the Secretary, which is the next phase of
7 our process.

8 And again, I'd like to just walk the Committee
9 members through that. We are going to use electronic
10 voting, and then we are also going to voice vote by member,
11 because we believe it is important for the community
12 submitters and the public stakeholders to know where we
13 came down on this particular recommendation for the
14 Secretary.

15 So a vote of 1 means does not recommend to the
16 Secretary. A vote of 2 means recommend the payment model
17 to the Secretary for limited-scale testing. A vote of 3
18 means recommend the proposed payment model to the Secretary
19 for implementation. And a vote of 4 means to recommend the
20 proposed payment model to the Secretary for implementation
21 as a high priority.

22 So those are the four categories, and if we're
23 ready we could provide the summation of our criterion

1 voting, that would be helpful.

2 Yeah, it just takes a minute for them to
3 transition. Yes, Kavita.

4 DR. PATEL: Maybe I can ask now, not just the PRT
5 but I'm thinking out loud. I know we'll see all of our
6 criteria and perhaps I'm too, kind of, colored by
7 yesterday. If we feel like they really met a number of the
8 criteria, with the exception of one of the high-priority
9 criterion, that we are all kind of dancing around, like
10 some form of technical assistance, which this committee is
11 not allowed to provide -- we have already covered that -- I
12 actually don't feel -- I struggle because the criterion and
13 the way we voted on them is eerily similar to kind of how
14 we arrived on yesterday's proposal, but that we moved
15 forward for different reasons, for limited-scale testing.

16 My hesitation is that I think this is like still
17 short of qualifying for limited-scale testing yet offers so
18 much promise and opportunity. So I'm curious, as we only
19 have the three options. We don't have a 2A, you know,
20 technical assistance before limited-scale testing, then
21 pass Go. I'm kind of struggling with how we take something
22 that has a real -- obviously, by our voting, we think
23 there's some real merits to the actual proposal, novelty,

1 some interesting potential around risk adjustment,
2 inclusion of a high-priority condition, et cetera, et
3 cetera. And what do we do with that? We're kind of in an
4 in-between category space, and that's where I'm struggling,
5 myself, to be out loud about it.

6 So is there a 1, 2, 3, and then like a 4, you
7 know, I'm still struggling, kind of question, because
8 that's where I'm at.

9 CHAIR BAILET: Thank you, Kavita. Harold?

10 MR. MILLER: I think -- well, I'll speak for
11 myself. Many of us are struggling with that. I guess I'm
12 struggling with that. I think the -- we've said before
13 that even if we do not recommend we will provide comments,
14 suggesting the nature of that, to distinguish between we
15 really didn't think this was a good idea at all versus it's
16 a great idea but it's got some weaknesses in it.

17 At least the way I am thinking about it is that
18 if there is a sufficiently high level of technical
19 assistance or revisions needed to get it to the point where
20 limited-scale testing would be desirable, then I would put
21 it in the no category, that it really needs to have that
22 done. If it's in the category where maybe a little bit of
23 technical assistance but, frankly, most of the stuff it

1 needs is going to have to be worked out in an actual test,
2 then I would lean on the -- which is where I leaned
3 yesterday, which was I didn't think that the revisions were
4 of sufficient scale to really stop it, and I felt it could
5 move forward.

6 I feel in the other direction on this. I think,
7 to me, that there are enough things that really have to be
8 refined and clarified about this that you couldn't just
9 say, take that, do a little bit of tweaking, and go test
10 it. But I do think that, ultimately, that no matter what
11 we do, in terms of -- or what they do in terms of revising
12 the methodology, I still think it would need to go limited-
13 scale testing, if it stays in this same kind of category,
14 because it's so different and so potentially -- raises
15 issues that have never been tested before. That's at least
16 where I am.

17 CHAIR BAILET: Thank you, Harold. Elizabeth.

18 VICE CHAIR MITCHELL: Actually, I may have just
19 agreed with Harold. I am so intrigued and impressed by the
20 innovative nature of this but I'm with you, Kavita. I
21 don't see the readiness for testing. And so I'm wishing we
22 had more categories, but really, I think, going to be
23 relying on the comments to make that point that technical

1 assistance, data, everything we've already identified that
2 is needed is exemplified here.

3 CHAIR BAILET: Thank you, Elizabeth. Len.

4 DR. NICHOLS: So I agree. I think -- I like the
5 way you framed it and I think of everything as a continuum.
6 And to me the question is: What are the elements of work
7 that need to be done before I would feel comfortable having
8 it tested anywhere? And, here I see three. I see the risk
9 adjuster issue, I see the information technology connection
10 issue, and I see the integration pathway protocol issue.
11 And to me, CMS can do the first two. The clinicians have
12 to do the pathway, but that's precisely what I mean by
13 parallel track, to get us to a better proposal with the
14 technical assistance in hand.

15 CHAIR BAILET: Bruce.

16 MR. STEINWALD: You know, we've talked a lot
17 about making recommendations for implementing a model, and
18 wondered about how often those would be accepted by the
19 Secretary. Now wouldn't it be something if we recommended
20 against implementation and they said, "No, we think we will
21 implement it." We never considered that.

22 [Laughter.]

23 MR. STEINWALD: All of that is just background to

1 saying that we have to rely on our comments, and to the
2 extent that we think there is substantial merit to this
3 approach, we want to get that clearly in the record, and
4 hope that CMS could find a way, if not through a re-
5 proposal through PTAC but maybe another mechanism for
6 pursuing that approach.

7 CHAIR BAILET: Thank you, Bruce. Grace.

8 DR. TERRELL: It might be useful for us to say
9 here, in public, that the way we set up the PRTs, if any of
10 the three high priorities was recommended against by the
11 PRT, then the PRT did not recommend it to go forward, is
12 sort of the way we've set it up. What happened yesterday
13 is -- and as we have reiterated -- is that the PTAC can
14 overrule that. It can determine that those three high
15 priorities do not, in and of themselves, mean that it can't
16 move forward if there's other merit, and that's what we did
17 yesterday.

18 So to get to the point that everybody is making
19 with respect to the continuum, we don't recommend but yet
20 we may think that there are some things out there that
21 could make it better, then there is the likelihood that we
22 can recommend for limited-scale testing because it's far
23 enough along, versus the, let's go forward with this with

1 all -- you know, all deliberate speed. Those types of
2 things are not necessarily constrained by the don't
3 recommend but they do imply a certain level of readiness
4 that's out there.

5 What we're now talking about today is in the
6 ability to comment we may be able to provide broader
7 thoughts, even if we don't recommend, it could move
8 something forward, but it's not actually part of the
9 process that we've got right now, and it doesn't mean that
10 the PRT process that has been put in place actually speaks
11 to that per se, although it probably does signal about what
12 some of the strategies are going to be.

13 CHAIR BAILET: Thank you, Grace. Bruce, did you
14 have an additional comment, or --

15 MR. STEINWALD: Sorry.

16 CHAIR BAILET: Any other comments from the
17 Committee?

18 [No response.]

19 CHAIR BAILET: So, like yesterday, we are only
20 able to do a voice vote, but I wanted to just remind folks,
21 and folks on the phone, because they can't see the summary
22 slide that is now up. Ann, if you could just summate where
23 we are, and then we will go ahead and do a voice vote, and

1 we'll start on this side of the room, with Paul, and go
2 around, just to keep it balanced.

3 Ann?

4 MS. PAGE: Do you want me to read --

5 CHAIR BAILET: Yeah, if you could. Yeah, just
6 the summation.

7 MS. PAGE: Okay. This is the summary of the
8 voting that just occurred on the proposal, whether or not
9 it meets the individual criteria. For Criterion 3 and
10 Criterion 7. Criterion 3 is Payment Methodology, high
11 priority. The Committee voted it Does Not Meet that
12 criterion. And for Criterion 7, Integration and Care
13 Coordination, the Committee voted that it Does Not Meet the
14 criterion. For all the other criteria -- Criterion 1, 2,
15 4, 5, 6, 8, 9, and 10 -- the Committee voted that the
16 proposal Does Meet those criteria. So 2 out of the 10
17 criteria were found to not meet the Secretary's criteria,
18 and the remaining eight, the PTAC voted that it does meet
19 those criteria.

20 CHAIR BAILET: Thank you, Ann. So now we're
21 going to start with Dr. Casale, for rendering a
22 recommendation opinion.

23 DR. CASALE: Yeah. My vote is a 1, do not

1 recommend.

2 CHAIR BAILET: Bob?

3 DR. BERENSON: Do not recommend.

4 CHAIR BAILET: Kavita.

5 DR. PATEL: One, do not recommend.

6 DR. FERRIS: One, do not recommend.

7 VICE CHAIR MITCHELL: One, do not recommend.

8 CHAIR BAILET: My vote is one, do not recommend,
9 and one thing we did yesterday that we're not doing today
10 was we provided a little backstop for our thinking on the
11 vote, and I guess I'll maybe -- I feel compelled. I feel
12 compelled to do that. We can do it afterwards? Okay.

13 MR. STEINWALD: One.

14 DR. TERRELL: One.

15 DR. NICHOLS: One.

16 MR. MILLER: One, because of what I said earlier,
17 which is that I think it does need more technical
18 assistance, but I do think that something like this should
19 be -- if that proves successful, moved forward.

20 CHAIR BAILET: So maybe we'll come back around
21 starting with you, Len, and provide that background.

22 DR. NICHOLS: I couldn't agree more. I think
23 this proposal is so creative, we need to nurture it. But I

1 think we need to protect it from itself, and that's what
2 that technical assistance would do, in my view. And,
3 again, I see three strands. I see the -- I would just say
4 the risk adjustment sector, the information technology
5 connection, that is not trivial. And while some people can
6 do it, not everybody can. And working out how more could
7 do it would be a worthwhile investment. And, third, I
8 really think this care integration pathway stuff is pretty
9 crucial. It could be specialty societies involved and all
10 kinds of stuff.

11 CHAIR BAILET: Thank you. Grace?

12 DR. TERRELL: The aspect of technical assistance
13 is something that we're going to have to understand in far
14 more detail and explore. One of the things that was said
15 in testimony today is how helpful he found some of the
16 tables and he wished that he had had access to some of that
17 information prior to being able -- prior to writing the
18 proposal or in the process of that. And if we're really
19 going to get a lot of this type of creative proposals from
20 the medical community, that's going to be something that
21 we're going to have to understand at the level of PTAC but
22 also CMS, is that what type of information that could be
23 available can we provide the broader community, not

1 particularly an individual but the broader community, that
2 would allow a far more creative process and once that's
3 iterative that could go on forward from this.

4 So as we're making those comments in this
5 proposal, I would suggest that at our next time to
6 communicate with one another that we also be thinking about
7 how we would do that much more explicitly and understand
8 what the constraints might be on the part of CMS.

9 CHAIR BAILET: Bruce?

10 MR. STEINWALD: Despite our unanimous vote on do
11 not recommend, I think the comments should be framed very
12 positively, as others have said as well.

13 CHAIR BAILET: I agree, Bruce. I again commend
14 Dr. Ikeda for his innovative approach to something that is
15 extremely needed in this population of patients. But I do
16 want to make the distinction of our comment about the
17 grades of sort of hitting the hurdle where we think we
18 could support a recommendation for limited-scale testing.
19 And I think in this particular proposal there are still
20 enough unanswered questions relative to the payment
21 methodology reasons we've discussed.

22 I agree with you, Len, relative to the
23 information technology and the dissemination of that

1 information, again, because of the complexity of these
2 patients. But I also want to underscore the challenges
3 that this model will have with implementation relative to
4 coordinating with other specialists using the backdrop that
5 we have now, which is this Bluetooth technology. So I do
6 think that that needs more work, and I completely agree,
7 again, with you, Bruce, that this has to be -- I feel
8 compelled that we should frame this up as something that
9 needs to be supported to the point where we can get it into
10 the field. It's just not ready at this point.

11 Elizabeth?

12 VICE CHAIR MITCHELL: Thank you. One of the
13 things I liked best about Dr. Ikeda's letter was his wish
14 list, and if we had a wish list, I would -- sort of a PTAC
15 incubator for really promising models. But we don't have
16 that. So I'm going to, again, just reiterate my
17 appreciation for the innovative and really just forward-
18 thinking approach, but my concern about readiness, and I
19 will pile on to the very positive comments.

20 DR. FERRIS: The problem with being on this side
21 of the table is that you've already made all the comments,
22 so I don't have to make any. Grace says go to lunch.
23 Right.

1 I did want to, in addition to agreeing with
2 everyone, just highlight what Bruce said about, you know,
3 CMS saying even though PTAC didn't recommend it, actually
4 it's so important we should do it. That is actually the
5 message that CMS should take from this because if you look
6 at the scale of the problem with hospital admissions in the
7 United States from COPD as a large fraction of those being
8 avoidable, which we've clearly shown in our setting, there
9 actually are few epidemiologic targets as rich as this one
10 is. And so it should be a priority to -- and in addition,
11 one can't imagine -- or I should say it in the positive:
12 One would imagine that whatever solution comes to address
13 that problem is going to look a whole lot like what is in
14 this proposal.

15 And so you take those two things together, and
16 you come to the unavoidable conclusion that this should be
17 a priority to develop and test this model or some model
18 that comes out of something similar to this. And that
19 should be actually at the very highest priority for
20 Medicare.

21 Thanks.

22 CHAIR BAILET: Kavita?

23 DR. PATEL: The only additional comment I would

1 make, I guess our own wish list, because we had Dr.
2 Ikeda's, is that with the care coordination, we spoke
3 yesterday -- I'm not sure if you were able to hear it. We
4 spoke yesterday about kind of distinctions between a novel
5 payment -- or a physician-focused payment model such as
6 this one and kind of these concepts like a specialty
7 medical home. Or we even asked today about kind of what
8 are the inadequacies of a chronic care management fee,
9 which is an existing kind of model. In the proposal
10 itself, it references the oncology care model. Just to
11 help think through potentially in whatever next version of
12 this there is, to help think through how can the actual
13 functions of that care coordination, which I think as a
14 clinician you almost take for granted because you know you
15 have to do it, you don't have a choice in any clinical
16 setting, but how that directly ties to the payment model,
17 to the quality metrics. And just as bold as you were about
18 the novelty in the HIT and the novelty in the risk
19 adjustment, think through kind of how to tie that novelty
20 back to what we're tasked with, which is looking at the
21 payment models.

22 CHAIR BAILET: Bob, final comments? Paul?

23 DR. CASALE: Yeah, just to -- and, again, at the

1 end it's hard to add much. But, you know, as I think about
2 it, this model, as everyone has said, is incredibly
3 creative and innovative. This is the type of thing that
4 gets physicians jazzed. I mean, they really get excited
5 because, as Bob related about his relative ending up on a
6 ventilator and Dr. Ikeda said, yeah, he sees this every
7 day, people end up on a ventilator that he could presumably
8 have prevented. And, you know, so this is the type of
9 creative, innovative model that we would encourage.

10 And again, I think the problems, I think Len has
11 highlighted the three areas that really need improvement.
12 But I think that message to the Secretary should be clear
13 about the positive aspects of this model.

14 CHAIR BAILET: Thank you. Elizabeth, do you have
15 a final comment?

16 VICE CHAIR MITCHELL: I don't really want the
17 last word, but this isn't meant as an afterthought, but
18 something that hasn't been said that I think is really
19 important in our comments is that I think the savings from
20 avoided hospitalizations is really important. And so I
21 guess building on your point, Paul, we are getting folks at
22 the right time, and I think the potential for savings are
23 also really significant. So I just wouldn't want that to

1 not be included in the comments.

2 CHAIR BAILET: Thank you, Elizabeth, and I thank
3 the members of the Committee for a very rich, engaged,
4 spirited discussion.

5 At this point a lot of the comments that we've
6 made along the way I know will be incorporated into the
7 recommendation to the Secretary. But at this point, if
8 there are other comments as we -- one of the next steps now
9 is for the staff to work with us to frame up the actual
10 letter, and that's an iterative process that we'll all be
11 able to participate in. But if there are additional
12 comments that haven't been made that you think are
13 important for the staff to hear at this point in time, this
14 would be a good time to share them. Len?

15 DR. NICHOLS: I guess the only thought really is
16 picking up on what Dr. Ikeda said about how useful -- and
17 we discussed it today -- how useful those tables were, we
18 need to figure out a way to get there quicker, and I think
19 we should put that in a letter to the Secretary, that we're
20 working on ways to be more proactive. And, you know, we
21 know why we didn't -- why we got stymied before. We wanted
22 to do -- and we couldn't. We got to find a way to get
23 tables to people in the middle of the preparation of the

1 proposal.

2 CHAIR BAILET: Thank you, Len. Any other
3 comments?

4 [No response.]

5 CHAIR BAILET: So that concludes the deliberation
6 and the recommendation process for the proposal, the CAMP
7 proposal, and, again, I want to thank Dr. Ikeda for coming
8 all the way out from Sacramento. I cannot underscore the
9 value in having you here and hearing from the proposer
10 directly live. I certainly know that -- speak personally
11 that I found it tremendously helpful yesterday and today,
12 and I hope that we can continue as a Committee to keep that
13 bridge and encourage folks and actually work with them to
14 make sure that they can come, because it is invaluable to
15 this Committee and our process. So, again, thank you.

16 I do want to say at the end, because of your
17 comment about BlueShield, I do think it's important for the
18 folks in the room to know that, yes, I am an executive with
19 BlueShield and, yes, I am sure that your practice has
20 relationships, contractual relationships with BlueShield.
21 But I personally have not been involved or talked with your
22 group about this particular model, and it did not influence
23 my voting and reflections on it. But we can have an

1 offline conversation about ways that potentially we could
2 leverage the assets of the plan to work with your practice,
3 again, because I agree with the point made earlier about
4 the invaluable efforts that this will provide to this
5 community and, more importantly, to the patients.

6 So if I in my position with BlueShield can do
7 something that can help accelerate this process, I'm all
8 in. So I'll be following up with you after as well. Thank
9 you.

10 So we are not quite at lunch, and because of the
11 amount of work required to review these processes, I'm
12 going to make a recommendation for my teammates to
13 consider. We could break for lunch now, or we could begin
14 the next review process with the PRT report. We could
15 break at that point. We could potentially -- because we
16 have a number of public comments, we could potentially
17 begin that process and then break. I look to my Committee
18 for their input on what you'd like to do. Bob?

19 DR. BERENSON: I think we just should break for
20 lunch and move the schedule up with the extra 20 minutes we
21 have so that we begin at 20 to 1:00 instead of 1:00, if the
22 people are all around. That's what I'd recommend.

23 CHAIR BAILET: Yeah, okay. And I guess I'd also

1 float out we could take a shorter lunch, too. We probably
2 should, given all the work that's in front of us.

3 Elizabeth, you had a --

4 VICE CHAIR MITCHELL: Yeah, my only concern is if
5 people are coming for the scheduled 1 o'clock that we --

6 MS. STAHLMAN: It wasn't scheduled at 1:00. It
7 was scheduled immediately following the first one.

8 VICE CHAIR MITCHELL: Oh, okay. Then I would
9 recommend a short lunch break, and starting as soon as we
10 can.

11 CHAIR BAILET: Okay. Say that again?

12 MS. STAHLMAN: 12:30 would be 45 minutes.

13 CHAIR BAILET: 12:30 would be 45 minutes, so
14 we'll reconvene at 12:30. Thank you.

15 [Whereupon, at 11:44 a.m., the meeting was
16 recessed, to reconvene at 12:30 p.m. this same day.]

17

18

19

20

1 AFTERNOON SESSION

2 [12:34 p.m.]

3 CHAIR BAILET: All right. If we could kill the
4 music.

5 [Laughter.]

6 CHAIR BAILET: Yeah, kill the music. We're going
7 to go ahead and continue. So welcome back, everybody. We
8 are the PTAC, and we have a member who is on her way down
9 but I thought, in the interest of time, what we'd like to
10 do is go around the room, specifically, and speak to any
11 conflicts relative to the Brandeis-ACS proposal, starting
12 with Paul.

13 DR. CASALE: Do I have to introduce myself or
14 just say my --

15 CHAIR BAILET: No, your conflicts. We've
16 introduced ourselves --

17 DR. CASALE: Okay. Yeah, okay.

18 CHAIR BAILET: -- earlier this morning.

19 DR. CASALE: Great. I have no conflicts.

20 CHAIR BAILET: Bob?

21 DR. BERENSON: Just two things to say. One, I've
22 known Frank for quite a while but I have not, in any way,
23 been involved with the development of this. And it just

1 occurred to me that I graduated from Brandeis but that was
2 quite a long time ago --

3 [Laughter.]

4 DR. BERENSON: -- and the statute of limitations
5 has run out. So I have no conflicts.

6 CHAIR BAILET: Timothy.

7 DR. FERRIS: So I, too, know Frank, in multiple
8 situations and, in fact, we co-chaired the Consensus
9 Standards Approval Committee for the National Quality Forum
10 together. But, more importantly, related to this specific
11 application, I submitted a grant application to do a
12 validation of the grouper, and although that was not
13 funded, have known Chris Tompkins for many years prior to
14 the discussions of this, and I have participated in
15 meetings with CMS about this grouper, on multiple
16 occasions.

17 And based on that prior interaction, not with
18 these individuals but around this specific proposal,
19 although I was not specifically in the development of the
20 proposal, I felt it best to recuse myself from voting, but
21 thought that I could potentially contribute, with full
22 disclosure, to the deliberations, and so have offered, and
23 the group has accepted, that I will participate in the

1 conversation but will not vote.

2 CHAIR BAILET: Thank you, Tim. Elizabeth.

3 VICE CHAIR MITCHELL: Thank you. I would
4 consider myself among the friends of Frank and have worked
5 him on the Measures Application Partnership and discussed
6 Louisiana and alligators and other things, and co-presented
7 before, and I have spent time with Frank and his team,
8 gaining an understanding of this proposal, over the last
9 few years. He came to me, but I think that had more to do
10 with the lobster rolls than the proposal. But I do not
11 believe that that exposure has created any sort of conflict
12 in my review.

13 CHAIR BAILET: Thank you. And seeing Frank, I
14 met Frank once --

15 [Laughter.]

16 CHAIR BAILET: -- about six years ago, but it's
17 wonderful to see you again, and I have no conflicts, based
18 on that.

19 Bruce.

20 MR. STEINWALD: Bruce Steinwald, no conflicts.

21 CHAIR BAILET: Grace.

22 DR. TERRELL: I've had a great conversation with
23 Frank about alligators, grandchildren, in the airport in

1 Delta Club in Atlanta. I have heard him speak about this
2 proposal, or about a payment methodology twice in a public
3 forum and setting. And with respect to Brandeis, I have
4 participated as a speaker and participant at various types
5 of forums on payment reform, in more general terms.

6 DR. NICHOLS: So I think I might be the only
7 person, living or dead, that's never met Frank. I'm
8 looking forward to this afternoon. I have no conflict.

9 CHAIR BAILET: Thank you.

10 MR. MILLER: I appear to be more objective than
11 most because I have never talked about alligators with
12 Frank.

13 [Laughter.]

14 MR. MILLER: But I do know Frank professionally,
15 and we have presented together at various meetings. I also
16 know Chris Tompkins from Brandeis, and we've had many
17 conversations over the years about payment issues, but I
18 was not involved, in any fashion, with this particular
19 proposal and do not feel that I have any conflicts.

20 CHAIR BAILET: Thank you. So, without further
21 ado, Grace, we are going to turn it over to you as the lead
22 reviewer, to hear from the PRT.

23 DR. TERRELL: Thank you, Mr. Chairman, and ladies

1 and gentlemen. I want to first thank the rest of my PR
2 team, in Bruce and Harold, and we'll go through, as those
3 of you that have been here the last couple of days, the
4 same type of formatting as we talk about our proposal.

5 So to remind those of you, again, who have seen
6 this, our presentation essentially starts with a proposal
7 coming forth. This one was in December. It was the very
8 first one to actually be proposed to the PTAC. There is a
9 preliminary review team that essentially is assigned by the
10 Chairman and Vice-Chairman, which includes two to three
11 PTAC members, in this case three, who had no relevant
12 conflicts of interest. At least one physician served on
13 that review committee, and at this point it was me.

14 The PRT identifies any other information that's
15 necessary. After reviewing the proposal, additional
16 information is provided by the submitter, and in this case
17 we had a series of rounds of conversations that started
18 with some questions and then subsequently went to a phone
19 conversation -- a phone conference that lasted -- those
20 that involved recorded conversation to get further
21 clarification. We then had a series of meetings at the PRT
22 level and prepared our report, which we will summarize for
23 you, with respect to the criteria that are set forth by the

1 Secretary.

2 MS. PAGE: Does your clicker work?

3 DR. TERRELL: Yeah. I just hadn't used it yet.

4 I'm just waxing eloquently here. My clicker works.

5 [Laughter.]

6 DR. TERRELL: So this proposal is quite different
7 than the other two that we've heard about, with respect to
8 both approach and scope. So it is based upon episode-based
9 payment models, where the episode groupers are defined by
10 updated versions of an episode grouper developed for CMS
11 previously by Brandeis University.

12 The proposed model targets procedures and
13 conditions broadly, including over 100 procedures and
14 conditions that are designated as payment episodes,
15 identified for potential focus. This includes a breadth of
16 conditions, as far as upper respiratory tract infections,
17 appendectomy, colonoscopy, cataract surgery, acute simple
18 fibrocystic or dysplastic breast disease, juvenile
19 arthritis, lung resection, coronary artery bypass grafting,
20 open heart surgery, liver transplant, heart failure, and
21 cancers.

22 The initial implementation was proposed to focus
23 on over 75 procedures in 10 clinical areas involving 75

1 separate medical specialties.

2 The advanced alternative payment model entities
3 would enter into risk-based contracts with Medicare and
4 take accountability for the cost and quality of episodes of
5 care. The entities could be single-specialty practices,
6 multi-specialty practices, or convener groups of small
7 provider practices with or without ties to particular
8 facilities, as long as the entity is able to perform its
9 management and fiduciary responsibilities.

10 Contract with CMS would involve Medicare payments
11 for every instance of a procedure or episode or condition
12 defined in the contract during a performance period for
13 which the entity's affiliated qualified payments provide a
14 service paid for by Medicare, and each entity participating
15 in the model would identify its affiliated, qualified
16 providers who would participate under the business
17 agreements. Physicians would participate by contracting
18 with the alternative payment model entity.

19 Physician payment continues in the usual fashion
20 through the Medicare Physician Fee Schedule, but the APM
21 entity is at financial risk, based on participating
22 physicians' attributed role in providing care. Attributed
23 roles are determined by clinical algorithms that

1 retrospectively identify all clinicians who participate in
2 the care of a patient for each type of episode, and infer
3 the nature of each clinician's role. Savings or losses
4 attributed to each participating QP are based on the
5 episodes he or she is involved in and his or her specific
6 role in that care.

7 Retrospective bonus payments and penalties are
8 paid for to -- or paid by the APM entity, based on the
9 differences between observed and expected spending for the
10 episode. The APM entity would engage in gainsharing with
11 affiliated qualified providers as agreed upon in their
12 business agreements and guided, at its discretion, by the
13 team-based physical attribution framework.

14 When spending exceeds expected amount,
15 participating providers may be required to contribute to
16 repayments to CMS, and the model will build in stop-loss
17 provisions to protect against catastrophic losses.

18 With respect to quality, improvements in quality
19 and efficiency are expected to result from the financial
20 incentives and use of the clinical affinity groups or sets
21 of clinicians who regularly participate together in
22 episodes of a given type. These decisions and services are
23 intended to influence the way in which patients are treated

1 for a type of episode.

2 Quality measurement is focused on two categories
3 of measures: episode-based quality measures and all-
4 patient-based quality measures, but measures are not
5 specified. In the early transition period of the model,
6 accountability would be focused on reporting of quality
7 measures to allow participants to transition into the model
8 and set a baseline for performance-based payment
9 adjustments in later years. Over time, the Secretary would
10 set a minimum threshold of performance on quality measures.

11 So the summary of the PRT review team, with
12 respect to the 10 Secretary's criteria, is that we were
13 unanimous on all of the criteria. It met all of the
14 criteria per our assessment, with the exception of number
15 2, Does Not Meet criteria with respect to Quality and Cost,
16 which is a high priority, and number 4, Does Not Meet
17 criteria with respect to Value over Volume. As is the
18 current policy of the PTAC, whenever a proposal does not
19 meet one of the high-priority criteria, then it is not
20 recommended by the PRT.

21 So, in conclusion, we have 10 criteria. We did
22 not recommend to go forward because we did not think that
23 it met two, and we will go into greater detail in a minute

1 about our thoughts on all those, but I wanted to stop at
2 this point and give both of my other reviewers a chance to
3 comment if they wanted to.

4 MR. STEINWALD: Just to emphasize what you said,
5 in passing, this is a very different proposal from the two
6 that we have reviewed so far. It's different in structure,
7 and I would say it's different even in philosophy, so it
8 should be a very interesting conversation.

9 MR. MILLER: I thought you did a great job with
10 your summary, Grace. Thanks.

11 DR. TERRELL: Wow. Amazing. A miracle has
12 occurred in Washington.

13 [Laughter.]

14 MR. MILLER: Well, then no.

15 DR. TERRELL: All right. Let's get into the
16 actual criterion.

17 So for Criterion 1, this is a high priority. The
18 scope of this is related to the broad aims to expand on
19 CMS's current alternative payment model portfolio by either
20 addressing an issue in payment policy in a new way, or
21 including alternative payment model entities whose
22 opportunities to participate prior to this had been
23 limited.

1 So our conclusion with this is that it meets the
2 criterion. We believe that there is broad-scope model --
3 that this is a broad-scope model that would provide a
4 payment mechanism for a large number of clinicians covering
5 a broad range of services, from time-limited procedures to
6 ongoing management of patients with chronic conditions, in
7 inpatient ambulatory and outpatient facilities, which is
8 not currently possible with most of the grouper
9 methodologies that are part of Medicare's portfolio.

10 Initial implementation proposes to focus on 75
11 procedures in 10 clinical areas involving 75 separate
12 medical specialties. This is additional evidence of this
13 criterion being met. Expansion into acute and chronic
14 conditions would increase the scope of the model with
15 potential for over half of all clinicians in the country to
16 have greater than 75 percent of their professional fees
17 covered by this methodology. So the scope is quite broad.

18 However, details were missing on how the model
19 would impact provider payments and patient care in specific
20 areas. Information lacking about how the APM would
21 function for the majority of episodes described was
22 missing, and the nature of this particular thing was about
23 the breadth and scope, and we did not get as much

1 information about -- from a specificity point of view.

2 Support for the model has been indicated by
3 physicians involved with surgery and the hospitalist, but
4 an episode payment model for many hospital procedures that
5 are recommended in this model are already being tested by
6 CMS, such as the Bundled Payment for Care Improvement
7 Initiative is already in there. So there are some other
8 things that would partially involve some of the things in
9 this model but not all of them.

10 Criterion 2 was the crucial one with respect to
11 Quality and Cost, another high priority. The proposal is
12 anticipated, if it is met, to improve health care quality
13 at no additional cost; maintain health care quality while
14 decreasing cost; or, number three, both improve the health
15 care quality and decrease cost.

16 Our conclusion was it did not meet the criterion,
17 and the points we would like to make about that is the
18 current MIPS quality measures identified as the starting
19 point for quality reporting, that the proposal basically
20 stated that current MIPS reporting data sets were unlikely
21 to produce clinically meaning improvement in outcomes of
22 care, when rigorously evaluated, yet that's where the
23 current proposal was starting.

1 There were no penalties for reductions in quality
2 in the payment model, and quality primarily was based on
3 reporting on processes rather than outcomes. Moreover,
4 initial requirements were for reporting, not performance on
5 measures.

6 There was insufficient assurance of adequate
7 quality protections to offset the financial incentives for
8 lower spending. Spending could be reduced in ways that
9 would not be beneficial to patients.

10 The proposal asserts that new grouper software
11 takes into account all spending in an episode of care, but
12 it does not describe how physicians will control cost of
13 services they do not deliver directly, such as post-acute
14 care cost, and does not explain whether the risk adjustment
15 methodology adequately addresses differences in patient
16 needs that can affect cost.

17 The cost participation is optional. Less than
18 full participation would leave Medicare at risk for the
19 portion of spending attributed to physicians in the episode
20 not participating in the clinical affinity group.

21 Overall, the PRT felt there was insufficient
22 information describing the ways in which care delivery
23 would change in order to improve quality and reduce costs,

1 and the reasons those changes could not occur under current
2 payment systems.

3 Criterion number 3 is high priority and it is
4 about Payment Methodology. The criteria is that it would
5 pay APM entities with a payment methodology designed to
6 achieve the goals of the physician-focused patient model
7 criteria. The payment model criteria addresses, in detail,
8 through this methodology, how Medicare and other payers, if
9 applicable, would pay the APM entities, how the payment
10 methodology differs from the current payment methodologies,
11 and why the PFPM cannot be tested under current payment
12 methodologies.

13 The PRT conclusion was that this proposal Met
14 this criterion. The payment methodology is described in
15 sufficient detail with respect to its general principles
16 and specific examples were provided in response to follow-
17 up questions. However, the payment methodology is
18 dependent upon CMS updating the episode definitions in the
19 episode grouper methodology, over time. The methodology is
20 asserted to be applicable within other payment models, such
21 as ACOs, for most types of providers, in most settings, and
22 for most procedures and chronic conditions, but no specific
23 examples were provided describing how the model might be

1 successfully implemented in such a broad range of settings.

2 Because the same basic methodology is intended to
3 be customized to each of a large number of conditions,
4 procedures, and settings, additional details will need to
5 be developed before it can be implemented for all of those
6 conditions, procedures, and settings.

7 The model proposes to assign each clinician
8 involved in patient care one of several designated clinical
9 roles. These include primary provider, principal provider,
10 episode provider, supporting provider, and ancillary
11 provider.

12 Each clinical role a priori would be assigned a
13 fixed portion of savings amount determined by policy, yet
14 no information supporting the proportions proposed nor any
15 process defining how those proportions might be adjusted
16 over time were included in the information.

17 Criterion 4 was Value over Volume, and this
18 proposal criterion is about anticipating to provide
19 incentives to practitioners to deliver high-quality health
20 care. The PRT conclusion was that the proposal Did Not
21 Meet the criterion. The proposed models could incentivize
22 efficient provision of services within episodes of care
23 where there are opportunities for greater efficiencies.

1 However, quality of care is neither rewarded nor penalized
2 unless savings occur. Insufficient mechanisms to ensure
3 that savings are not achieved at the expense of quality or
4 to encourage or reward quality even when no change in
5 spending is present. Use of retrospective episode groupers
6 is intended to provide information and standards for
7 individual providers, episodes, and patients for
8 accountability. However, reducing spending within
9 individual episodes does not necessarily achieve savings in
10 total cost of care unless accompanied by methods of
11 controlling a number of episodes provided or ensuring
12 clinical appropriateness of episodes.

13 Although the proposal indicates that utilization
14 of procedural episodes would be controlled through their
15 nesting within condition-based episodes, the proposal would
16 not restrict procedural episodes to only be implemented
17 inside condition-based episodes, nor is there any
18 requirement that the physicians who would be accountable
19 for managing utilization under condition-based episodes
20 would actually participate in the model.

21 Criterion 5 of the Secretary's criteria is
22 Flexibility in that it should provide the flexibility
23 needed for practitioners to deliver high-quality health

1 care.

2 The PRT conclusion was that the proposal Meets
3 the criterion. The model could be used in inpatient,
4 outpatient, and ambulatory settings for multiple procedures
5 and chronic conditions involving multiple types of
6 providers. The model permits flexibility with respect to
7 the number and types of physicians who could participate in
8 clinical affinity groups.

9 However, some issues need to be resolved, we
10 believe. It's unclear how independent practices in
11 different specialties with overlapping but not identical
12 service areas could effectively participate since not all
13 patients in one practice in a clinical affinity group would
14 be in other practices in the group and vice versa.

15 The proposal asserts that rural, critical access,
16 and small group providers can participate under the
17 umbrella of a new corporate entity or convener group.
18 However, the proposal does not describe how to overcome the
19 logistical challenges or potential regulatory or monetary
20 hurdles to accomplish this. The model does not appear to
21 provide for direct payment for innovative services not
22 eligible for payment under the current payment systems and
23 does not explain how physicians would provide such services

1 without payment. It's unclear whether and how physicians
2 would have greater flexibility to control post-acute-care
3 costs and other types of non-physician services.

4 Criterion 6 is the Ability to Be Evaluated by
5 having evaluable goals for quality of care, cost, and other
6 goals for the physician-focused payment model. The PRT
7 concluded that the proposal Met this criterion. An
8 evaluation could be performed by comparing changes in
9 spending under the episode, group, or model for
10 participating versus non-participating practices. However,
11 the model would be very complex to evaluate because not all
12 clinicians in a clinical team are required to participate,
13 and there may be many different combinations of physicians
14 participating in clinical affinity groups. While creating
15 flexibility in implementation, this increases the
16 complexity of evaluation because of the potential for
17 multiple configurations of clinical affinity groups and for
18 interactions between variations in care delivery and
19 variations in the clinical affinity group composition.

20 The model depends upon the ability to identify
21 members of the care teams accurately with respect to the
22 role -- primary provider, principal provider, ancillary
23 provider, et cetera -- and their contributions across

1 settings and the ability to report quality measures of
2 greater specificity than is currently required by payers.

3 Criterion 7 is specifically about the Integration
4 and Care Coordination, and it is designed to encourage
5 greater integration and care coordination among
6 practitioners and across settings where multiple
7 practitioners or settings are relevant to delivering care
8 to the population treated under the physician-focused
9 payment model.

10 The PRT concluded that it did Meet this
11 criterion. The model includes innovative ways to support
12 multiple clinicians working together as part of clinical
13 affinity groups. The model aims to increase integration
14 across specialties by identifying clinicians who regularly
15 participate in a given type of episode for measuring and
16 reporting utilization and quality data. However, no
17 apparent minimum threshold for the level of integration is
18 required, nor is there any way to encourage or require
19 support by and coordination with the physicians who are not
20 part of the alternative payment model entity. The
21 voluntary nature of the involvement of members of the care
22 team may result in less integration and care coordination
23 than would be desirable or necessary to successfully reduce

1 spending and ensure quality.

2 Criterion 8 is Patient Choice. It is designed to
3 encourage the greater attention to the health of the
4 population served while also supporting the unique needs
5 and preferences of individual patients.

6 PRT did conclude that it met this criterion. The
7 patients are not limited in which physicians and other
8 providers they can choose for the different components of
9 care included in episodes. There is no requirement for
10 gatekeeper arrangements or narrowed networks that would
11 limit patient choice.

12 The model may improve attention to individual
13 differences in patient characteristics by including social
14 needs conditions and health-related preferences, for
15 example, by incentivizing attention to the social
16 determinants of health outcomes as a driver of adverse
17 variances in cost and quality. However, it was not clear
18 whether the risk adjustment methodology would adequately
19 protect against participants avoiding high-needs patients.

20 If the model allows a wider range of clinicians
21 to participate in advanced alternative payment models than
22 what exists in the current CMS models, then expansion by
23 demographical, clinical, or geographical diversity may be

1 incentivized.

2 Criterion 9 is Patient Safety, and it is designed
3 to answer the question, How well does the proposal aim to
4 maintain or improve standards of patient safety? We
5 concluded that the proposal Meets the criterion. The model
6 aims to address patient safety by ensuring that episode
7 spending measures include costs resulting from excessive,
8 delayed, or avoided care, and poor outcomes of care.
9 Because episode definitions would include cost of treatment
10 of complications, there are implicit penalties for an
11 increase in patient safety problems.

12 Process measures used for the quality component
13 would also help ensure patient safety. However, the
14 initial quality measures only provide incentives for
15 improvement if there are savings, and the model does not
16 describe how disruptions in care transitions and care
17 continuity would be addressed if all clinicians involved in
18 services prior to and after the transition were not
19 participating.

20 Criterion 10, Health Information Technology, is
21 designed to encourage the use of HIT to inform care. We
22 concluded, Mr. Chairman, that the proposal Meets the
23 criterion. The model requires at least 50 percent of

1 eligible clinicians in each alternative payment model
2 entity to use CEHRT for clinical documentation,
3 communication, and patient care, similar to the requirement
4 for advanced alternative payment models. The model does
5 not restrict current health information integration efforts
6 and may incentivize the use of technology that promotes
7 improved care coordination in monitoring the factors
8 affecting rates of complications. The model requires
9 identification of providers as either primary, principal,
10 episodic, supporting, or ancillary; and its required
11 reporting of quality measures may require enhancements of
12 current coding practices for claims reporting. However,
13 the need for technology to identify high-risk patients or
14 technology-enhanced care innovations is not directly
15 addressed in the proposal.

16 In summary, key issues identified by the PRT, our
17 overall conclusion was the proposed model should not be
18 recommended because it did not meet one of the high-
19 priority criteria pertaining to quality and cost of care,
20 and it does not meet the criterion for value over volume.
21 The broad scope of the proposal and the limited detail in
22 how it would affect individual conditions and procedures
23 make it difficult to determine whether it would meet the

1 criteria for physician-focused payment models in all cases.

2 The PRT does not recommend limited-scale testing
3 because the proposal did not identify a small number of
4 specific clinical areas, episode types, and venues that
5 would be appropriate for limited-scale testing. And the
6 PRT believes that models could have considerable impact if
7 these concerns were adequately addressed in a revised
8 proposal.

9 Since the writing and presentation of the report,
10 we have received additional written material from the
11 proposers, and I'm going to ask Bruce Steinwald to sort of
12 summarize some of our thoughts on that.

13 MR. STEINWALD: Specifically, the letter dated
14 April 7th?

15 DR. TERRELL: Yes.

16 MR. STEINWALD: Yeah. Well, you heard me say
17 earlier that this is a very different proposal, both in
18 scope but also in philosophy, and let me illustrate that
19 latter point by example. In our response or in our
20 preliminary report, we express some concern that we're
21 unable to determine how clinical care would be changed by
22 the implementation of a model of this type, what specific
23 kinds of changes would be made. And in the proposals we

1 reviewed already, it was pretty clear. It was pretty clear
2 that they were talking about a subset of Medicare patients
3 with a specific condition that are treated in a certain way
4 now and how that treatment could change as a result of the
5 clinical model that underlies the payment model.

6 In response to what we said, their response in
7 this letter of April 7th was, "The ACS-Brandeis model does
8 not begin with predetermined care redesign or formulate in
9 advance the strategies of mechanisms for change. We
10 designed the model to allow providers and provider groups
11 to find their own way toward high-quality and high-value
12 care. The model can provide opportunities for numerous
13 specialties in diverse settings to participate in an APM.
14 Instead of laying out a prescriptive care pathway, the ACS-
15 Brandeis model provides new incentives for the delivery
16 team to evaluate each episode of care individually for
17 variation in quality of cost and then drive innovation."

18 In other words, the philosophy here is create a
19 set of incentives and allow those incentives to operate
20 differentially depending on the condition, the diagnosis,
21 the nature of the care provided, and even the venue of
22 care. So they don't want to be prescriptive of how they
23 expect care to be redesigned. They want the clinicians on

1 the ground to make those decisions and be influenced by the
2 payment incentives that the model provides.

3 DR. TERRELL: Mr. Miller, do you want to add
4 anything?

5 MR. MILLER: I'll add one thing, which is that we
6 are evaluating physician-focused payment models as defined
7 in MACRA, and MACRA includes physician-focused payment
8 models as an alternative payment model. It further defines
9 an alternative payment model as something that is
10 implemented under the Innovation Center's authorizing
11 language or the shared savings program. And, interestingly
12 enough, I don't think a lot of people realize this. The
13 Innovation Center's authorizing statute does not actually
14 mention payment models of any type anywhere. It doesn't
15 mention episodes; it doesn't mention bundles. It doesn't
16 mention anything like that.

17 What it actually says that it is authorizing is -
18 - this is language from the statute -- "payment and service
19 delivery models where there is evidence that the model
20 addresses a defined population for which there are deficits
21 in care, leading to poorer clinical outcomes."

22 And one of the things that we struggled with with
23 this proposal was that it did not clearly identify where

1 the deficits in care were with poorer clinical outcomes
2 that were going to be addressed and how they would be
3 addressed.

4 On the one hand, I think the broadest level one
5 could say, well, you know, there's evidence that there's
6 deficits everywhere and that there is something to be done.
7 But we felt that it was difficult to really evaluate
8 against the criteria without some information about that.
9 And that does not translate into a -- we thought that it
10 needed to prescribe the exact intervention, but that it did
11 need to identify what kinds of things could be potentially
12 improved through the model and some indication that the
13 model, in fact, would remove whatever barriers existed
14 today if there were any. And that was where we struggled a
15 bit, was to understand that given, as Grace said, the
16 breadth of the model, which was proposing to do this across
17 a wide range of conditions and a wide range of specialties,
18 without that level of information.

19 DR. TERRELL: So to go back to the comments to
20 Paul that I made or in response to Paul's comments this
21 morning that I made earlier before lunch, we have been
22 talking for two days about care models versus payment
23 models, and in the other two proposals that we evaluated,

1 there was a very defined care model for which sometimes
2 there was a struggle with respect to a payment model that
3 might fit it. The clinician started with an idea about how
4 their particular services that they perform could be
5 greatly improved, wrote about that in both cases, I
6 believe, quite eloquently, and then many of the issues that
7 we had were around the payment model.

8 This particular situation, to Bruce's point, is
9 the opposite, and it's philosophically opposite. And that
10 isn't necessarily bad or good, but it just means that you
11 have to think about it very differently when we're
12 evaluating it. So if this works, this could be the game
13 changer because it applies -- does apply to so many
14 specialties, so many forms of care, inpatient, outpatient,
15 all across the sort of traditional medical spectrum,
16 multiple specialties.

17 So our instinct, I believe, was to try to get
18 details and examples of how it might work with particular
19 examples so we could get our arms around it because of the
20 breadth of it.

21 So the response back that -- well, not the
22 response back, but what we got in this letter since our
23 report came out is basically saying that the philosophy is

1 that this payment model, does it necessarily a priori need
2 to start with a care model? I don't know that I disagree
3 with that or that the rest of the PRT disagrees with that,
4 but there's criteria that the Secretary put forth with
5 respect to this specifically talking about quality and
6 other things that are related to patient care per se. So
7 it kind of goes -- and we go back in that direction.

8 So as the entire PTAC, I believe, today is
9 deliberating on this and the specific criteria, a broader
10 question that we have is if indeed this is correct, you
11 start with the payment model and everything else shall fall
12 from that if the payment model is the correct one. How
13 will we be able to know that, evaluate it, or make
14 recommendations? Because I believe that as a Committee we
15 started from a very different point of view, perhaps.

16 So, with that, Mr. Chairman, we've finished our
17 report to you.

18 CHAIR BAILET: Thank you, Grace, and the other
19 members of the PRT Committee. A lot of material. It's
20 clear that there was significant dialogue, including a
21 transcript of the phone conversation, among other
22 interactions with the team, and I'm impressed by the scope
23 and scale of the work that you guys did to try and provide

1 the background for us to have the kind of deliberation that
2 this model deserves.

3 Before we get into asking specific questions,
4 Kavita, you were out of the room when we declared potential
5 conflicts, and just to complete that requirement, if you
6 could.

7 DR. PATEL: So I've heard this proposal presented
8 in meetings and have had conversations with Frank over the
9 years about the summary of the proposal, but not ever in
10 this detail as it's currently presented. Mostly in the
11 form of presentations to larger groups.

12 CHAIR BAILET: Thank you. So I'm going to turn
13 it over to the Committee colleagues to ask clarifying
14 questions, comments regarding the proposal to the members
15 of the PRT. Kavita?

16 DR. PATEL: Can I just -- because I found myself
17 riveted by the transcript that you all had with, I think,
18 Frank, with Dr. Opelka and Dr. Tompkins. But I just want
19 to make sure I am reading it correctly.

20 In your PRT recommendation around the -- there
21 was an issue the PRT had with the quality metrics.
22 Actually, let me go back and state that in the kind of
23 value -- in the quality conversation, we've never really --

1 the criterion does not go into any detail about process
2 versus outcome measures. There's really just quality. So
3 I would just push and understand a little bit of why there
4 was that pushback about the process measures when, as we
5 known, in quality most of what we have, unfortunately, are
6 process measures.

7 But then if I read the transcript, it does appear
8 that Dr. Opelka in the transcript kind of highlighted that
9 there's a novelty to the measures that they're thinking
10 about that would also lead to kind of potential registries
11 and PROs, and that, in fact, they are looking at kind of
12 building that out. Am I describing that accurately?

13 DR. TERRELL: So this is actually pretty
14 relevant to the conversation that you all were having
15 yesterday where you had what was in front of you and said
16 this is where it is now and then as opposed to aspirations,
17 and I think a lot of where we were was that they were
18 starting with what there is right now out there with
19 respect to MIPS.

20 We were pushing them a little bit on trying to
21 get some sense of granularity as opposed to the general
22 types of quality measures that are out there versus ones
23 that -- how would you have a methodology to do this for all

1 these different types of specialties?

2 And then what they talked about is ways that they
3 aspire to how this might go forth in the future, but it's
4 not there yet.

5 The other thing that I probably should have
6 emphasized more in my report is that they very much see
7 this as a process, that we are starting somewhere. We need
8 to get the entire physician community to another place, and
9 it's not going to be flipping the switch. It's going to be
10 incremental stages.

11 Our critique was not with what they were aspiring
12 to, but with the lack of granularity that we could get to
13 because of their general principle that it would come sort
14 of from the grassroots efforts of the individual practices
15 and societies and the concern that at the initial stage,
16 there was not a quality requirement, per se, unless it was
17 tied to savings.

18 MR. MILLER: Well, just let me add two. There's
19 sort of two separate issues. One is what would the quality
20 measures be, and then what would be the standard
21 performance?

22 I think we felt that the goal was a good goal to
23 try to move to outcome measures, but as a practical matter,

1 they weren't available virtually anywhere yet. They were
2 proposed to be developed, and they said explicitly
3 somewhere that that process was just starting for them.

4 The second issue was that under the quality
5 framework that, initially, it was simply pay for reporting,
6 even with whatever there was that existed. And so the
7 concern was that in the initial years, there would be these
8 financial incentives to reward people for reducing
9 spending, which could come in good ways and bad ways, and
10 that the only quality adjustment for that that we saw in
11 the proposal was that if people had reported measures -- it
12 didn't matter what they did on the measures. If they
13 reported measures, then they would be okay to receive the
14 savings, and the applicants may clarify or correct that if
15 that's not right, but that, I think, was our concern. It
16 was that, in the long run, the model might well be
17 desirable and work, but it wasn't clear when the long run
18 would occur.

19 CHAIR BAILET: Elizabeth.

20 VICE CHAIR MITCHELL: Thank you.

21 Bruce, you have said that this is, in part, a
22 different philosophy, so this is a potentially
23 philosophical question. This model seems very strong in

1 flexibility, choice, improvement, but how would you
2 evaluate it in terms of accountability, whether it's the
3 sort of pay for reporting versus pay for performance? Can
4 you speak to that at all?

5 MR. STEINWALD: I can start. So remember the
6 model doesn't change the way -- it doesn't change the
7 Medicare fee schedule. It doesn't have a per-member, per-
8 month. It doesn't pay for services that are currently not
9 paid for.

10 It relies on the entity that the physicians
11 participate in to drill down the incentives to the
12 individual physicians and other qualified providers to
13 change their behavior, but to change their behavior in a
14 way that's particular to the condition and to the nature of
15 the care, surgical, non-surgical, and also probably the
16 geography of it.

17 So, in a sense, they can't -- this is my
18 interpretation. They can't specify exactly how those
19 incentives would work at the individual provider level
20 because they might be very different, depending on the
21 condition and other circumstances.

22 And now to get to accountability, because that
23 was your question, and I obviously didn't answer,

1 therefore, in my mind, it's hard to specify accountability
2 when you can't specify the incentives at the individual
3 practitioner level.

4 MR. MILLER: So just to elaborate on that, there
5 is clearly accountability in the model for spending within
6 an episode. There is not accountability for the number of
7 episodes, depending on what the episode is. So the episode
8 could be as narrow as a surgery, or it could be as broad as
9 managing a condition. There's not really a distinction in
10 the model, but it is not required that anyone pick the full
11 range of things. Someone could simply be doing the
12 surgical episodes, so then there would be no accountability
13 for whether the number of surgeries went up, et cetera.

14 The second issue is that there is only
15 accountability for a portion of the spending in the episode
16 based on how -- which of the clinicians were participating.
17 So there's an allocation of the dollars. X percent goes to
18 this provider, and Y percent goes to that provider. And if
19 they're not all participating, then only a portion of that
20 spending gets allocated to the entity. The rest stays with
21 Medicare.

22 And then the third issue is there is not clearly
23 accountability for quality performance, at least in the

1 short run, because of it being a reporting of measures
2 rather than outcomes, if that helps.

3 CHAIR BAILET: Bob and then Len.

4 DR. BERENSON: Yeah. I want to follow up. I
5 feel a little bit like Denzel Washington, who played the
6 lawyer in Philadelphia, who said, "Speak to me like I'm a
7 10-year-old," because I don't understand some basic things
8 about how the payment actually works and the role of the
9 grouper.

10 I'm looking at various tables in their proposal,
11 and there's a column that says "expected cost." Where does
12 expected cost come from? The grouper? Let's just say it
13 is a -- oh, I don't know -- a hernia repair. How do we
14 know the expected cost? What is that? Where does it come
15 from? Is it from the grouper?

16 DR. TERRELL: Yes.

17 DR. BERENSON: All right. So the grouper tells
18 us what -- all right.

19 [Laughter.]

20 CHAIR BAILET: Could you dumb it down for us,
21 Grace?

22 DR. BERENSON: "Yes" is good. "Yes" is good.

23 The actual cost, then, is what? The actual

1 billings that were submitted with the usual prices that
2 Medicare uses for paying the relative -- whoever submitted,
3 whether it's the physicians or a hospital or whatever? And
4 so the incentive on the recipient, the APM recipient, or
5 whatever they are called, is to generate behavior that
6 produces that savings, and the role of the grouper is then
7 to establish the baseline. Is that how it works?

8 DR. TERRELL: Yes.

9 DR. BERENSON: All right. That helps me a lot,
10 actually, because I didn't quite understand.

11 CHAIR BAILET: You're pretty easily satisfied,
12 Bob.

13 DR. BERENSON: My second question is, to what
14 extent do we know anything about the effectiveness of the
15 grouper? Now, this is a modified CMS grouper, and as I
16 understand it, working with the people who helped develop
17 the original CMS grouper, but what do we know about the
18 performance of it, the validation that the grouper actually
19 does what we want it to do? Because that seems to be a
20 core part of this whole proposal.

21 MR. MILLER: Well, I'll say -- and, again, the
22 applicant can clarify this, but I would say not much do we
23 know.

1 We have seen a description of how the grouper
2 work is supposed to work sort of in general. We have not
3 seen really the detailed clinical logic behind the grouper.
4 We've seen some information about what codes are in, et
5 cetera, but not the actual -- there's a detailed logic as
6 to when a code is in and when a code is not in, under what
7 circumstances, et cetera. We have not seen that.

8 And I have not seen any actual statistics showing
9 issues of variance, et cetera, how wide was the variance on
10 that and how often did the individual cases occur and were
11 there different patterns around the country, et cetera, et
12 cetera, et cetera. We have not seen any of that.

13 DR. BERENSON: All right. Because what I'd like
14 to have some clarification on -- we heard from CMS a while
15 ago, CMMI, that they're not actually using the CMS grouper,
16 perhaps for the resource part of what was the value-based
17 modifier and now the resource component of MIPS, but not
18 for its own BPCI or its own bundles. And I never got a
19 straight answer as to why not, but I would ask the
20 question. If it's not good enough for CMS, is it good
21 enough here with a new version?

22 Do you want to contribute?

23 DR. TERRELL: Yeah. I want to just -- I don't

1 know that I'm answering your question, but it may give some
2 clarification. If you think about the current grouper that
3 CMS is using, it is only DRG-focused inpatient.

4 DR. BERENSON: Okay.

5 DR. TERRELL: And one of the things that this is
6 about is it was developed by Brandeis for CMS to basically
7 be thinking about groupers outside of that context. So we
8 should have probably emphasized that this was developed to
9 think about could you do groupers that were ambulatory,
10 that were chronic condition outpatient-based, and create,
11 if you will, bundles of bundles within that context, that
12 you could have broad application for multiple conditions
13 and episodes.

14 So CMS went far with that, fairly far with that,
15 to my understanding. However, the types of payment models
16 that they determined that they would put in place ended up
17 being all inpatient.

18 Subsequent to the work to develop this by CMS,
19 there has been additional work that we do not have the
20 specifications on with respect to some of the questions
21 that were answered that was put forth by the American
22 College of Surgeons on top of the other work that had been
23 done.

1 DR. BERENSON: Okay. That's helpful.

2 MR. MILLER: I'll further clarify. So CMS has
3 two groupers that it has developed. One is this one. One
4 is a different grouper process that Acumen has been
5 developing for it, and they've just announced a new set of
6 clinical committees to develop new versions of the grouper
7 under Acumen.

8 We asked CMS what their intentions were with
9 respect to the different groupers and did not get a clear
10 answer on that. My impression was because they had not
11 clearly resolved that and were not able to say that.

12 And we can again ask the applicant this, but my
13 impression is that from what we've seen in terms of CMS
14 behavior right now is that the episode grouper for Medicare
15 is not the default model that CMS is using, I think to your
16 point.

17 So that's a long-winded answer to say this does
18 not appear to be the model that CMS has chosen to use in
19 its own resource measures.

20 MR. STEINWALD: Okay.

21 DR. BERENSON: But one of the -- I have two quick
22 -- oh, did you want to respond?

23 MR. STEINWALD: Yeah. This will be a good

1 question to ask the applicant when he has an opportunity to
2 come to the table about the grouper and its central role in
3 the payment model.

4 DR. BERENSON: Okay.

5 MR. STEINWALD: It would be good for you to
6 prepare that.

7 DR. BERENSON: Okay. But, I mean, one of the
8 attractive parts of this is now this grouper isn't
9 inpatient only. Right? And that is one of the attractive
10 parts.

11 My final question is that the applicant, the
12 proposal -- I mean, a lot of the sort of notion here is
13 that you can do a large number of episodes, both procedural
14 episodes and conditions, and embed procedures within
15 conditions, et cetera. But are they interested and willing
16 to see this tested with a manageable number of episodes?

17 DR. TERRELL: You can ask them directly, but the
18 implication that has been from my point of view, yes, I
19 believe.

20 DR. BERENSON: Okay. Thank you.

21 CHAIR BAILET: Thank you, Bob.

22 Kavita.

23 DR. PATEL: Bob asked some of this. I'll just

1 ask, in your PRT section on quality and -- sorry, not
2 quality and cost -- on value over volume, you mention that
3 some of this issue with like the nesting within condition-
4 based episodes, that the proposal would not restrict the
5 procedural episodes to only be implemented inside
6 condition-based episodes, nor is there a requirement about
7 physicians being held accountable, a little bit to
8 Elizabeth's point for managing utilization.

9 It strikes me in reading through all the kind of
10 voluminous information that they had really tried to kind
11 of boil the ocean, so to speak, with so many permutations.

12 So my question in my own reading of this with
13 what was in front of me, it seemed like there were so many
14 like possibilities that it was almost hard to kind of grasp
15 your hands around kind of how would this play out. They
16 offered some examples, but you could probably conceive of X
17 to the nth degree of those examples.

18 So is that what really hurt? In your discussion
19 around not meeting the criterion -- because I find this to
20 be potentially like a huge game-changer with what you said,
21 the ability to coordinate, the ability to not be dependent
22 on MS-DRGs for a lot of the problems that those convey
23 inside current bundles, which are still largely facility

1 based. And so can you just go through -- did you all
2 struggle with that, or did it really just come down to the
3 need that the applicant should really have tied this to
4 better accountability?

5 DR. TERRELL: You know, I think for me -- and the
6 other two reviewers can answer individually -- I believe
7 the question that you're asking is actually intrinsic in
8 their methodology, and so if you believe that this is a
9 methodology that allows really maximum breadth and
10 flexibility, then part of what they're saying is that,
11 "Well, we can use it for just almost anything if you accept
12 our methodology as being something that allows physicians
13 to be held accountable for cost and quality of care."

14 So what we tried to do in all of our questions
15 back to them was to get very focused on specific examples,
16 so we could get our heads around it.

17 But I think for the PRT or for CMS, whomever
18 would go forward with thinking through this, one of the
19 central questions will be, Is that true? Will it work just
20 as a methodology for any possible situation? That's what
21 would make it a game-changer if suddenly you have a way of
22 having intrinsic, in a payment methodology, the ability to
23 make sure that doctors' behaviors were maximized for

1 patient benefit.

2 So what our reservations were, were twofold, I
3 think. One was show us. Show us really, really
4 specifically. Don't boil the ocean, but give us a small
5 vessel where we can really see all the pieces of it. But
6 because the way that they were conceiving it was broader
7 with the maximum amount of creativity at the local level,
8 we didn't quite feel that we got that.

9 So the question is, if the methodology itself is
10 adequate, do you worry about it? One of the statements in
11 their letter that they just sent to us that I presume we
12 all read says, "Well, we don't think you're thinking of --
13 that this methodology may not actually work for your
14 criterion." Well, they're not our criteria. They are the
15 Secretary's criteria, so there may actually be a disconnect
16 between that, and if that's the case, we need to understand
17 how the PRT would actually function to make recommendations
18 if it doesn't meet criteria as they were set forth by the
19 Secretary.

20 MR. MILLER: I would just add two specific
21 things. So on the issue of value and volume -- and this
22 is, in a sense, where the flexibility of the model becomes
23 one of its weaknesses, is because it's conceivable that,

1 certainly, people who are well motivated could pick this
2 and do exactly the right thing with it. It's also possible
3 otherwise, and so on the volume side, there is the
4 possibility that someone could save some money inside of an
5 episode and decide that it's really profitable to do that
6 episode now and to do more of those episodes, which would
7 then encourage more volume. That's a possibility. It
8 doesn't mean that that's guaranteed to happen. It could,
9 possibly.

10 And then the other possibility is that within an
11 episode, somebody could stint on care to generate savings
12 for which there is no quality measure to protect against
13 that, which would mean that value would potentially
14 decline.

15 There could be many other similar examples I
16 could cite where this would actually support higher value
17 over volume. The problem was there was no assurance of
18 that, and because it was kind of up to people to pick what
19 they wanted to be in, they could clearly, if they wished,
20 pick ones that might not achieve that versus ones that did.
21 That was sort of an additional concern.

22 CHAIR BAILET: Tim.

23 DR. FERRIS: That's a great conversation because

1 I want to pick right upon that point and just ask the PRT,
2 if it's of value -- if there's any reason to think that it
3 is not valuable to know whether or not, in the context of
4 the implementation of this model, total cost of care went
5 up. So if, in the context of a measurement -- ongoing
6 measurement of total cost of care, or volume associated
7 with any one of the chosen -- and I understand that this
8 was not part of the proposal, but I'm now thinking from an
9 externality perspective, in the context of a measurement of
10 the implementation of total cost of care writ large, or a
11 more narrow cost of care around the volume of the specific
12 chosen -- and this comes up, by the way, in all the bundled
13 payment issues. But I'm not trying to problem-solve.

14 Is there any reason why one couldn't measure that
15 larger cost or largest sets of volume metrics in order to
16 be sure that the implementation actually didn't produce
17 those negative consequences that you guys just described as
18 being possible?

19 MR. STEINWALD: Well, the answer, I think, is
20 yes, but -- like so many other answers are. So it's hard
21 to generalize. You know, I'm sure if you constructed the
22 right kinds of episodes and measurement you could measure
23 what needs to be measured. But when you're in the ocean,

1 you know, it's hard to generalize an answer to a question
2 like that.

3 MR. MILLER: Well, the -- their model actually
4 does incorporate that, because they have an episode measure
5 for the bigger episode. So you could say, if I'm worried
6 that there is going to be too many orthopedic surgeries
7 delivered, there is an episode definition for
8 osteoarthritis. Again, to Bob's point, we don't know how
9 well that works but there is one.

10 But in the payment model for knee surgery, if
11 only the surgeons and the anesthesiologists, et cetera, are
12 participating, as least as I could tell there is nothing
13 that says that there is any sort of way that that -- I
14 mean, the interesting thing is you don't have to invent
15 one. They have it in the model, but the payment model per
16 se doesn't seem to -- again, we can ask them, but it
17 doesn't seem to connect those two together.

18 DR. FERRIS: That's interesting. Thanks.

19 And I guess the other question is around -- maybe
20 stepping back from this proposal a little bit and thinking
21 about this as the third of our deliberations. We've been
22 talking a lot about payment model and care model and the
23 need or lack of need for a connection between those two,

1 and I just wondered, your response in sitting here, again,
2 as Kavita was saying earlier, thinking out loud. It seems
3 as though if you have a -- if we have a very narrowly
4 focused proposal, we need a credible care model, but it
5 also strikes me, being someone who lives in the ACO world
6 in which we took risk in an ACO, and I will say, on Day One
7 we didn't exactly have a care model. We just sort of, like
8 -- you just started doing stuff.

9 The broader -- it's possible, then, that the
10 generalizable rule here is that the broader -- the
11 incentive system across total costs of care, the less you
12 need to be prescriptive about a reasonable accountability
13 for the care model, like something plausible in a care
14 model. And I just wondered if you thought that was nuts.

15 DR. TERRELL: I think that may not be nuts, if
16 you think about those of us who are foolish enough to be in
17 some of these at-risk from Day One ACOs, such as you and
18 such as me. The freedom that we had to develop things was
19 just part of the broadness of it.

20 Having said that, if this is going to be broadly
21 applicable for, what, 75 percent of clinicians in a -- you
22 know, in most settings that we traditionally provide care
23 right now, it would seem to me there needs to be the

1 ability to actually demonstrate, to the question that was
2 asked, that Bruce answered, that, in this particular
3 situation, if not ahead of the time for all people in all
4 places that care is provided, some way of actually
5 demonstrating that as opposed to "if you build it, they
6 will come," or they will save, or they will have high
7 quality.

8 We've done that, round one. You and I are
9 victims, or poster children, or whatever, of the successes
10 and failures of that approach. But I believe that part of
11 the purpose of PTAC is to have a different approach and a
12 different level of scrutiny and say, get specific with us
13 so that we can help the Secretary get better at designing
14 these things to be as maximally successful as possible.

15 And part of the issue, since they're doing an
16 incremental approach, is how do you measure that when there
17 is incrementalism, because that's where you get into some
18 of these quality concerns that we had, is if you're
19 starting off here and eventually want it to be far more,
20 you know, 10 years from now in a far more ideal situation,
21 you're measuring during a stage that is under perpetual
22 change. And as a result of that, we felt that there just
23 needed to be some specificity that would allow at least a

1 direction for -- where there could be some testing or
2 analysis that could be done to give us more comfort with
3 that.

4 MR. MILLER: I would also add to that, I think
5 there is now a reasonable body of evidence that says that a
6 pure pay-for-performance model or a pure shared savings
7 model does not automatically result in success, that some
8 people have been able to use it for success and some have
9 not. So I think that's part of the concern here, is that
10 there is some experience with that.

11 And we are -- you can say that there are kind of
12 two things that one can do under one of those models. One
13 is that if one thinks there is simply overuse going on, and
14 this now encourages people to reduce it, then it's good
15 enough, and there are references in the proposal to that
16 being a focus, but there's not really any explanation of
17 exactly what those things are that says here's the thing
18 that would be reduced.

19 However, one thing that is not in the model at
20 all is that there is absolutely no change in the underlying
21 payment system, and we've just seen two proposals come in
22 with people saying, "I need to get an up-front payment to
23 do something differently, I think, to be able to achieve

1 these things." And so this model doesn't have that. And
2 so what that says to me is that under that structure, what
3 it's really doing is it's focusing on areas where we think
4 there is simply overuse for the sake of no good reason,
5 that this will now encourage the reduction of. But it's
6 kind of across the board and it doesn't -- there's not a
7 good way to distinguish, are you reducing the actual true
8 overuse and not ending up getting a little bit of underuse
9 built in there at the same time.

10 DR. TERRELL: But I would add to that, not just
11 over- and underuse but lack of coordination. I mean, I
12 think one of the real merits and strengths of this proposal
13 is the fact that it allows the creative, non-siloed
14 collaborations, almost spontaneous collaborations between
15 those that are already naturally involved with the care of
16 patients as it's currently construed. And part of their
17 argument, and I think it's a good one, is that, you know,
18 you basically have everybody motivated around these general
19 principles and you allow them to be in entities where they
20 can put these things in place, then it's not just over- and
21 under-utilization but it's let's figure out how to actually
22 work in integrated ways where you get improvements in
23 quality and savings naturally as a result of not having

1 what is the perpetual complaint about the U.S. health care
2 system, which is its siloed effect, and that is sort of
3 intrinsic in fee-for-service, where you have the individual
4 payments.

5 CHAIR BAILET: Len.

6 DR. NICHOLS: So I'm trying to figure out the
7 signal we're sending, and what I think we're saying is
8 don't try to bring us a unified field theory of
9 civilization. This is too complicated. There's too many
10 potential applications.

11 But here's what really kind of got me curious
12 about what we really want to say. The judgment of the PRT
13 is the payment methodology meets criteria, but somehow we
14 don't get quality and cost improved and somehow value over
15 volume doesn't work, and that really makes me think, maybe
16 we're not looking at these criterion right, or maybe the
17 criterion don't fit this particular configuration.

18 So I want to ask you two questions. Would you be
19 more inclined to support something like this if, in
20 addition to the bundled business, it essentially said I
21 have a total cost of care constraint that I'm going to hold
22 myself accountable for, and are we not then saying you've
23 got to take into account total cost of care?

1 And the second obvious question, maybe, is, would
2 this not have been met more favorably if they sort of spent
3 less time explaining how it could apply to everything and
4 more time showing exactly how it would apply to a
5 particular maybe payer or situations?

6 DR. TERRELL: I'll answer the second half of the
7 question, which is that seemed to be what all three of us
8 were craving, was to -- if we bought the concept that it
9 was broad and if it was successful it would be the Holy
10 Grail, then you had to give us concrete examples, and I
11 think we really, really dug to try to get that and couldn't
12 get it to the level that we wanted. And it wasn't that we
13 felt that those concrete examples were going to define it
14 per se, but we needed to get our arms around it, using
15 them. So I think that that assessment of -- our assessment
16 is correct.

17 MR. MILLER: I would add that we -- and, again,
18 we are learning as we go, all of us, on this, right? -- but
19 the way at least I think, and Grace and Bruce can disagree
20 if they want to, but I think we tried to focus on the
21 payment methodology criterion as to whether we thought it
22 was clearly and precisely enough defined that we could
23 understand exactly how it would work, as opposed to the

1 other criteria where we tried to assess what result it
2 would have, and whether it met those criteria.

3 DR. NICHOLS: Yeah. Okay.

4 MR. MILLER: And I think that may be a little bit
5 different than the way we were doing some of the other
6 proposals, but, I mean, clearly, with the others, we
7 thought there were flaws but it was also that we really
8 just weren't quite sure exactly how it worked. I think we
9 concluded, we were pretty clear about exactly how they
10 meant to make it work.

11 And the issue, to me, with the examples, was that
12 in the absence of clearly defined quality measures, you
13 know, outcome measures, et cetera, and some of the
14 protections that we talked about, if it had been clear that
15 lots of work had been done, saying here's what we expect to
16 happen, here's people who have signed up, here's what they
17 are planning to do, we would have said, okay, well, clearly
18 maybe there might be some weaknesses but there's lots of
19 positive stuff that's clearly already lined up to happen,
20 but we couldn't see that.

21 And then when you say it's a jump ball and
22 somebody might sign up to do the wrong thing and somebody
23 might sign up to do the right thing, and we don't know

1 which one is going to sign up, that said, boy, we're just
2 not comfortable saying -- again, I think I'm speaking for
3 myself, but that's kind of where at least I came down.

4 MR. STEINWALD: Yeah. The other two proposals,
5 you know, we were all impressed by the clinical reforms
6 embedded in their proposals and then they were found
7 deficient in trying to overlay or partner a payment model
8 with the clinical reforms, where the payment model would
9 support and expand and courage the kinds of clinical
10 transformations that their models envisioned.

11 So this is very different. I mean, we thought
12 that the payment model, even though it was not without some
13 issues of what to do about non-participating, and how do
14 you make sure that the clinical affinity group has got what
15 you want in it, but giving that the benefit of the doubt
16 and saying, okay, we understand the payment. Now what we
17 don't understand is how you can partner that payment model
18 with any number of clinical transformations in different
19 clinical areas, different kinds of episodes, different
20 geographic areas. How do you make that shell of a payment
21 reform work for all of those different kinds of clinical
22 situations that you could envision?

23 And, by the way, there's probably some overlap.

1 As we've talked about, there's always overlap between these
2 criteria. There's probably some overlap in the
3 difficulties we had with Criterion 2 and Criterion 4, very
4 similar reasons.

5 CHAIR BAILET: Paul.

6 DR. CASALE: So one area I guess I'm struggling
7 with is this team-based fiscal attribution -- and I know
8 you highlighted that in your report; it was in one of those
9 "howevers," amongst the howevers -- in terms of the
10 clinical roles. And, you know, I mean, I see the table and
11 I can imagine how that might work, or does work even now in
12 BPCI, with an elective hip replacement or something. I
13 would struggle more in a complex Medicare patient who is
14 acutely ill, who comes in -- who may then be involved in
15 multiple episodes within here. And even one of the
16 letters, I think, from the radiation oncologist was like,
17 "Well, you have me in the supporting role." I know these
18 are examples, but sometimes I'm the episodic provider,
19 whatever, you know.

20 So in the model, they mentioned about clinicians
21 identified through billed services, assigned by algorithm,
22 and there are issues in that with PCP assignment in ACO,
23 right? I mean, so how exactly would that -- and

1 alternatively they say providers could designate
2 themselves, but then you worry about the food fight, as
3 Harold likes to bring up, about, well, you know, who's who.
4 And then is there an opportunity for patients to identify
5 who their providers are?

6 So, anyway, I was wondering what kind of
7 conversation you might have had around all that.

8 DR. TERRELL: We had some conversation around it.
9 My understanding is that there is some proprietary
10 algorithm that's part of what they've developed, but we
11 didn't get into the details of that. Part of it would
12 probably have to be self-identification or coding within
13 the context. They gave some very good examples, in fact,
14 one in cardiology with respect to, you know, you could have
15 a primary care provider who is managing hypertension and
16 lipids, and then they end up with an acute event, and
17 there's a cardiologist, and then they end up with, you
18 know, CT surgery or whatever. And they were able to
19 basically give very specific examples of how that whole
20 thing might work, and I thought that was a great example,
21 in broad ways, where somebody could pop from role to role,
22 depending on the particular patient and their particular
23 role in it.

1 It would seem that they're basing this on
2 methodology that's been developed that we didn't get the
3 specific details of, on claims, and on patterns that they
4 can identify from broad, you know, access to claims that
5 have been there for a long period of time.

6 The types of things that you are talking about --
7 well, what about the identification, what's going to happen
8 within the clinical affinity group with respect to this --
9 I don't think that was answered. You could still have
10 doctors fighting internally over the dollar, depending
11 upon, you know, the usual types of incentives or lack
12 thereof that are in there.

13 But it appears that, I wouldn't call it machine
14 learning but they have obviously got big data knowledge
15 that informs this model and would likely get better over
16 time, as they're able to do analysis of patterns with these
17 new types of identifications put into the model.

18 With respect to patients -- we actually asked it
19 probably more related to patient choice -- a patient
20 wouldn't necessarily say this is my primary provider or my
21 episodic provider, but the patients have complete choice.
22 They could go to a particular primary care physician who is
23 not part of the clinical affinity group, and that piece may

1 be carved out of the overall payment model that the
2 clinical infinity group would have, or not. There was,
3 again, that flexibility in there, but it did not preclude
4 patient choice. But it appeared that there was some sort
5 of deep knowledge that was based upon some stuff that's
6 already been developed, with respect to the Medicare
7 database.

8 MR. MILLER: I'll just clarify. If the clinical
9 affinity group, which I think is a wonderful idea, was
10 constituted in the maximal sense, that everybody who was
11 involved with the episode signed up and was part of the
12 alternative payment entity, then they would basically be
13 collectively accountable for all the spending, however the
14 episode was defined, and then they would be under the
15 model, completely free to figure out how they wanted to
16 divide up the money.

17 But if they're not all involved, then there are
18 some default rules, and the default rules include both sort
19 of the -- I believe sort of an attribution rule in the
20 model that says, so how do I decide whether you're the
21 primary or you're the episodic, or whatever, and then they
22 get it. That's somewhat irrelevant if everybody was
23 involved, because whatever the grouper said whoever it was

1 it wouldn't matter because you'd get the whole thing and
2 then you'd have to divide it up, and again, the applicants
3 can clarify that.

4 But that was one of the complexities that made it
5 difficult to assess this. If you had said we're only going
6 to do this when the whole clinical affinity group signs up,
7 it would have removed one degree of complexity but all of a
8 sudden now you can be assigned -- you can pick whatever
9 episode you want and you can have whoever in your clinical
10 affinity group, and it may or may not be all the key
11 people, and that really starts to create some interesting
12 questions about what's really going to happen here.

13 DR. BERENSON: I will be asking our guests when
14 they're up here, but I just wanted to pursue a little more,
15 the grouper and what it does and doesn't do.

16 So Harold has already surfaced the issue of
17 appropriateness and the potential for value and growth when
18 you are paying for procedures.

19 On the condition side, we haven't talked as much
20 about that, although Harold mentioned it, that the concern
21 that conditions will come out of the woodwork, that people
22 will have conditions. Is there any logic in the grouper
23 that determines that a patient who is being treated -- I

1 mean, who is being billed for congestive heart failure
2 actually has parameters consistent with congestive heart
3 failure that they actually have the condition, as far as
4 you know?

5 DR. TERRELL: It's a claims-based system.

6 DR. BERENSON: Oh, okay. So we still have that
7 issue, then, that we would have, and any condition-based
8 payment episode, we have the issue of having to establish
9 sort of the minimum severity.

10 All right. Then final question.

11 DR. TERRELL: Having said that, Bob, again, what
12 I alluded to with big data or knowledge or machine
13 learning, if you see somebody who's having certain bundles
14 of services performed, you may well be able to infer that
15 they have congestive heart failure, even if somebody never
16 makes a claim to it, or if they're on Lasix and they've got
17 pulmonary edema listed as a diagnosis in others.

18 So we didn't get very -- into the details with
19 them about the specificity of that, but I believe my
20 understanding from what we did get from them was that the
21 way this is built out, oftentimes -- and it should get
22 better over time -- you should be able to, by sophisticated
23 analysis of patterns of data, get pretty good at

1 understanding who really has certain things.

2 I mean, if somebody is coding congestive heart
3 failure, but they never have a chest x-ray, an
4 echocardiogram, or prescription for an ACE inhibitor or
5 something, then that may well be something that the type of
6 methodology that they have would actually protect against,
7 which is something that some of the other methods don't
8 have.

9 DR. BERENSON: All right. So --

10 MR. MILLER: I don't believe that's in the model
11 as it's defined today, and we can ask them that.

12 DR. BERENSON: And I just wanted to sort of go
13 back to Len for a second. When you mentioned earlier total
14 cost of care, you were referring to total cost of care for
15 the episode, for total --

16 DR. NICHOLS: Yeah.

17 DR. BERENSON: -- because it seems to me -- go
18 ahead.

19 DR. NICHOLS: Well, because what I understood the
20 critique to be, you can't control the number of episodes if
21 you only focus on the cost inside the episode, therefore
22 the inference being you've got to have some more global
23 metric to feel comfortable about control of episode.

1 DR. BERENSON: I see. Okay. I got your point.

2 To me, one of the advantages of having an episode
3 grouper is that you can hold people accountable for what
4 they have control over rather than things that have to do
5 with all sorts of other conditions, and that is a --
6 depending on who you're paying for what purpose, you either
7 do want to do total cost or you want to say you're
8 responsible for back surgery --

9 DR. NICHOLS: I'm with you.

10 DR. BERENSON: -- and we're not going to hold you
11 accountable for congestive heart failure.

12 DR. NICHOLS: I take your point.

13 DR. BERENSON: Okay.

14 DR. NICHOLS: All I was trying to get to was the
15 thinking in the PRT about why --

16 DR. BERENSON: And to be able to deal with the
17 volume issue. Yeah, I got that. Okay. That's a tradeoff.
18 Thank you.

19 CHAIR BAILET: So I don't want to truncate the
20 dialogue, but I do want to make sure -- no, Kavita. You're
21 going to be the last. I'll call on you, but you will be
22 the last Committee participant until we can have the
23 presenters come and also hear from the public. I just want

1 to make sure we have enough sand in the hourglass to have
2 the deliberation that's required.

3 So, Kavita, you've got the last shot.

4 DR. PATEL: Very brief. And I'll ask Dr. Opelka.
5 This is proprietary to Brandeis. They were awarded the
6 kind of episode grouper by CMS. There are obviously other
7 commercial groupers. This kind of riffs a little bit on
8 the proprietary notion that we've talked about with other
9 models. Is it such that your exploration has kind of
10 deemed that this is incredibly tied to that proprietary
11 use, or could there be some ability, flexibly, which gets
12 to maybe like Criterion 5 with the ability to bring rurals
13 and kind of overcome these monetary hurdles? Did you talk
14 about that?

15 DR. TERRELL: So the issue is if it's a grouper
16 that's actually a Medicare-CMS product, probably something
17 would be proprietary.

18 So, for example, if we ended up with the overall
19 principles of this particular proposal were accepted by us
20 and accepted by CMS and wanted to go forward, then, in
21 theory, there could be other types of other products that
22 could provide the same service. But since it would
23 actually be at the Medicare level, how that would be done

1 and administered likely -- whomever got that, likely there
2 would be a Medicare contract involved.

3 DR. PATEL: I guess a different way of asking is,
4 is the burden of the cost for that -- I mean, right now,
5 that's being borne out by Medicare because they're using
6 that in the QRUR and VBPM. I mean, so is there -- I didn't
7 see any reference that there would be any cost for that
8 methodology to be taken up by CMS. I think that's the
9 assumption. I just want to make sure I'm clarifying that.

10 DR. TERRELL: You can ask the proposers, but I
11 was assuming that the methodology in the grouper
12 methodology has to reside in those who actually make the
13 payments as opposed to an intermediary.

14 MR. MILLER: We are not clear on how that
15 progresses. If Medicare were endorsing it and maintaining
16 it as their public use grouper, it would be a different
17 thing. It's not clear that they are, and then there are
18 enhancements to it that we're not quite clear, the nature
19 of what that is.

20 CHAIR BAILET: All right. Thank you.

21 If we could now call Dr. Opelka and the ACS team.
22 As you come up, if you could identify yourselves. We've
23 got opportunity for 10 minutes of comment.

1 DR. OPELKA: Good afternoon. Frank Opelka with
2 the American College of Surgeons.

3 DR. TOMPKINS: Chris Tompkins on the faculty of
4 Heller School, Brandeis University.

5 DR. OPELKA: I'm going to make a few brief
6 remarks, and then I am going to ask Dr. Tompkins to make a
7 few more.

8 First of all, I want to thank you, the PTAC, and
9 particularly the PRT for the job you've done. We certainly
10 didn't make it easy on you, and we really appreciate the
11 depth at which you've approached this.

12 I was going to make a few remarks, which most of
13 you have already made. So I'm going to stay away from some
14 of those and focus, if I can, on the question of quality
15 over cost and value over volume for just a few seconds,
16 because I think these two go together, and we're missing
17 some subtleties that's in the proposal in the way that it's
18 been discussed.

19 The way the model works is we would identify
20 within an episode whether the team that's engaged in that
21 episode has actually established shared savings or whether
22 or not there are losses relative to an individual patient
23 risk-adjusted expected cost. So that's an individual

1 patient risk-adjusted expected cost. Did you save money,
2 or did you lose money on that deal?

3 That then translates into four tiers of quality.
4 There are four tiers of quality, and those four tiers only
5 exist if you're in the episode-based measure framework,
6 which is a new measure-based framework proposal we've put
7 forth to CMS. That measure-based framework proposal
8 includes high-value process measures, such as the goals of
9 care. It also includes outcome measures, which are
10 currently in the MIPS program, and it has, now in
11 developmental phase but will be ready by this fall, PROs
12 that are specific to the episode. So if there was a goal
13 of this episode, did we meet that goal in a PRO? So there
14 are, indeed, outcome measures.

15 That creates four tiers. If you're on the
16 savings side, you must not just participate to reach the
17 highest tier. You must perform. You must be in the top
18 decile of performance. So it does have performance level
19 built within it along with participation. It also has new
20 levels of participation we've never seen before. Fifty
21 percent of that episode must have a PRO. We've not reached
22 that in anything else we do.

23 Now, if that particular episode that's in use

1 doesn't yet have all the elements, which all those elements
2 were included in the proposal for measurement, but if that
3 particular episode doesn't have it, we default to the MIPS
4 measure set, which we don't think is optimal. It does not
5 allow you to reach the fourth highest -- the highest tier,
6 the fourth level. You can only get to a score of good.

7 In all four of those tiers, it influences whether
8 you're on the losing side or you're on the winning side.
9 So if you're in the loss column and you score in the top
10 decile, your loss is forgiven, but if you are in the lowest
11 measure, then you pay and bear the full risk of the loss.

12 If you're in the positive, in order to get the
13 full positive, you've got to be in the top decile. If you
14 are unacceptable, even though you had shared savings, you
15 get nothing.

16 So quality is influenced in both the upside and
17 the downside risk of the model, and I don't want that to be
18 lost. So this model has within it a whole new set of
19 measurement, which has gone through the NQF process and is
20 continuing to emerge and develop, and it pushes an entirely
21 new envelope in where we are in measurement today.

22 So let me turn to Chris for a few other comments.

23 DR. TOMPKINS: First of all, thank you for a

1 gracious opportunity to be here.

2 Twenty years ago, almost exactly, I had a
3 gracious opportunity to brief a few senior leadership in
4 this very building with regard to a design report that we
5 had just submitted to the Office of Research and
6 Demonstrations in which we had devised a payment system we
7 called the Medicare shared savings payment system. Twenty
8 years ago.

9 Now, that was the Roaring '90s. In the Roaring
10 '90s, managed care was trying to displace the culture of
11 health care that had grown up organically in prior decades.
12 And those of you who were there remember the outbreak of
13 schizophrenia, which was the term of art, where you had
14 delivery systems that were well entrenched in their
15 productivity measures and compensation systems, and yet you
16 had this aspirational call of managed care backed up by
17 concrete contracts saying, "We don't want your productivity
18 measures. We want the nascent concepts of value."

19 And the Medicare shared savings program was an
20 attempt to cure the schizophrenia because the biggest
21 anchor holding back the delivery systems was the fee-for-
22 service Medicare system, especially for specialists who
23 were doing quite well, thank you, under the productivity

1 measures in the fee-for-service system.

2 Now, that was the Roaring '90s. Managed care was
3 the impetus then, and now we have MACRA. We are believing
4 that MACRA is a new impetus for reform that will create
5 demand on the part of MIPS-eligible clinicians to try to
6 seek refuge from MIPS and in APMs when they can actually be
7 effective.

8 I've had doctors say this to me, "If you're going
9 to ask me to do so much, please let's make it worthwhile,"
10 and we're trying to open up the space that doesn't really
11 exist well. It is space. It's empty space. We're trying
12 to fill it in the APM space where specialists in
13 particular, but emphasis is on team-based care, where we
14 have every clinician's role in every episode for every
15 patient they see, for every service they provide, and every
16 dollar that they spend and every dollar that they save or
17 lose is accounted for in the system.

18 It's an x-ray machine that everybody steps into,
19 but it's an opportunity to show your effectiveness, so yes,
20 it pitches a -- call it a bundle price, target price,
21 expected value, expected cost, and it says under the almost
22 universally panned fee-for-service system with all of its
23 lack of coordination and all of its fragmentation, this is

1 what you see. This is what Medicare spending -- this is
2 what's not sustainable. This is what led to SGR. This is
3 what led to MACRA. This is what has to change, and here is
4 your opportunity to do it.

5 Now, back in the day when we did the Medicare
6 savings program, we sort of like created a blank canvas.
7 Tim, you referred to that. Right?

8 Game on. The ACO. Now, what is your care plan?
9 Right? Well, you had some ready to go, but it wasn't all
10 out there. This is a little bit more like paint by
11 numbers, because now instead of just a blank canvas, we
12 have every condition known to humankind catalogued and
13 grouped, and all the major procedures and all the
14 clinically relevant services that pertain to those
15 conditions are encoded in the clinical logic by their
16 clinical relevance and association to the clinically
17 meaningful episode framework that it's all designed around.

18 Now, it wasn't easy to anticipate what to speak
19 on, but I was flying into Washington. It seems like
20 yesterday, but this morning. And knowing I was coming into
21 Washington, I decided that I had to organize my comments
22 around an acronym, and so the acronym I decided was SPRINT,
23 just so I could remember it without referring to my notes,

1 without putting on my glasses.

2 Now, the first S is -- this is now the
3 implementation plan. So the S is specifications. We've
4 done all this. You've done most of what you've done, and
5 we've done most of what we've done without contact. Very
6 much of it was CMS. At some point, there has to be meat on
7 the bone. There has to be the specifications that only CMS
8 can provide because they have the authority to do it. They
9 wrote the QPP regulations. They know what has to fit, and
10 the two things that they have to weigh in on are what are
11 these entities, what are their governance, what's the
12 rules, minimum case size and so forth. We're certainly
13 willing to give the technical backup for that, but they
14 have the authority and the perspective to make that
15 decision.

16 The second one -- and I watched you all on TV
17 yesterday, so this is my second day. Maybe I missed it,
18 but I don't remember very much discussion about qualified
19 participation in advanced APMs. When you read through
20 MACRA and when you read through the QPP, the idea isn't
21 that a MIPS-eligible clinician puts a little toe into the
22 APM world but otherwise stays in MIPS. The idea is that
23 the body of your clinical work is carried over into the

1 APM, and on top of the grouper, this APM has what we do
2 call the fiscal attribution logic, but what it does is it
3 tracks every clinician's work every day of the week.

4 There are some clinicians who maybe do the same
5 thing every day, every day of the week. Most don't, and so
6 if you're trying to capture the body of work that most
7 clinicians do, you have to be able to follow them as they
8 go from this condition to that condition or into the OR or
9 maybe consultation, maybe surgical consultation, and you
10 need to track all that. And that becomes what we call the
11 episode clusters that are defined around each clinician.

12 Those clinicians affiliate. They become
13 qualified participants in advanced APM entities, and that's
14 where the risk is born. And those of you who have read the
15 proposal know that that's the case.

16 So I'll go faster now. Those are the
17 specifications. One of the things that the PRT asked us
18 several times was, "Well, who is interested? Who is going
19 to participate?" So that's the P in SPRINT, participation.

20 CMS has thrown demonstration parties before, and
21 nobody shows up. We don't know in advance, and without
22 those specifications, nobody is going to say, "I commit to
23 this model." If there's an eight percent downside risk,

1 what's the upside risk, and what kind of industry is going
2 to form around this? And industry has formed around ACOs.

3 The I -- and you'll be glad to know two letters
4 that are taken up in my next category are called
5 "information protocols." This provides a tracking of every
6 single dollar, savings or loss, in the clinical framework.
7 As I said before, CMS is now in a position to push out
8 information data formats that they don't do right now.
9 They give raw data out, but now for CMS's own internal
10 monitoring and evaluation purposes and for the sake of
11 participating organizations, they can say, "Here it is.
12 Here's the x-ray results."

13 And working with the information protocols with
14 CMS around what kinds of ways to frame it, what patterns to
15 reveal and so forth, now suddenly the lights are turned on,
16 and you have the cost drivers for all the episodes you're
17 participating in and all the patients you're seeing.

18 So lastly in my SPRINT acronym is tracks, t-r-a-
19 c-k-s, because it isn't necessarily true that we just turn
20 the switch and this whole thing, the whole blossom opens up
21 all at once. No. Some grounded experience seems to be in
22 order, and again, this is where CMS could weigh in as well.
23 What are the tracks? You could have a procedural episode

1 track, so you have surgicals, specialists,
2 anesthesiologists, radiologists, so forth, who form around
3 procedure episodes because that's what they do, but that's
4 actually not all they do, and that's not all they want to
5 do. They give surgical consultations, and they give
6 follow-up visits as well. But nevertheless, one track
7 could be procedural episodes. Another could be acute
8 conditions. Another could be chronic conditions, or you
9 could cut it another way.

10 But the point is in a rapid cycle adoption
11 process, step up to the game-changing Holy Grail, as has
12 been referenced by various people around the table.

13 CHAIR BAILET: Thank you both for your comments
14 and participation in helping create this proposal.

15 I'd like to turn it over to the Committee now for
16 questions specifically to the submitter. Thank you, Bruce.

17 MR. STEINWALD: You touched on this under your S
18 in SPRINT, the role of the grouper. But I wonder if you
19 could expand on that a little bit, and especially identify
20 the unique features of the grouper and how its essential
21 role is in the payment system that you propose.

22 DR. TOMPKINS: Well, you know, when we started
23 developing the episode grouper, we realized that existing

1 groupers really were not designed for the Medicare
2 population where you have simultaneous conditions and
3 simultaneous episodes happening all the time. So it was
4 designed with that in view.

5 First of all, it exists. That's an advantage of
6 having it. It does the accounting whereby through the
7 clinical logic and the episode construction logic, you're
8 able to take a whole stream of administrative claims sorted
9 by beneficiary and sorted by data service and say why was
10 this service done. And so, therefore, the episode grouper
11 for Medicare -- I won't get into too many of the technical
12 details. It's a SAS program, but some earlier questions
13 were asked about this. It was designed by -- it was
14 developed at CMMI with oversight from the Office of
15 Information Services, which puts quite a lot of high
16 standards on software that's developed by or for CMS. And
17 we had a professional software development team at Booz
18 Allen Hamilton that complied with all of those OIS
19 requirements and all the testing requirements and all the
20 documentation requirements, and CMMI would tell you right
21 now it's the best, most tested, most openly tested and best
22 documented grouper bar none in the industry.

23 It has some tricks up its sleeve, which others

1 don't. For example, it can allocate services to multiple
2 episodes co-occurring, but it will divide the dollars and
3 allocate them so that when you're attributing actual costs
4 to the episodes, you're not double counting dollars.

5 It recognizes by way of clinical logic and
6 association that the procedures are done with respect to
7 the indication, which are the conditions, and you can roll
8 it -- yes, the procedure episodes can stand alone for their
9 own analytical and payment purposes, but they roll up into
10 their conditions, which are the indications for that
11 patient. Sometimes procedures are done for different
12 indications. The grouper knows which indication it was, so
13 you can roll it up to the condition episode. Similarly,
14 when you review the condition episode, all of those
15 procedures are now rolled up into it.

16 There's another episode association we call
17 "sequelae," which are -- we borrowed this definition from
18 Merriam-Webster, which are the aftereffects or secondary
19 results. That is, if you're having a condition, other
20 conditions can emanate from them. Heart failure can
21 emanate from an AMI. Post-surgical infection can emanate
22 from a surgery. These are formed by way of their episodes.
23 Some of them can be used for analysis. Maybe some of them

1 only serve the purpose of capturing the services relevant
2 to that clinical concept and then rolling it up into the
3 parent or causal episode.

4 So, without double counting, across all episodes,
5 all the complexity in the world, we can keep track of
6 dollars, every dollar, without double counting it. Also
7 the savings and also the losses.

8 CHAIR BAILET: Paul?

9 DR. CASALE: Thank you for presentation. You
10 know, when I think of episodes, I always first think of
11 BPCI, you know, because that's my initial thought. So when
12 I look at BPCI and those 48 conditions, I mean, people are
13 speaking with their feet. Most are doing elective joints
14 and CABG, right? Not very many are doing chronic
15 conditions. And as I think through your motto, again, I'm
16 always trying to -- I sort of need some reality. So I
17 think of the elderly patient with sepsis who then has an
18 MI, ends up with a PCI, then has a vascular complication
19 and ends up with an embolectomy, then gets a small bowel
20 obstruction. I mean, you know, so the episode and the -- I
21 struggle a bit on how all of this comes together without
22 getting ultimately to including the total cost of care.

23 So I don't know if you could comment on that,

1 because I do struggle with how this all works in these
2 complex Medicare patients as opposed to what's currently
3 going on in BPCI, which is mostly around elective --

4 DR. TOMPKINS: Well, I'm not sure what -- I'll
5 take a stab at the -- the grouper would acknowledge all of
6 those conditions, right? Each one gets triggered. Each
7 has a certain duration. It will assign services by way of
8 clinical relevance to each one. If clinicians have decided
9 that there are relationships among those episodes and it's
10 not spurious or just happens to be, there's no all-cause
11 here. If there's a connection made, it's because clinical
12 reviewers have decided that there is an appropriate
13 connection to be made. So the grouper will do all that in
14 the background.

15 Now, the question about BPCI, when ACA was
16 passed, that launched a lot of things. Some things were
17 parallel inside of CMS, and BPCI as a bundled team or a
18 portfolio started underway, just like as authorized under
19 ACA, the episode grouper formation had its own track. And
20 so they sort of grew up organically differently. BPCI is
21 pretty much hospital-based DRG.

22 Philosophically, not to go down this road too far
23 unless you want to, philosophically, we think that the

1 triggering moment, the definition, should be as early as
2 possible so that you maximize the chances for arbitrage.
3 And most things don't appear out of nowhere in the
4 hospital. So for one thing, to be able to go upstream and
5 recognize that physicians have ambulatory practices, too,
6 and those patients are often seen there, the grouper has
7 already tracked that, and the patients with those
8 denominators, with those conditions, now are at risk for
9 going in the hospital. The grouper will keep track of
10 that.

11 BPCI has grown up sort of out of convenience, I
12 would say, piggybacking on the DRG system. I don't think
13 that the DRG per se would meet our criterion for the label
14 which occurs at the earliest possible moment before those
15 arbitrage and opportunity, because as we all know, the DRG
16 label is put on, and the DRG dollars are out the door even
17 after the discharge has occurred.

18 Now, do you --

19 DR. CASALE: Yeah, I think a bit. I think a
20 couple things still that I struggle with is ultimately when
21 you get the dollars down to the physicians, so who is --
22 you know, which role are they playing in these very
23 complicated --

1 DR. TOMPKINS: Right.

2 DR. CASALE: -- condition, you know, episode
3 within episode within condition.

4 DR. TOMPKINS: Right.

5 DR. CASALE: And then second is around, you know,
6 if this is -- in terms of creating -- you know, as Bob
7 always says, what triggers the condition, so will people
8 end up with more conditions that might encourage, you know,
9 more episodes within the episodes?

10 DR. TOMPKINS: Well, we've had -- I think even
11 some of the go-around with the PRT involved questions about
12 specific anecdotes. We had one with CMMI, too. The
13 patient who has this and then this has this. If we had
14 more time, which we don't right now, but if anybody wants
15 to submit it as a question, we can actually deconstruct
16 that and say, well, this was this episode, here was the
17 care team for that, here's this episode, here's the care
18 team for that.

19 But let me go back to 1997 for a minute, which is
20 when we had the Medicare -- again, my comments about that.
21 The idea was a cultural shift. It was a cognitive shift.
22 It was to say however we're organized, however we behave,
23 whatever our clinical thresholds are for what we do should

1 be governed towards the prime objective of value and not
2 productivity and volume. So whether you happen to be the
3 supporting provider here but you're the episodic then, and
4 then you're an ancillary here but over here you're the
5 medical specialist who's the primary, the idea here is that
6 we are trying to manage our patients towards value.

7 So even though the grouper has to sort of keep up
8 with all that detail, the clinicians hopefully are rising
9 above it and saying this is our patient, and even though
10 this is a sequence of events and there's some caregivers
11 that are coming and going, the general thrust here is to
12 give excellent care at the lowest possible cost.

13 Now, the question about -- I mean, I made the
14 joke about the epidemic of schizophrenia, so now you've
15 generalized it, right? If you had an episode for
16 schizophrenia, then suddenly everybody has it. That's sort
17 of the notion here.

18 Well, the grouper can -- in the grouper there's a
19 component called the "episode identification rules," which
20 have to do with what are the diagnosis codes which are the
21 triggers for the diagnosis. You can also add additional
22 criteria to it. You say I'm not going to recognize this,
23 or I'm going to stratify this condition if it -- we're not

1 going to recognize it unless the test was given before a
2 confirmatory diagnosis was given or if a definitive service
3 is provided in addition to the diagnosis code. That option
4 is there. But let me just take that one example and make a
5 general reference back to some other things.

6 It's a SAS program that's constantly reading
7 clinical metadata tables, so those trigger codes are often
8 a table, which can be reviewed and modified. And we can
9 test or we can review and modify those codes and those
10 tables as necessary in order to optimize against the
11 occurrences of a rise in diagnosis codes and so forth. But
12 let me tie it back up, because I'm now trying to touch on
13 everything.

14 The entirety of the Medicare population
15 experience in dollars is poor -- you know, is represented
16 in the claims and is organized by the grouper, and you can
17 put to the test the incidence rates, the prevalences, the
18 cost profiles, and so forth of any- and everybody you want
19 to. So you can monitor for the existence of undue
20 occurrences or occurrences of conditions that don't seem to
21 have the supporting services of the cost profile. But if
22 physicians are going to, you know, be so concerned as to
23 undermine every effort, then, I mean, I can see that that's

1 an unintended consequence. This is something we want to
2 monitor. But I don't think at this point, with the
3 implementation of MACRA, I think we take our best step
4 forward and then we try to monitor for maybe things we
5 don't want that are unintended consequences.

6 CHAIR BAILET: Tim.

7 DR. FERRIS: Great. I want to pick up on that
8 last comment because I really liked your analogy of the
9 blank canvas for the ACO and the paint by numbers with
10 this. And all analogies fall down and misrepresent the
11 complexity of what's going on, but just given that, the
12 paint by numbers here, it seems to me, if I understand our
13 PRT's evaluation, which I'm sure in many ways I don't, it's
14 really -- it's safe to say it's really, really complicated.
15 And if I read between the lines, there is some anxiety
16 about unintended consequences which can't possibly be
17 anticipated given the myriad number of interacting parts
18 within this model.

19 And so one of the things about the blank canvas
20 and the ACO is that what people do in order to achieve ACO
21 is -- it's actually a small whole number. They do care
22 coordination, they do site of care, they do -- and,
23 actually, in surveys of what ACOs are doing, they come up

1 with 12, maybe 15 things, and you can look at those 15
2 things and say, is this likely to hurt patients? Are they
3 likely -- you know, what's the potential unintended
4 consequences?

5 I don't think any brain is capable of -- with
6 such a complicated system, of thinking through what the
7 potential unanticipated consequences are of such a
8 complicated -- at least certainly my brain isn't. And so I
9 wonder, given that set of -- that characterization, which,
10 please, tell me if you think that -- in what way that
11 mischaracterizes the comparison. What would you recommend
12 to PTAC given all the uncertainties about how those
13 uncertainties are managed, the uncertainties around
14 unintended consequences? How does one think about the
15 testing and implementation of such a complicated model
16 where the unanticipated consequences are - can't be
17 anticipated.

18 [Pause.]

19 DR. OPELKA: So I'm stalling while he's going
20 brilliant on me.

21 So we think a model like this is something you
22 roll out. You begin with a starting spot, and we thought
23 it would be easier to begin in the procedural episode world

1 as the initial place to do this, and beginning with the
2 various team members that are within there and build this
3 out from there.

4 The challenge that we have -- and there are many.
5 We could list 100 challenges with this model as we think
6 through it. When the world has told us leave MIPS and go
7 to APMs, well, when I think of it, just for general
8 surgery, I've got 10 different types of general surgeons
9 out there. Am I going to build 120 versions of the COPD
10 model in the individual siloed APMs? We'll never finish.
11 We'll never get it done.

12 We needed a framework that we could build upon
13 that meets the practice model, first of all, of a general
14 surgeon. The second part of this was I as a general
15 surgeon, in the world today of Medicare, we don't practice
16 alone. These patients are far too complicated. There
17 needs to be a connection across this episode, this time
18 window of care that everyone is coming together and we're
19 all going to measure cost and we're all going to measure
20 quality and we're all going to have shared accountability.

21 Now, can I create that initial rollout that
22 starts with the small enough group that we can build on the
23 way we practice, that we can put that construct together?

1 And the long view of this is actually -- it is to learn
2 enough about how big I can build the episode, how I can get
3 out of just procedural episodes and build the condition,
4 and then build larger conditions so that I'm heading toward
5 the ACO construct. The closer I get to that ACO construct,
6 the more I can get into population health-based payment
7 systems. So that's the overall plan.

8 Now, how do I start that small enough and at the
9 same time be able to account for where people will try and
10 game this, where we're stepping off? And how do we
11 actually keep up with the ability to leverage what's
12 happening in the clinical data world to backfill this?

13 We don't think claims-based alone is a big enough
14 solution, but once we start making that connection to the
15 clinical world with the claims world, we've referred to it
16 affectionately as "walking in the cold fusion," someone
17 else called it "unified theory." We think both are
18 correct. So if we can have cold fusion and unified theory
19 come together, we can do that. But that's where we're
20 going. How do I take the clinical knowledge that's out
21 there and says you have to prove to me you have this so
22 that you belong in this episode? That gets more
23 complicated the deeper you go into these episodes. So

1 what's the initial starter set that I can start to build
2 the framework, that we can start to shift the logic, that
3 we can start to move the culture?

4 So we chose what we thought were rather tight
5 episodes that people could plausibly understand all the
6 services that are in there, and they could plausibly come
7 together to figure out how they're going to optimize care.

8 Do you want to add to that?

9 DR. TOMPKINS: Well, I'm certainly not the
10 clinician around the table, so I -- no, we are opening up
11 space here, and there's plenty of room for innovation and
12 some of it could go wrong. The cold fusion I think is a
13 part -- the episode framework for the first time at least
14 points toward the capability of borrowing in the clinical
15 information that clinicians already use surrounding
16 virtually the same clinical concepts and episodes. And so
17 additional information can be brought for severity
18 adjustment, for clinical outcomes, and so forth.

19 But like I said, even compared to ACOs, all the
20 services are now catalogued, so this is not like, you know,
21 hiding or moving around in the dark. This is not -- I was
22 going to say that's where you would want to stay in MIPS,
23 but I won't necessarily make that comment. But to step out

1 into the APM where this is really so carefully articulated
2 in terms of what the clinical context was and which
3 physicians were involved and what was the role and where do
4 they bill and what do they do, now match that with cold
5 fusion when you have the clinical information pouring in
6 that shows much even richer -- you know, at some point I
7 think we trust most of the clinicians and innovators to do
8 the right thing with this opportunity. And at the very
9 least, it takes away the nefarious incentives that have
10 been probably pushing for a lot of unintended consequences
11 right now.

12 CHAIR BAILET: Len.

13 DR. NICHOLS: So, Frank, I'm glad I met you.
14 What I want to get to, though, is the ability of this
15 grouper to learn. It seems like there is a lot of magic
16 baked in here, and here's my paint-by-number attempt to
17 grapple with the complexity here. It seems to me the
18 genius of it is you can map every configuration of
19 professional patient interaction and pull it up in these
20 different directions, episode or clinical, aggregate, all
21 the way up as far as you want to go.

22 The flip side, what's not so pretty about that,
23 at least to my economist mind, is that, therefore, we are

1 setting, as targets, or the benchmarks, or the goals, or
2 whatever, the bundle against which you judge yourself,
3 today's fee-for-service activity, and yes, beating that's
4 better than doing it, but how do we learn to have better
5 goals? Can your grouper -- is it dynamic in that sense?

6 DR. OPELKA: And I'm sure Chris will probably
7 want to jump in here, too.

8 From a clinical sense, what woke up the community
9 -- and I used to just think it was the surgical community,
10 but a lot of other specialties have come inside the grouper
11 and sat with us, and looked at this -- what woke us up is
12 we had no clue, in an episode of care, how many different
13 tax IDs are hitting that episode of care, and how many of
14 them were not apparently warranted. We had no idea, and I
15 would say that the average physician is completely
16 clueless. This was the first attempt for us to see why is
17 a coronary artery bypass in one community got 18 tax IDs
18 and another got 65, and yet, risk-adjusted, they're the
19 same, and the outcomes and length of stay are the same.

20 What's happened here is just patterns of behavior
21 have just emerged and never gotten cleaned up, so can we
22 create a logic, using the grouper, that then provide
23 analytics back to the field? If the analytics don't come

1 back, if they just tell you're an outlier to the bad, good
2 luck, we've not done anything.

3 DR. NICHOLS: Right.

4 DR. OPELKA: But if I can show that you are out-
5 imaging everyone else, you're out-consulting everyone else,
6 this is where a lot of the questions we got from the PRT
7 was, give us the formula that goes in here. Well, on these
8 one-off APMs, that's easy to do. There is a care plan.
9 But the variation is so different, in different markets,
10 for different reasons. We don't want to be prescriptive.
11 We'll ruin the opportunity to get people to actually look
12 inside and understand what's different. We actually want
13 to get that feedback. We want to create the learning
14 cycles that share with everybody, just like the ACOs share
15 as much as they can about where they found and save money.
16 We think this allows you to go inside an episode and begin
17 to wonder, why are we different? Is this warranted or not
18 warranted? Does it influence the overall outcome of care,
19 and how do patients feel about it in the PRO sense of the
20 word?

21 So that's the linkage we see, that if we start
22 making these changes, we have to have an episode based to
23 measure framework, and it has to tie back to the patients.

1 It has to have the PRO, or we're not going to have the kind
2 of feedback we want.

3 And the other side of this is we made this
4 argument to the PRT, so we've been looking at the standard
5 quality metrics we used in surgical care, and they don't
6 allow us to get to the kinds of confidence intervals that I
7 can't tell you something isn't random. And so the standard
8 outcomes, like mortality and SSI, I'm tortured by small
9 numbers. In order to make this work, I need the PRO. I
10 really need the patient input in this whole cycle.

11 So all of that -- we can't make this work by just
12 pulling it out and saying let's just look at the grouper.
13 All of those components have to come together -- the
14 feedback loops, the learning environment, and measurement
15 that ties back in to the patient experience of care.

16 Do you want to --

17 DR. TOMPKINS: Maybe a footnote to that. Len,
18 your question -- I was tracking part of it -- was just to
19 say that right now, your beating historical or current
20 standards, because the grouper acknowledges that all these
21 clinically relevant services, although in many cases
22 unwarranted, shall we say, are included in the expected
23 cost, and so, therefore, the motivation and the opportunity

1 is to beat that. And I think your question was, in the
2 next chapter.

3 DR. NICHOLS: Yes.

4 DR. TOMPKINS: Right. Well, if the grouper is
5 still doing what it's doing, then it will still assemble
6 the clinically relevant services, but the margin will go
7 down, and the margin will go down to the point where the
8 "expected cost" -- in other words, what's the norm -- is
9 actually correct. I mean, if you -- the pressure right now
10 is to move -- is to push on the efficiency frontier, right?

11 DR. NICHOLS: Right.

12 DR. TOMPKINS: And as long as you can push on the
13 efficiency frontier, and beat the norm, the expected cost,
14 then there's a margin there. With hundreds or thousands of
15 clinical laboratories working on the innovation and moving
16 the frontier, there could be a time when that margin really
17 gets to be very small, which is a nice place to transform
18 the payment or the expectation into a prospective payment,
19 without relying on the savings, you know, the comparisons
20 and so forth, and the shared savings to drive the
21 difference.

22 So you could, with the innovation, if you pounded
23 all that excess out, then you could actually reach the true

1 efficiency frontier for treating that condition or
2 providing that service, and then you're golden, because now
3 you know what to pay, and you're not going to pay more than
4 that because more than that is not warranted.

5 DR. NICHOLS: And you would know you hit that
6 frontier by the fact the variance across the country just
7 got to be zero?

8 DR. TOMPKINS: The variance would get to be zero
9 and the average would get to be, you know, correspondingly
10 lower. But I look forward to that day, right? I mean,
11 that presumes a lot of success here.

12 CHAIR BAILET: Elizabeth.

13 VICE CHAIR MITCHELL: So my question is on the
14 present, and after a couple of years I think I've gotten my
15 head around the theory. I get it. But this is potentially
16 a very basic question about practice that probably has an
17 obvious and maybe brief answer.

18 So you're talking about the feedback loop, this
19 incredible information that illuminates where every dollar
20 went, who did what, the x-ray machine. Where does that
21 information go? Who gets that and then assigns dollars,
22 risk, performance? Is that just sort of your average, or
23 maybe above average practice manager? Does that require

1 sort of super powers to understand these reports? Do you
2 need a Tim Ferris? I mean, who governs this? Where does
3 the information go?

4 DR. OPELKA: So this has been part of the dialog
5 we've had with the Innovation Center. How do you structure
6 this with the APM entity? How do you allow that APM entity
7 to get into the ability to consume and educate and build
8 the clinical affinity groups?

9 What's happening is the grouper to the APM entity
10 is pretty prescribed, but then what happens from the APM
11 entity down to the point of care, that's where things start
12 moving, and that's where, when we saw the ACO industry come
13 out, there was a whole new industry that got around this.
14 How do we get around this, understand this, and begin to do
15 this?

16 We think that these kinds of changes have lots of
17 different elements to them, including not just the claims-
18 based information but the quality-based information. And
19 when you take risk in this environment it's not just
20 insurance risk. It's operational risk. Before I jump into
21 an episode of care, do I have the team to do it? Because
22 now I'm at risk in a loss environment, do I have the team
23 to perform on quality?

1 So those elements of assuming that operational
2 risk, along with the physical risk that's involved here,
3 all have to be constructed. Part of that's on the
4 specialty society. How do we come together and teach each
5 other in this new model? How do we distribute that and get
6 the field ready for this kind of work?

7 CHAIR BAILET: Bob.

8 DR. BERENSON: Thank you. So there's a lot that
9 I like about the approach, so I don't -- consistent with my
10 style, I'll go to the stuff I don't like and ask you about
11 that, actually, partly to try to solve these problems and
12 see if we can't get those taken care of.

13 So one is this issue of appropriateness. Now you
14 said, and I agree completely, that there's practice
15 variations with lots of different ordering patterns of
16 imaging, different numbers of doctors, et cetera, et
17 cetera. We also know from Dartmouth and elsewhere that
18 there's dramatic variations in the incidence of procedures.
19 Similarly, it's not like this is a theoretical problem.
20 It's a real problem, and in your responses to the PRT you
21 basically said, well, until we get measures of
22 appropriateness there's not a lot of progress we can make.

23 So are you dismissing things like expectations of

1 following evidence-based guidelines, or having second
2 opinions outside of the bundled payment? I mean, are any
3 of those process requirements, something that should just
4 be dismissed and we should just sort of do our best to
5 respond if we find that this becomes a problem?

6 DR. OPELKA: No, and I think this is a keen area
7 of focus. It's been, I think, pretty much under-invested
8 by the industry as a whole, and probably because the
9 current solutions that have been put into place are so
10 difficult to put forth and develop that it will take us too
11 long to do. So what alternatives do we have?

12 First of all, for a proxy, the first proxy that
13 we put in place is to try and develop these goal-of-care
14 initiatives. So if there is a procedure out there, what is
15 truly the goal of care, get agreement by the whole team
16 with that goal of care, including the patient, and then
17 link the assessment of that with the PRO. So we think
18 that's a poor man's version of the first step toward
19 appropriateness. That would be a dramatic shift from where
20 we are today, but we think that's a great first step.

21 Rolling in things like the clinical pathways,
22 guidelines have not yet strong enough. They've been
23 guidelines and not really harsh pathways. Can we break the

1 problems that we have with the HR companies and get these
2 interoperating and moving into the clinical environment? I
3 think there are a small number of specialties, us being
4 one, that's working on how do we build that into the
5 workflow solutions, and we think that gets us a step closer
6 to appropriateness of care. But we're not going to solve
7 that in this payment model. We may get more improved
8 measures, but to get into a RAND-style type appropriateness
9 measure scale is -- it takes a long time to develop those
10 measures and there's probably not going to be as much bang
11 for the buck if we can get through some IT solutions.

12 So we are all in favor of it. Where we are today
13 isn't far enough, and we're more than happy to move that
14 direction. It's just not going to happen overnight.

15 DR. BERENSON: Let me ask one other, which is, as
16 I was reading this, one of the concerns I had was it's --
17 even though it's a dramatically new approach to payment
18 through episodes, to some extent it is still based on
19 current patterns of billings. And then I found, actually,
20 Steve Wiggins' letter to us. So I just want to get your
21 comment. He's from Remedy Partners and he actually spoke
22 to us about BPCI last month.

23 "The proposed APM examples include an implicit

1 assumption that allocation of risk and reward is
2 appropriately tied to the physician's relative billings.
3 We believe this is an erroneous methodology for attributing
4 savings. Spending and quality outcomes are most often
5 controlled by practitioners billing far less than
6 surgeons."

7 How would you respond to that kind of criticism?

8 DR. OPELKA: Well, the model that -- and, Chris,
9 you may want to jump in here, too -- the model that we're
10 putting forth isn't just physician billings. It's all Part
11 A and Part B, and if you gave us Part D we would have
12 rolled that in too, because we think -- one of the key
13 points of this methodology is we're looking at as much cost
14 as we can, within what we think is an episode, and within
15 what we think plausibly assigns to that episode, not just
16 what I, as a clinician, can influence, but we, as the team,
17 can influence. And we can build in larger components to
18 this team, other than the clinicians. The APM can partner
19 with the hospital. The hospital could form the APMs. So
20 could an ambulatory surgery center. We're not excluding
21 anyone from coming into the risk environment and being part
22 of looking at the total spend, and trying to figure out
23 what's warranted and what's unwarranted, and how do we

1 maintain or improve quality in that process.

2 DR. BERENSON: But I'm referring, more
3 specifically, to at least the perceived existing
4 distortions in RBRVS-based fee schedules that pay lots more
5 for people doing the procedure than perhaps the people who
6 say we don't need a procedure, as an example. There's no
7 sort of -- I mean, an alternative is to give an entity a
8 bundled payment and let them make the decision about how to
9 allocate the dollars, rather than just accept the
10 established billings that come in. Is there any way to
11 change that?

12 DR. TOMPKINS: Well, just to clarify, I think
13 what you're referring to, or he's referring to, are the
14 proportional allocations in the fiscal attribution model,
15 where the surgeon gets 40 percent, and the -- that's what
16 you're referring to. Well, we never said, and it's
17 actually not true that those were derived from "the
18 physician billing profiles." And I'm not saying that our
19 method was necessarily worse, or better, but it wasn't
20 that. So just from a factual point of view, that was never
21 the point.

22 So I think that the question here, Frank, is how
23 do you -- this is an optimization problem. Right? You

1 have a dollar saved or a dollar lost. You're all
2 accountable. How many cents on the dollar are you versus
3 her versus him? And so it's an optimization problem that
4 has to do with how much of the responsibility and the
5 ability to effect outcomes resides in one person or one
6 role versus another? And Frank, you've had a lot of
7 conversations with --

8 DR. OPELKA: Yeah. So we -- there are a couple
9 of different parts of this. So first of all, the initial
10 attribution model that came together is just inferential
11 and it was sticking a flag in the ground. We think that's
12 an area that should go undergo ongoing governance. How do
13 we think about different episodes and how might we allocate
14 them differently? And we're fully in favor of that but we
15 had to start somewhere. And believe me, when I presented
16 this to the surgical boards, and I said, you know, "This is
17 where we want to go," they wanted the surgeon at 85
18 percent. And then when I reminded them there was a
19 downside, then they wanted the surgeon at 15 percent. So
20 everyone is acting out of their own self-interest here, and
21 I get that. But we just set a point of reference to begin
22 with, and we think that these episodes can evolve in this
23 regard.

1 Secondly, a lot can happen at the APM Entity.
2 This attribution is part of the payment between the payer
3 and the APM Entity, but the APM Entity may reallocate that
4 whole risk entirely differently, depending on where they
5 feel the effort is within a community. And we've seen this
6 within the peri-operative surgical care, where a primary
7 care may say, "I'm doing all this pre-op work and I'm
8 taking care of the patient in the post-op period. Why
9 aren't they being appreciated for that?" and they can. But
10 that is a negotiation that is at the community level, at
11 the APM Entity, and that was baked in as part of the
12 flexibility of this program, because care is so different
13 in each part of the country.

14 DR. BERENSON: So that theoretically could apply,
15 then, not to just the allocation of the risk but to the
16 allocation of the dollars in the bundle. Right? In the
17 episode.

18 DR. OPELKA: That's correct. That is absolutely
19 correct.

20 DR. BERENSON: And let me ask the final question
21 and then I will move on, is you've got lots of surgical
22 subspecialties endorsing the model, at least for testing.
23 Do you think it's feasible to find a geographic area where

1 you could actually get a broad interest in demonstrating
2 more than just one or two episodes but really trying to
3 test the model, which is very broad-based?

4 DR. OPELKA: We actually got this question from
5 the PRT, too. We've not gone out, as the College of
6 Surgeons, and done some kind of market assessment. We
7 don't really have that tool or that instrument or that
8 capability. We've had a lot of interest from different
9 private sector payers, who have been interested in the
10 model, and we've had interest from ACOs, who look at this
11 model as something that would be very useful to them in
12 trying to understand the working episodes that are within
13 an ACO.

14 So that's been our limit. We've been focused on
15 trying to get the model through the process here, and, you
16 know, we, of course, are very flexible with how do we begin
17 a rollout and learn and expand the rollout, whether that's
18 regionally or on some other different scale. We've been
19 willing to work with the Innovation Center with regard to
20 that. We're not closed up.

21 CHAIR BAILET: Harold.

22 MR. MILLER: Four questions. So we'll stipulate
23 that there is clearly variation in care around the country,

1 and unwarranted care. Although various and sundry efforts
2 to try to look at that more deeply have been found that
3 some of that variation and unwarranted care is actually
4 warranted care, because there were things about the patient
5 that weren't being measured, that whenever you looked more
6 deeply found that, in fact, the variation was appropriate,
7 which goes to the issue of the difficulty of risk
8 adjustment.

9 So it's one thing to have this episode grouper as
10 an analytic tool, to say we need to give information to
11 people to see where there are opportunities. The challenge
12 becomes when you try to turn it into a payment model and
13 you base payment on it.

14 So this gets into the question of kind of what's
15 the protection for quality. And in the letter that you
16 sent just before this meeting, the pages aren't numbered so
17 I can't tell you the page, but it's just above the 4(b)
18 criteria and value over volume response. You have the
19 statement, "The model effectively prohibits participating
20 providers from benefitting financially from reductions in
21 care that lead to poor performance and quality --
22 prohibits," which is a powerful, strong statement, but does
23 not seem to me to be consistent with the quality structure

1 you described earlier.

2 So could you explain exactly how it prohibits
3 that from occurring?

4 DR. OPELKA: Well, in the sense that the quality
5 is measured, in both process outcome and PROs, we're not
6 stopping anybody from what they're doing, but they will pay
7 -- they will -- if they underperform in the quality space
8 there, then bearing the risk of that underperformance.

9 MR. MILLER: But they could, if they reduced
10 spending and they were not in the worst quality, but they
11 had also diminished quality somewhat, my understanding of
12 the model is they will get some savings back, just not as
13 much savings. So it's not prohibiting them from
14 benefitting financially. It might reduce what they might
15 otherwise get. Am I correct? Because it doesn't say you
16 have to maintain--

17 DR. OPELKA: You're looking at the same coin.
18 I'm looking at the head; you're looking at the tail. It's
19 six of one, half a dozen of the other.

20 MR. MILLER: I'm not sure it's six of one and
21 half a dozen of the other, but okay.

22 DR. OPELKA: Seven and five.

23 MR. MILLER: So there are other episode

1 approaches that try explicitly to distinguish between the
2 desirable care and the undesirable care, and to distinguish
3 those in the model, as opposed to saying here's the total
4 spending in the episode, and if you reduce that, you get
5 some share of that; but say if you reduce the undesirable
6 spending -- and it sounds as though in your model you
7 actually do have some of the undesirable sequelae
8 identified.

9 Did you think about structuring the model that
10 way potentially initially to say that we would just focus
11 on the undesirable -- what we measure to be undesirable
12 care, hospital admissions, readmissions, complications, et
13 cetera, as opposed to it being based on total spending?

14 DR. TOMPKINS: I'll start. No, not really. The
15 grouper actually forms three different dependent variables
16 and can calculate risk-adjusted sequelae costs for any
17 episode. So if you're interested in knowing the extent to
18 which there's a larger excess in a sequelae cost than would
19 be presumed or expected because of the risk-adjusted
20 results for that patient, you can do that.

21 The reason I give the short answer first, no, is
22 because we didn't think that as a payment model we wanted
23 to at all divide, because we think the inferences, the

1 scientifically based inferences about the cost performance
2 at the patient level are all inclusive with respect to
3 cost, and we thought that managing both the sequelae costs
4 and the directly assigned services, what we called them,
5 were all part of the same bundle or episode and ought to be
6 equally available for -- but clinicians looking at it would
7 probably have an eye at the sequelae costs and say, "This
8 is what we want to avoid. Who wants this to happen?"

9 MR. MILLER: But one could structure a payment
10 model slightly differently than what you did that would do
11 it that way because the episode grouper would, in fact,
12 support that.

13 DR. TOMPKINS: It would be -- yes, if one would
14 want to, then one could because it does, yes.

15 MR. MILLER: The third question is several years
16 ago Medicare did commission some analyses of the commercial
17 episode groupers around the market then to try to see
18 whether or not they were grouping sensibly or not, and it
19 had some clinicians look at them also and found that in a
20 number of cases they were -- because of the problems with
21 the claims data, were assigning things badly, that cases
22 were being assigned to an episode that just did not really
23 make clinical sense when one went back and looked at that

1 particular case.

2 I don't really understand. What has been done in
3 that sense to validate the grouper that you have? Because
4 you've developed it with clinical input. But has there
5 been an effort to run specific cases and then take a sample
6 of them and look at them to be able to determine whether or
7 not the results made sense to clinicians so that they would
8 say, "Yeah, boy, that's working perfectly. What that group
9 didn't do makes sense to us?"

10 DR. TOMPKINS: As part of the development
11 process, I had a number of subcontractors -- I mentioned
12 the software developer Booz Allen, but we also had the New
13 York QIO IPRO, which was part of our clinical team, and we
14 also had subcontractors which were the AMA PCPI and ABMS,
15 and we had external clinical reviewers who were looking at
16 the codes and the logic and some of the output. Was it
17 thoroughly satisfying and did we -- no. It was
18 interactive, and it was part of the cyclical development of
19 the episodes. We're now embarking on similar parallel
20 projects to further kick the tires and vet it even locally
21 to have data from a particular organization look at the
22 results of the grouper, the organization has those
23 physicians and has those patients and has that history, and

1 we'll be validating the results from that perspective. So
2 it's an ongoing discovery process. We --

3 MR. MILLER: So you're planning to actually look
4 at actual cases and how well it worked, but haven't done
5 that yet. Okay.

6 Final question --

7 DR. TOMPKINS: Well, we look at actual cases. We
8 have what we call "patient vignettes," where the actual
9 claims history of a person is looked at in every degree of
10 detail, and then we cross that to "did the grouper trigger
11 an episode here, did it trigger" -- if so, which, which,
12 and it opens it up to become a matrix, and you now know all
13 the episodes that are open at any given time, and then you
14 further follow the chronology of services, and you can
15 follow the footsteps of the grouper to see which episodes
16 that service was assigned to. And that process has -- was
17 part and parcel of the --

18 MR. MILLER: What I was really getting at was if,
19 in fact, the model is implemented, people will be getting
20 assigned episodes, and the question will be: Will they
21 feel that those episodes that they got assigned made sense
22 to them? And the question is: Has sort of a sample run of
23 that been done so people got a report on what would have

1 been their episodes had the grouper been in place and said,
2 "Yep, boy, that makes sense to us, what we got assigned"?

3 DR. TOMPKINS: Well, the fiscal attribution
4 logic, which followed after the episode development, is
5 where a lot of that happens. And as you know, we don't
6 assign an episode to a single clinician. A clinician
7 doesn't get assigned a clinical role in an episode unless
8 there's an actual bill that says this is the service I
9 performed that's clinically relevant to that episode.
10 There could be some breakdown. But, I mean, this was
11 looked at very closely, and part of the overall enterprise
12 is to maintain, I think this -- I would say this is a
13 national resource. This question about proprietary came
14 up. CMMI developed and paid for the software. They own
15 it. But somebody needs to -- you know, we all get updates
16 to our apps on our phone and everything else. Somebody
17 needs to stay on top of that development. The clinical
18 data tables have to change for no other reason than
19 clinical practice changes and coding systems change.

20 So instead of having everybody sort of scattering
21 and working on their work and doing all this over here, if
22 we all contributed a lot of that effort towards the single
23 resource that articulates the clinical logic and the

1 relationship between services and episodes, et cetera, then
2 that in turn benefits everybody.

3 DR. OPELKA: So just to add to this, as part of
4 this project, what we did was we took the data files that
5 are part of every episode, and we pulled together the
6 clinicians who are involved in the episode, and we walked
7 through an in-depth exercise about all those data files,
8 asking the clinician what is appropriate and what is
9 plausible. And they could narrow these episodes down very
10 tightly with appropriateness of care, but then we wouldn't
11 find the variation. So we had to work with the clinicians
12 and say, "But what would plausibly be out there that we
13 ought to include in this episode?" So that as the episodes
14 were built, we can actually bring up and appreciate where's
15 the waste? From a clinical perspective, let the physicians
16 look at this and say, "Yeah, I know that happens all the
17 time. It shouldn't happen, and it's happening all the
18 time, and it needs to be in that episode because we need to
19 know about it."

20 So we built these episodes with another
21 generation, because there were several already, generations
22 that had reviewed this. But all of these were refreshed
23 with all the specialties who were willing to participate,

1 and we continued to open it up to more who want to come in
2 and review the data files to update them. Those need to be
3 kept current. Care changes. New drugs come out. New
4 treatments come out. All kinds of thing change. So
5 episodes are dynamic, and they need to be managed.

6 MR. MILLER: Final question. If a small
7 physician practice came forward and said, "We'd really like
8 to participate in this for managing a chronic disease," so
9 a gastroenterology practice says, "I'd like to manage this
10 for" -- "manage my inflammatory bowel disease patients," or
11 a pulmonology practice wanted to manage their COPD
12 patients, and said, "We've looked at the data. There's
13 nothing that we're over ordering here, but our patients
14 are, in fact, showing up in the hospital more than we think
15 is necessary or desirable, and we think that we could do
16 something different to try to keep the patients out of the
17 hospital, but it would require us to be able to hire
18 additional staff, et cetera, which are not supported under
19 the current fee schedule," there's nothing under this model
20 that would pay them differently. How do you anticipate
21 that a practice like that might be able to participate?
22 Would they have to look to some larger alternative payment
23 entity that would front money for them? Would you see

1 potentially there being additions to the fee schedule that
2 would only be billable if they're in this alternative
3 payment model, or what?

4 DR. TOMPKINS: I mean, this is a parallel
5 question that's come up in the ACO world where the original
6 conception was that if you really believe in what you're
7 going to do and generate the savings to come up with a
8 business model, an ROI calculation, and borrow from your
9 savings or get a bank loan, because if you're that
10 confident, then it will eventually pay for it through the
11 shared savings.

12 As the portfolio of ACOs over the time, they've
13 explored other options, and just like that, it's possible
14 that CMMI would consider a portfolio of models that operate
15 generally under this umbrella, where there's an advance
16 payment or other kinds of billable services that are only
17 allowed by the demo, and they're added to the actual cost,
18 and when the shared savings reconciliation is done, those
19 are netted out. And the cash flow has been preserved by
20 the practice, and their hypothesis has been proven true,
21 and the savings allow them to reconcile with a net
22 positive.

23 DR. OPELKA: I think there's --

1 MR. MILLER: So that is not part of your model
2 now, but it could potentially be if that was a barrier to
3 small practices participating.

4 DR. TOMPKINS: Yes.

5 DR. OPELKA: So I think there are many ways from
6 a behavioral economist standpoint as to how to get
7 engagement, and you're describing one. And we know it's
8 very effective.

9 MR. MILLER: Well, I wasn't talking about
10 engagement. I'm talking about a barrier, that they face a
11 specific barrier to being able to deliver the care, and the
12 question is: How would they get the resources to do it?

13 DR. OPELKA: So, again, you could reduce the
14 downside risk. You could increase the upside reward. You
15 could gain other partners who would be willing to share
16 with them. Or you could frontload them. There are
17 multiple different ways to create that incentive for
18 engagement, and we have not been prescriptive to say this
19 is the only way. We're working to listen to whatever
20 incentivizes the payer to help move this and get it going.

21 CHAIR BAILET: Thank you, Harold. Kavita.

22 DR. PATEL: I'm just trying to brush up, because
23 I remember, I think, Chris, you wrote a report for CMS on

1 the groupers. I'm trying to make sure it's the same report
2 that's included in here.

3 DR. TOMPKINS: We included the design report in
4 the original submission.

5 DR. PATEL: That's right, and so I just wanted to
6 make sure it's exact -- because I remember reading that
7 report before it was in our appendix. I just wanted to --
8 because I know one of the criticisms around the groupers
9 has really been the risk adjustment piece. So just tell me
10 -- it seems like given that we're using claims, so there's
11 that limitation, that you've done as much as you could
12 sequentially to kind of enhance the validity of this risk
13 adjustment. Do you feel like you're -- and there's
14 criticism of the current kind of bundles model with MS-
15 DRGs. Can you just talk about maybe in comparison or
16 contrast to how this is a bit more robust?

17 DR. TOMPKINS: Well, if you -- I don't know, take
18 a reference point. You could take BPCI, which basically
19 just allows the DRG and --

20 DR. PATEL: Right.

21 DR. TOMPKINS: Or you could take another
22 reference point, ACOs, take your pick, which has the HCC.
23 In contrast to either, or both, in each EM there's a risk

1 adjustment component that tries to get as much information
2 as we can from the claims. So, for example, there are two
3 features. One's called a "stratification feature," the
4 other is called a "risk factor table."

5 So, for example, if you were to have a surgery
6 episode for hand-wrist-forearm, that surgery isn't just put
7 out there, and whether you do only fingers or only hands,
8 you know, it articulates what we call subcategories. So if
9 for this patient it was as finger surgery, that is
10 different than the next patient for whom it was a wrist.
11 And also the surgical technique is available in the
12 stratification, and etiology, the indication. So there are
13 a lot of ways in which we sort of set it up with as much
14 information. That's the stratification.

15 Now on the risk factor table, there are
16 demographics. The default is HCC for most of the episodes
17 that are running in the background. But for the episodes
18 that we call forward for profiling or for payment, they're
19 all built on -- they're all customized. You know, the HCC
20 just looks at total cost. That's the dependent variable.
21 Here we say no, it's the episode-specific. We want to
22 predict COPD costs for the next 90 days. So, in other
23 words, it's very time specific. It updates every 90 days,

1 and it looks at the patient's history at the time of the
2 onset of that 90-day period, and also looks -- so, for
3 example, if you were guessing about the expected costs of a
4 patient with COPD, you would probably want to know whether
5 or not that patient today has pneumonia. The grouper knows
6 that, call that an "open risk factor." You probably also
7 want to know whether the patient had pneumonia recently but
8 it's over. The grouper knows that, preserves that as a
9 recent episode.

10 So whether it's a procedure episode or whether
11 it's a condition episode, the grouper with its formation of
12 500-plus episodes and over 1,000 clinical concepts allows
13 all of them potentially to be risk factors for any episode
14 that's in the library.

15 In the process of developing the customized risk
16 adjustment model, what we did was we had a claims base of
17 millions of Medicare beneficiaries. We looked at all the
18 instances in which that particular subject episode was
19 triggered. And we allowed the grouper, the software, the
20 statistical software, to look for the comorbidity factors
21 or the recentness of these various things, and we did Monte
22 Carlo simulations 500 times each, and we'd only include a
23 risk factor if it was found to be statistically significant

1 in the same way in at least 80 percent of those Monte Carlo
2 runs. And then the variables that come from that process
3 are subject to clinical review as a last pass to make sure
4 that they have face validity, clinical credibility, and
5 they're not just a way in which a spurious correlation has
6 been found.

7 So all the episodes that refer to the 100-plus
8 episodes have customized risk factors that were designed in
9 that way. The episodes that run in the background that are
10 not necessarily called forward for payment are amenable to
11 the customized risk adjustment models, but otherwise rely
12 on demographics and HCCs.

13 DR. PATEL: And you mentioned that obviously CMS
14 has this software, so the burden -- just to clarify, the
15 potential burden of the cost, the updates, et cetera, would
16 not necessarily be part of an APM -- you know, part of a
17 barrier to participation because there's an assumption that
18 this is CMS's responsibility.

19 DR. TOMPKINS: Well, there's an assumption that
20 CMS, going on other payers, we hope, would see that, again,
21 the common resource that everybody benefits from. So, for
22 example, if you were to take prostate cancer condition
23 episode, that's a condition episode that ought to be looked

1 at very closely by the oncologist. But treating that type
2 of cancer or other types of cancer, there are surgery
3 episodes that can pertain. There are external beam
4 radiation episodes that can pertain. There's implanting
5 radioactive material in the tissue that can pertain.

6 Every time somebody works on the episode that
7 pertains to their clinical work, everybody benefits. So
8 the radiation oncologists benefit when the medical
9 oncologists clarify the chemotherapy and the other services
10 relevant to that, and likewise when the surgeon clarifies
11 the services that are -- the codes that are relevant to
12 that. So when you have a complex unfolding of simultaneous
13 treatments and episodes, again, everybody benefits from the
14 other's work, because when you clarify the competing or
15 contemporaneous episodes, it's to everyone's benefit to
16 clarify what actually should belong in the subject episode.

17 DR. PATEL: And then one more question, and I
18 actually wanted -- I meant to say this: I think one of you
19 -- both of you may have mentioned all the models that we
20 review are not meant to be advanced alternative payment
21 models, so our purview -- I guess just as a -- it's
22 something that actually we had to kind of go back to
23 statute and remind ourselves that -- I think there's been

1 an assumption that anything PTAC recommends would
2 potentially qualify as an advanced alternative payment
3 model. Our obligation was really physician-focused payment
4 models, which would qualify potentially as an advanced --
5 sorry, an alternative payment model and potentially an
6 advanced alternative payment model. So I thought that was
7 just a point of clarification.

8 And my last question is for Dr. Opelka. There
9 are some letters in here that offer pause and some
10 criticism. You have obviously -- I think everybody's
11 wrestling with what feels like there's something really
12 genuinely just kind of as I said game-changing there, but
13 it's incredibly complex. And then no disrespect to our
14 government colleagues in the auditorium or listening. It
15 feels like once you hand this over to a bureaucracy, that
16 potentially there are errors that might occur as part of
17 implementing such methodology.

18 All right. We can put that aside for a second.
19 Can you just speak to -- you mentioned that you haven't
20 really looked at a geographic market. You haven't really
21 kind of gone out and solicited, you know, will this
22 practice be willing or will this group of surgeons at this
23 employed facility be willing to do this. Can you describe,

1 just because I know you've been doing this for years, in
2 talking to your colleagues, kind of describe how you think
3 this model can actually change the way -- you know, the
4 behavioral economics of it, change the way people are
5 practicing. What's really kind of motivating you to keep
6 working at this? I know you've talked to CMS -- you know,
7 I know you presented nationally about this. Where do you
8 see something that could really fundamentally change the
9 way we practice medicine?

10 DR. OPELKA: So I'm not sure we're going to
11 fundamentally change the way we practice medicine. We want
12 to change the way we pay for it. We don't think that the
13 current fee-for-service environment in the RBRVS world does
14 a patient any favor. It silos the care. It pulls the team
15 apart. It doesn't bring the team together.

16 We believe that most of the surgical care that's
17 out there is team-based care, particularly in the modern
18 era of all the different options we have and all the
19 complexity of patients we have. I don't know anybody who
20 really says, "I really, truly just practice alone" anymore.
21 There is so much involved with the primary care physicians,
22 with the medical specialties, with anesthesia, with the
23 post-op care, and all the post care choices now, that this

1 has all got to be a team. And everyone seems to get into
2 their own little focus and then they don't pay attention to
3 how are we coordinating all across each other. And the
4 government has been trying to do that in the current fee-
5 for-service system, using a measurement system which we
6 don't think has gotten the engagement.

7 So our fundamental basis was prior to us even
8 having MACRA, we began building the episode-based
9 measurement framework, because that's how we practice. We
10 practice as teams of physicians, gathered around a patient,
11 trying to optimize their care. And we looked at surgery in
12 phases of care. We think there's a pre-op phase, the peri-
13 op phase, and intra-op phase, the post-op, and a post-
14 discharge phase, and there are critical, crucial events
15 that occur in each one of those phases, and they're all
16 team-based and related care.

17 Along comes MACRA and says, hey, we will actually
18 allow for alternative payment models and we're going to try
19 and incentive people to move away from fee-for-service, and
20 then the MIPS program. That fit our core belief in
21 building team-based care, clinical affinity groups, around
22 an episode basis.

23 So with that, I have been working with Dr.

1 Tompkins when he first began on this journey with the EGM,
2 and we said, boy, we think there's a fit here. Can we
3 bring these two together and can we do it in such a way
4 that it actually is a race to optimal care? Can we create
5 that, and we believe we can.

6 So that's what put us forward. When we talk to
7 our members, and we go out and talk to the different
8 fellows of the College of Surgeons, they get this. It's
9 how they practice. They're not tracking the current
10 measures that are out there, but this is how they actually
11 practice medicine. So there's a lot of interest in the
12 rank and file in saying, I really want to see that model
13 take shape, because they know it's closer to how they
14 practice.

15 Now, the whole element of asymmetric risk, yeah,
16 they have more upside than downside to get people to
17 engage, those carrots that you have to put out there.
18 We're not expert in that. We're trying to figure that out
19 ourselves. We're working with the Innovation Center to
20 figure out where are their swim lanes, how far can they go
21 to make this work, and we're learning as we go here.

22 CHAIR BAILET: Thank you. Grace and then Bruce.

23 DR. TERRELL: So a couple of things. One is I

1 just wanted to, as a point of clarification, you had
2 asserted earlier that one of the things that the PRT had
3 been asking you for was a formula. I don't think that what
4 we were asking you for was a formula but something that was
5 actually a little different, which was a -- it could
6 certainly be hypothetical but a highly specific
7 hypothetical example of how this might look in a clinical
8 affinity group or a region, to the level that we could
9 really dig into the details. And I still think that's
10 important, not within the context that that particular one
11 would be the way it all worked out, but because it may be
12 the way your surgeons get it, but the level that CMS has to
13 get it or the health care ecosystem has to get it, in
14 general. There's a lot to that, that still, I think,
15 requires people to get a lot around their head.

16 The other thing that I wonder about -- two quick
17 things. One is, with respect to the cognitive
18 professionals -- so I could give an example of an
19 infectious disease consultant who make come in for 10
20 minutes on a case, happen to notice that a person has a
21 particular risk, or is getting ready to be septic, or
22 something like that, orders a blood culture or orders an
23 antibiotic and saves somebody from a sepsis episode that

1 could have been devastating. And within the context of
2 bundling, I still wonder if sometimes that type of quick
3 cognitive work that many, if not all physicians do in ways
4 that aren't currently measured is still something that
5 needs to be thought through in a little bit more detail,
6 which is one of the reasons I thought it would be helpful
7 to understand, at a broader level, how something like this
8 might look. So just little things like that could be
9 thought through.

10 The third, and this is actually the question
11 rather than the comment, is you have made the point, both
12 in writing and here today, that this is very different, and
13 I agree, to some of the other models that we've seen, and
14 where you're talking about a single specialty or small or
15 something that starts with a clinical idea.

16 So my question for you is not as rhetorical as it
17 sounded, but if this particular methodology were put in
18 place, would we need a PTAC? Okay, and by that I mean, if
19 this solves most of the issues, where we're looking at the
20 others, would all these other things be subsumed in what
21 you're doing?

22 DR. OPELKA: Well, first of all, let me go back,
23 before I tackle that question. I think your points that

1 you make about a concrete example and walking it through,
2 that's going to be crucial to implementation. It has to be
3 in the package to help everyone, and I think the PRT made
4 that point today, even better than in our discussion on the
5 phone. So that, to me, was very, very helpful. How do we
6 build out an example of claudication with all the elements
7 that are in there, or how do we build out an example of a
8 real procedure with all the elements and subtleties that
9 are in there? It won't be all the permutations of where
10 the waste and savings are. It would just be, how do you
11 actually go about thinking and changing your mind frame
12 into a clinical affinity group? So I think that's very
13 helpful.

14 We're not at all trying to replace the PTAC. We
15 think this process has been enormously valuable. I know
16 that there was a thought or a discussion earlier today
17 that, to me, you are trying to deliberate and build out who
18 and what you are. It's almost like you are building the
19 car while we're driving it, and I think you're doing an
20 incredible job. And I think that looking at these
21 different aspects of different alternative payment models,
22 this is just one --

23 DR. TERRELL: That's what I wanted to hear.

1 DR. OPELKA: -- and it may pick up a whole bunch
2 of different other types that want to fit within this
3 construct, but there are others --

4 DR. TERRELL: Okay. That's what I wanted to
5 know.

6 DR. OPELKA: -- and this is not the only one.

7 MR. MILLER: I'd like to quickly remind those
8 listening at home that PTAC is not paid, so putting us out
9 of business would not lose our incomes in any fashion.

10 [Laughter.]

11 MR. STEINWALD: Dr. Opelka, a while ago you
12 referred -- and let's see if I got the language right -- to
13 an initial starter set of tight episodes for rolling out
14 the model. I may have mischaracterized that. But my
15 question is, do you have a sense of what the minimum would
16 be -- clinical areas, types of episodes, venues? What
17 would -- you know, in contrast to the other two proposals,
18 where we've actually talked about testing and small scale,
19 what kind of scale do you think would be necessary to test
20 your model? How would you characterize that?

21 DR. OPELKA: So there are hundreds of episodes.
22 We've submitted the minimum starting set. That's our
23 proposal. That's where we're ready to begin. The concept

1 of a geographic area to do that, that's another question
2 altogether, and we would sit down with the Innovation
3 Center to begin that. But we think the starter set is what
4 we've put on the table today, the 54 procedural episodes
5 that are in the proposal. But you could go to 100, to 200,
6 shortly thereafter, depending on the level of interest, and
7 call for it in the market.

8 CHAIR BAILET: Great. Good discussion. I want
9 to thank both of you for hanging in there with us and not
10 only the work you did here today but also all the work that
11 you've done, not only creating the proposal but working
12 with the PRT to help us sharpen our thinking on it.

13 So now it's time to open up the floor to public
14 comments. We have several people here who want to make
15 comments. We also have, potentially, some folks on the
16 phone. So I'm going to go ahead and work through the list.
17 If you could come up to the microphone and identify
18 yourself. I believe that's Francois de Brantes from
19 Altarum Institute.

20 MR. DE BRANTES: Good afternoon. Yes, Francois
21 de Brantes from Altarum Institute, and thank you for
22 allowing me these few comments.

23 I was reflecting, really, on the last question about

1 putting the PTAC out of business, and pondering on why even
2 are we all here today. And we are here today for several
3 reasons, one of which is that despite what was promised in
4 the payment innovations from the ACA, the last
5 administration really failed to put out any type of robust,
6 comprehensive, physician-based payment models, and that's
7 the opportunity that is in front of you today.
8 Chris mentioned that there were a number of subcontractors
9 that worked on the episode grouper for Medicare. For
10 reasons that I won't get into, my prior organization, the
11 Health Care Incentives Improvement Institute's name was
12 redacted from the final report, but we were instrumental in
13 getting the team together to develop the initial prototype,
14 the result of which, Harold, actually did distinguish cost
15 between typical and avoidable complication. So I can tell
16 you that the ability to do that in EGM is absolutely there,
17 and to hone in on for clinicians on those feedback loops,
18 Elizabeth, on what exactly they need to pay attention to.

19 But what I really wanted to kind of assuage your
20 minds of is that you're looking clearly at something that
21 is very broad in scope, and potentially has multiple layers
22 of development. And when we started doing our work,
23 everyone looked at us and said, "Boy, jeez, you know, what

1 you guys are doing is really complicated." And I now tell
2 them, "No, it's not complicated. It's sophisticated," and
3 there's a difference between complicated and sophisticated,
4 because brute force simple hasn't worked in this country,
5 and with this model that has been presented to you, by the
6 combination of the American College of Surgeons and
7 Brandeis, you have a highly sophisticated model that has
8 been not just sprung up over the past couple of months but
9 has been curated for seven or eight years, has been vetted
10 extensively. And, Bob, if you're worried about, you know,
11 how is this going to play out in the field, it's playing
12 out today, because the Prometheus payment model and the
13 work that we're doing is the first cousin of EGM, and we're
14 deploying it today in market after market. The feedback
15 that we get from providers is always positive. And even at
16 a large scale, like in New York, under the Medicaid DSPR
17 program, we're now -- there are several layers of value-
18 based payment programs, all of which are based on an
19 episode-of-care model, some of them around mental health
20 and substance abuse, comprehensive chronic care episodes,
21 and the providers are organizing themselves to do good care
22 for the patients.

23 So, yes, I think that at the end of the day the

1 payment model does drive the care transformation. The
2 providers organize themselves around the needs of the
3 patients. They deliver on those needs. And what we can do
4 in payment is basically make sure that we're not getting in
5 the way of clinicians doing the good work.

6 The ACS and Brandeis model accomplishes that
7 role. We've been waiting in this country for physician-
8 focused payment models at a large scale, that can get us
9 out of the rut that we're in, and that's the opportunity
10 that you have in front of you today. I plead with you --
11 do not waste this opportunity. The American people deserve
12 it.

13 Thank you.

14 MR. MILLER: Can I ask Francois a question?

15 CHAIR BAILET: Go ahead.

16 MR. MILLER: So do you believe --

17 MR. DE BRANTES: I didn't know that was allowed.

18 [Laughter.]

19 MR. MILLER: We are making it up as we go along
20 here.

21 Do you believe that an episode model that
22 separates typical and avoidable spending is better than a
23 model that simply has a total episode cost, or do we not

1 know and we should try both?

2 MR. DE BRANTES: No. I think the evidence is
3 fairly strong that it does work better, because you can
4 hone in your feedback loops. When Elizabeth asked who gets
5 this information, the front-line clinicians get this
6 information, because they're the ones that are going to
7 change the care patterns. And that information about
8 what's working in your area, which patients are
9 experiencing more hospitalizations, more ED visits, how
10 much utilization is going on in delivering better outcomes,
11 is going to vary in Tennessee as it does in North Carolina,
12 as it does in New Jersey or New York, and the information
13 feedback loop that goes to the clinicians has to be highly
14 actionable and reliable.

15 EGM does that, and it gives you incredible -- I
16 mean, when Chris talks about it as an x-ray, that's what it
17 is, and it's no different than what we've done. Adding a
18 little flag on some of those elements that are avoidable
19 complications, you know, which we've defined and it's for
20 free, it's on our website, and it can be incorporated in
21 the EGM model tomorrow, is the easy stuff. The difficult
22 part is coming up with an episode construct, rules of
23 service assignment, a clinical logic that makes sense to

1 clinicians when they get those reports, and that's what
2 we've accomplished over the past seven years, and it's a
3 monstrous feat.

4 So there is this unbelievable asset that the
5 United States of America, the Federal Government owns, that
6 has been sitting on a shelf, and that can be deployed
7 tomorrow, to power probably one of the best alternative
8 payment models for physicians in the world. Let's give it
9 a try. Let's give it a try.

10 CHAIR BAILET: Wait. One more question before
11 you sit down. Sorry.

12 [Laughter.]

13 CHAIR BAILET: We're just wearing a hole out of
14 the floor there.

15 VICE CHAIR MITCHELL: Sorry Francois.

16 CHAIR BAILET: Sorry about that. Go ahead,
17 Elizabeth.

18 VICE CHAIR MITCHELL: So about 10 years ago I
19 invited Francois to come share his model with some fairly
20 sophisticated physician executives, and they said, "It's
21 very compelling but it gives me vertigo." That was one of
22 the quotes. It was so complicated. Now, I think you've
23 made remarkable progress. I think we have overcome some of

1 that, but I'm going to ask the same sort of question. How
2 does this maximize the information? It's great reports,
3 great analytics, but how do you get it to change practice?
4 How do you use the information, practically, in a real-life
5 medical practice?

6 MR. DE BRANTES: Well, I think it starts by not
7 forcing physicians into artificial constructs. So if you
8 start with what are your patients, what are their needs,
9 what are the problems, what's the constellation of episodes
10 that creates the markers around them, and you provide them
11 with that information, and you provide that in the context
12 of an upside/downside risk model, they have pretty much
13 everything that they need to figure out how to organize
14 themselves.

15 Where we get into the vertigo part is in the
16 example that Paul mentioned earlier, where you've got the
17 sequelae of all of these little things that occur, and, my
18 gosh, how am I going to find myself back into this portion
19 and that portion? The reality is that it happens today.
20 In other words, the interaction of the different clinicians
21 with the physician along a continuum of care exists today
22 in nature. It exists today in the fee-for-service world.

23 The only thing that EGM does is capture that

1 activity and then apportion the responsibilities and the
2 upside and downside according to the effect of the care
3 that the individual clinicians have given to the patients
4 along that continuum. In doing so, you're creating, again,
5 this absolutely essential feedback loop.

6 I don't know -- and Frank mentioned it -- I
7 remember the first bundle payment programs we did, we'd
8 show the clinician -- and Paul was in some of this, in
9 Pennsylvania -- we'd show the clinicians what the total
10 episode cost was. They couldn't believe it, right, because
11 the surgeon is used to seeing \$2,500 bucks and the episode
12 for knee replacement is \$25,000. Where does the rest of
13 the money go? Well, suddenly you realize where the rest of
14 money goes. Once you figure that out and once you have an
15 incentive to change that, it's incredible what happens.

16 The reason people had vertigo is because there
17 really weren't -- there wasn't an underlying, fundamental
18 incentive in the country to do anything. Ten years ago, it
19 wasn't Prometheus, it was Sisyphus, and today it's a
20 different story because of MACRA. Right? Today it's a
21 different story because of MACRA, and the thirst for this
22 information is phenomenal.

23 We see the reports going on in New York State,

1 for individual value-based contractors -- FQHCs,
2 individual practices and IPAs, et cetera -- and they're
3 transforming the way they care for patients.

4 So I'm really not worried about this, and I know
5 you ought to be because that's your responsibility. But
6 your responsibility is also to say, are we doing something
7 that's going to significantly improve the quality and
8 affordability of health care in America, and I'm here to
9 tell you, yes, you are. And let -- you know, yeah.

10 Kavita said you give it to the feds, who knows
11 what happens. Well, I think that's our joint
12 responsibility to make sure that the administration
13 implements it way it should, and I think the physicians in
14 the land -- I mean, let's -- I think you should take pause
15 and kind of think about this. Tens of thousands of
16 physicians across the country are standing up and saying,
17 "We're ready to be accountable. We're ready to take on
18 financial risk in the management of our patients." When,
19 in our lifetimes, has that happened before? That's the
20 responsibility you have. Thank you.

21 CHAIR BAILET: You're so compelling. Bob.

22 DR. BERENSON: Francois.

23 MR. DE BRANTES: Yes.

1 [Laughter.]

2 DR. BERENSON: I mean, there's tens of thousands
3 of docs in ACO shared savings programs as well.

4 MR. DE BRANTES: Two-thirds of them, by the way,
5 are saying now that they could the job just as well
6 outside.

7 DR. BERENSON: Well, okay. They're saying to
8 whom? I mean, that was my point. You're giving me
9 testimony. Have there been formal evaluations of the
10 outcomes of Tennessee and all the other places, New York --

11 MR. DE BRANTES: Yeah, and Arkansas I would say
12 is probably the most advanced, Bob, in their evaluation of
13 their program. They continue to show important results in
14 the improvement of the management of patients. You know,
15 the case studies that we've published on, for example -- I
16 mean, I can go from maternity bundles to other procedural
17 bundles to chronic condition bundles -- all show the same
18 thing, which is fundamentally what you guys talked about
19 earlier. This isn't -- and Tim mentioned it. This isn't
20 rocket science. It's about care coordination,
21 understanding how to manage patients, and then deploying
22 the resources around it. And the payment model just gives
23 you the incentive to do that. That's all.

1 Now, you can look at it in a redacted construct
2 and in a very tight kind of surgical space or a larger one
3 around a condition or an even larger one around total cost
4 of care. I think our experience and contention and
5 evidence is that when you do it at a level that matters to
6 the front-line clinician, change happens a lot faster.

7 DR. BERENSON: So you're going to send us those
8 evaluations?

9 MR. DE BRANTES: Yeah.

10 DR. BERENSON: Okay. That would be great.

11 CHAIR BAILET: Francois, un moment.

12 MR. DE BRANTES: Un moment.

13 CHAIR BAILET: Len.

14 DR. NICHOLS: Thanks for coming.

15 [Laughter.]

16 DR. NICHOLS: This is really a question for the
17 room, I mean really, but you're here and now I'll start
18 with you. Two things.

19 It seems to me what you've built is a vehicle to
20 do the world's best micro simulation of medical
21 transformation, so, A, has anybody played out what costs
22 would do over time and behavior and how that could go and
23 how agent-based modeling might help us get there? And if

1 we haven't talked about that, we can talk about that
2 offline.

3 MR. DE BRANTES: We can talk about that offline.

4 DR. NICHOLS: Okay. The second question is:
5 This is all great, but if it's so great, why hasn't CMMI
6 just done it? And why are you coming to us? What's up?
7 What's their deal?

8 MR. DE BRANTES: All right. So I'll give you
9 their answer.

10 DR. NICHOLS: Okay, good.

11 MR. DE BRANTES: For three years running, when we
12 had the bundled payment summit here in Washington, there
13 was always someone from CMS showing up to explain, you
14 know, the great work they're doing and the horrendous
15 Bundled Payment for Care Improvement. And I would always
16 ask: When are we going to have condition-based episodes?
17 When are we finally going to have episode of care payment
18 that matters to physicians?

19 The answer from CMS during the Obama
20 administration was: That is the role of an ACO. That is
21 the role of an ACO. That is why we stand here today.
22 That's why we don't have physician-focused alternative
23 payment models in this country to date, apart from the

1 ACOs, because the philosophy -- and it is a philosophy,
2 because the evidence suggests that most ACOs simply jack up
3 prices on the commercial sector. The philosophy was that's
4 where care coordination belongs. That's where the
5 management of patient belongs. Our contention is that the
6 management of patients belongs in the physician's hands.

7 CHAIR BAILET: Thank you.

8 Next up -- I am going to get this name right
9 today -- Dr. Gajewski. Is he still here?

10 DR. BERENSON: He left [off microphone].

11 CHAIR BAILET: Did he? I know he was here, and
12 he was planning on presenting. But he's not here.

13 So Steve Black-Schaffer from the College of
14 American Pathologists.

15 DR. BLACK-SCHAFFER: You knew what CAP stood for.

16 CHAIR BAILET: Well, I had some help here. I've
17 got some really good staff.

18 DR. BLACK-SCHAFFER: Very good. Given the hour
19 and the day, I will only talk about the one thing that we
20 thought was interesting, and I must say I think everything
21 possible just about has come up. But let me talk about our
22 concern with regard to this model, which we also think is
23 rather cool in most ways, and it has to do with the payment

1 methodology.

2 We applaud the submitter's aspiration -- and I'm
3 reading it so I don't go on forever -- to quantify a large
4 number of measures and qualify a large number of physicians
5 for APM participation. We share, however, a concern that
6 was expressed several times around the table about the key
7 last step in the model, which is the proposed fiscal
8 attribution framework. And, yes, obviously, everything can
9 be readjusted at the end, but there is a presumptive
10 attribution mechanism, and we think it's not only
11 suboptimal, it's potentially dangerous.

12 The model is built on clinically relevant
13 determinations of expected versus observed costs. However,
14 to achieve efficient and coordinated care, good information
15 has to be provided at the clinical actors, and this
16 information must be sufficiently specific to point towards
17 appropriate use and to point out inappropriate use, whether
18 that inappropriate use is out of ignorance or avarice.

19 As proposed, the model misses this crucial
20 behavioral economic opportunity. It does admirably
21 detailed work at the whole episode level to provide whole
22 episode information on observed versus expected costs. And
23 then it stops just short of bringing observed versus

1 expected costs down to the more granular and clinically
2 actionable level of the actual clinicians involved in the
3 model.

4 This key gap in actionable information exposes
5 the model to a tragedy of the commons, and it fails to
6 incentivize the clinicians at the granular level required
7 most intelligently to inform their individual actions in a
8 way that ensures their common interests are actually
9 aligned.

10 Instead, the model proposes the surrogate use of
11 clinical responsibility roles. These exist merely to
12 approximate the clinician's opportunities to manage
13 financial risk. And by using these, it fails to take
14 advantage of what I agree, and I think pretty much everyone
15 around the table has agreed, is the essential strength of
16 this model, that you actually have real information about
17 the observed versus the expected costs of those clinical
18 actors and all the resources involved. This is what we've
19 been being told, and it sounds really significant.

20 It is this real specific information which should
21 be used to attribute fiscal responsibility. With such
22 attribution, there is a remarkably coherent system
23 available to us all here, and I second the people who are

1 speaking about it enthusiastically. However, I would
2 observe that without it, opportunities for coordination are
3 lost. Coordination does depend upon information, and
4 opportunities for gaming the system are introduced.

5 And other than that, I would like to thank
6 everybody for their attention.

7 CHAIR BAILET: Thank you.

8 Nick Bluhm from Remedy Partners.

9 MR. BLUHM: Thank you so much for this wonderful
10 discussion. I believe that most of our concerns were
11 raised, either verbatim or otherwise, and I would say
12 perhaps what -- instead of sticking to the script, I would
13 say in response to some of the comments that were made
14 about complexity versus sophistication, if we look at the
15 BPCI initiative and the uptake, it was in part due to its
16 clinical relevance; that is, we can parse out whether
17 episode triggers should be before or during
18 hospitalization, but physicians understand that the episode
19 began at hospital admission. And I feel like to move the
20 episode grouper for Medicare, which -- and I remember
21 fondly my time with Dr. Perloff and Dr. Tompkins at CMMI --
22 to move it into the realm of sophisticated but
23 understandable, it will be important to have the technical

1 specifications, what everyone has been sort of circling
2 around, out in the open and to have, you know, the best
3 data scientists running a full set of claims through it to
4 understand how it works in practice. I think that is a
5 crucial step, and we think that it's a solid foundation,
6 but one that would benefit from that open public dialogue
7 based on analysis with the claims data set.

8 Thank you.

9 CHAIR BAILET: Thank you.

10 And Stephanie Stinchcomb from the American
11 Urological Association.

12 MS. STINCHCOMB: Hi. I'm Stephanie Stinchcomb,
13 director of reimbursement regulation for the American
14 Urological Association, and I'm presenting for the AUA.

15 The American Urological Association, representing
16 more than 90 percent of urologists in the United States,
17 wishes to thank the PTAC for their efforts toward a payment
18 system that incentivizes quality and high-value care for
19 Medicare beneficiaries. Urologists care for a large
20 percent of Medicare beneficiaries, and we look forward to
21 advanced alternative payment models urologists can
22 participate in when caring for Medicare beneficiaries.

23 The American Urological Association, through our

1 Alternative Payment Model Work Group, has worked
2 extensively with the American College of Surgeons and
3 Brandeis teams as they have prepared, modeled, and revised
4 the ACS-Brandeis advanced alternative payment proposal and
5 wish to publicly support the model. The AUA requests that
6 PTAC considers this model for testing or implementation.

7 We believe the model has the following strength:

8 It incorporates a broad range of specialties who
9 already work together to provide coordinated care for
10 Medicare beneficiaries.

11 It is comprehensive in scope and flexible in
12 design, which we believe will help us adapt the model to
13 best meet the needs of Medicare beneficiaries.

14 The framework is attractive to specialty care
15 providers because it allows individual specialties to help
16 craft the condition-specific models most appropriate for
17 their patient population.

18 The model ties quality to resource use, and as a
19 society, the AUA is very committed to quality measurement
20 and believes that quality measurement is a necessary
21 component of any advanced APM.

22 We appreciate the opportunity to make this public
23 comment, and we look forward to positive approval of this

1 proposal. Thank you.

2 CHAIR BAILET: Thank you, Stephanie.

3 We're now going to open up the phone lines. I'm
4 not sure who's out there, but we'll find out momentarily.
5 Operator, could you please ask if any of the folks on the
6 line want to participate?

7 OPERATOR: At this time if you would like to ask
8 a question, please press star, then the number 1 on your
9 telephone keypad. Again, that's star-1.

10 And your first question comes from the line of
11 Brooke Zollinger from Leavitt Partners.

12 CHAIR BAILET: Go ahead, please.

13 OPERATOR: Your line is open.

14 [Pause.]

15 OPERATOR: Your next question comes from the line
16 of Joshua Lapps from Society of Hospital Medicine.

17 MR. LAPPS: Hi, my name is Joshua Lapps from the
18 Society of Hospital Medicine, and I'm offering comments on
19 behalf of the society.

20 On behalf of the more than 57,000 hospitalists
21 now practicing in the United States and on behalf of the
22 Society of Hospital Medicine, the medical professional
23 association representing hospitalists, we want to express

1 our strong support for the proposal of the ACS-Brandeis
2 advanced alternative payment model. The model seeks to
3 provide novel incentives and tools for providing both
4 efficient and effective care by improving quality of care
5 and reducing costs. SHM and many of our national thought
6 leaders have been partners with ACS and Brandeis in the
7 development and evolution of this unique alternative
8 payment model, and including providing input in the
9 development of the model over the past year.

10 Under the model, financial risk would be
11 attributed to providers based on their individual role in
12 providing care to the patient, and payments can be adjusted
13 based upon the quality of care delivered. Unlike existing
14 CMS episode-based payment models, the ACS-Brandeis model
15 does not necessarily require hospitalization, which allows
16 for the inclusion of a myriad number of procedures
17 performed in the outpatient and other settings, as well as
18 episodes for acute and chronic conditions cared by for
19 medical specialties.

20 While the initial proposal is primarily for the
21 surgical patient, we believe that this patient-focused
22 approach, which has an emphasis on the team-based nature of
23 care, can be expanded to be for more than just surgical

1 care and could easily be translated to other forms of
2 specialty care, including the medical episodes for
3 hospitalists and the care that hospitalists are providing
4 every day.

5 If implemented, it's our belief that this model
6 will provide opportunities for participation in advanced
7 APMs to providers who have now lacked options for
8 meaningful participation under MACRA. This will enhance
9 the ability of many physicians to participate in
10 transformative delivery system reforms in a way that is
11 designed to be clinically meaningful to them and to the
12 patients they serve.

13 And so, in closing, SHM is strongly in support of
14 the ACS-Brandeis advanced alternative payment model, and we
15 hope that the PTAC will vote favorably in support of
16 advancing the model forward.

17 Thank you.

18 CHAIR BAILET: Thank you.

19 Operator, is there anyone else on the line?

20 OPERATOR: Again, to ask a question, please press
21 star-1.

22 [Pause.]

23 OPERATOR: And there are no questions at this

1 time.

2 CHAIR BAILET: Thank you, Operator.

3 Before we move into the next phase, I would ask
4 that we take a 10-minute recess, and we'll be back at the
5 top of the hour. Thank you.

6 [Recess.]

7 CHAIR BAILET: All right. There we go.

8 PARTICIPANT: A gong [off microphone].

9 CHAIR BAILET: A gong, okay. All right. I'm
10 just going to let my Committee colleagues get their coffee.
11 I want everybody appropriately caffeinated here for this
12 next phase.

13 DR. NICHOLS: We need bourbon for this one.

14 [Laughter.]

15 CHAIR BAILET: All right. We have one public
16 commenter who I believe is here, right? Yeah, I see him as
17 well, yes. I thought that was him, but now it's you.

18 MR. TERRY: Oh, I didn't register, so if you want
19 him to go first.

20 CHAIR BAILET: No, no. Please, go ahead.

21 MR. TERRY: Okay. Great. My name is Dave Terry.
22 I'm CEO of Archway Health. We work with dozens of
23 providers across the country who are active in all of the

1 Medicare bundled payment programs. We've been doing this
2 as a team since 2011.

3 I love these discussions. We're a bit more
4 practical, I think, than policy-oriented, although we
5 follow the policy very closely. In our experience, these
6 programs are working quite effectively, and we're in
7 support of the ACS-Brandeis program because anything in the
8 market that we see that engages the specialty providers we
9 think is a big step forward. I've worked for a lot of ACOs
10 over the years. I think these models are complementary,
11 not competitive, in that we always struggle within ACOs to
12 find ways to engage specialists, and these models really
13 help us engage specialists in different ways.

14 I also say it's complicated and sophisticated, as
15 Francois said, but these programs are much simpler to
16 manage than an ACO because we know the patients who are
17 sick, and we're only working with populations of people who
18 we know need care, have very large budgets, we can assess
19 them and provide specific care plans for those patients.

20 Having managed ACOs, population health, I would
21 be at risk for everyone in this room -- and I have no idea
22 where the health status is of most of the people in that
23 program. So while it's complicated to set up, they're much

1 easier to manage than ACOs, and we think complementary to
2 ACOs.

3 Just a couple comments on some of the things that
4 came up in the discussion. In relation to kind of care
5 plans and protocols, in our experience accountability and
6 data drive innovation, particularly for specialty providers
7 who have a lot of volume. We like to work with specialists
8 who focus on a few areas and do it a lot and really, really
9 well. And they then innovate when they're accountable and
10 they have data. And the guidelines often aren't that
11 helpful for that group, to be honest, because when we talk
12 to the specialists, they see the guidelines as more a
13 lowest common denominator tool as opposed to letting them
14 innovate in an environment of accountability and data.

15 Addressing one of Elizabeth's issues, in terms of
16 how to get the data to the providers, in our experience a
17 little bit of data goes a long way. They don't have a lot
18 of experience looking at this information. It's actually
19 not that hard to get meaningful information in the hands of
20 the frontline clinicians and to help them work with it.
21 And then they innovate, and we get out of the way. And
22 that's the most fun and impactful part.

23 The last thing I'd say is I think small practices

1 work great in our experience. We work with small practices
2 who have more volume in their specialty area than some
3 large hospitals. So we have a small group of orthopedic
4 surgeons that do 500 knees a year. That's more than many
5 hospitals.

6 And so they do need help spreading the risk, and
7 there are more reinsurance products and tools to do that.
8 But we're strongly in favor of any models that encourage
9 the specialty providers to take on more accountability and
10 have more opportunity to innovate.

11 I thank you for the opportunity.

12 CHAIR BAILET: Thank you.

13 Dr. Gajewski?

14 MR. MILLER: Do we give frequent flyer points,
15 Jeff?

16 CHAIR BAILET: What's that?

17 MR. MILLER: Do we give frequent flyer points
18 here?

19 CHAIR BAILET: Harold, I don't know where you're
20 going with that.

21 I understand, yes, please. Three minutes.

22 DR. GAJEWSKI: Thank you. But I also
23 complimented you, Harold, earlier. Anyway, thank you very

1 much, and thank you for getting my name pronounced
2 correctly. The third time was the charm.

3 I don't want to re-emphasize much of what I said,
4 but I do think as you deal with this sort of model, dealing
5 with the complex outlier patients and having outlier
6 clauses will be essential. You take one of my types of
7 patients to a surgical procedure with thrombocytopenia,
8 neutropenia, on immunosuppressant medicines, there is no
9 coding adjustment or acuity adjustment things out there for
10 them. You take those patients with some of the mental
11 health issues, the poor psychosocial systems that we've
12 never captured in any claims database, their post-operative
13 management is going to be more complicated, and there will
14 be failures. So how we deal with that, again, becomes a
15 problem.

16 The other issue, again, if right now we are
17 spending 35 to 40 cents of every health care dollar for
18 management of the costs of the transaction, how we can do
19 something about the cost of analytics, because everything
20 right now, for all these -- any program under MACRA to be
21 successful, we need more analytics. That was one of the
22 essential lessons I took from the MACRA summit. But how we
23 compensate for these analytics is important.

1 It is also very unclear to me, because I have
2 tried to get nursing personnel to actually enter a bunch of
3 this data into the EHR that I've been using, and they have
4 balked. They say that's got to be a doctor function for
5 all the details. And I see the frown, Harold, but, you
6 know, to get complex metabolic acid-base disorders with
7 hypercapnia in there, borderline personality disorder, the
8 nurses do not want to take accountability for that. They
9 demand that physicians do it.

10 Thank you very much.

11 CHAIR BAILET: Thank you.

12 Robert?

13 DR. BERENSON: I know we're supposed to be
14 heading towards voting. I'm going to make a suggestion and
15 see what people think, that this is too important to vote
16 today. This depends so much on the grouper, and I don't
17 know what the grouper does. I would like to have the time,
18 a postponement of our vote until the next meeting probably,
19 so that we actually can get a demonstration of it, to
20 actually see how it works. I would like to see the studies
21 that Francois says exists about the external evaluations.
22 I would like to know from CMMI what concerns they have and
23 whether it does reflect a bias against episodes in favor of

1 ACOs, to hear a little more about that.

2 And, ultimately, the sort of endorsements and the
3 notion of a complete transformation of health care through
4 payment is so important that I think we should take the
5 time to do this right. And I would not know how to vote
6 today if I had to vote. I regret I'd probably not be as
7 favorably disposed as the endorsements of it would have me
8 be if I could get more confidence by actually looking at it
9 in operation. Now, a two-, three-hour demonstration,
10 asking questions, may not be enough, but at least I'd feel
11 more confident that I knew what this black box was.

12 So I don't know what the urgency is for us to
13 vote today, and so that's the idea that I have, to ask the
14 PTAC's opinion about whether that makes sense.

15 CHAIR BAILET: Grace?

16 DR. TERRELL: I think that's relevant to the
17 comments that I was making earlier, that the PRT was really
18 feeling a need for a level of specificity that we never
19 quite felt that we got. And if it is possible to do that,
20 then I think that it would be -- I would agree with Bob it
21 would be useful. It potentially would have changed the
22 PRT's recommendation, I think, had we been able to have
23 looked at something with more granularity. But I don't

1 know what -- some feedback to us as to why the questions
2 that we were asking didn't seem to elicit that, what were
3 we not asking adequately might be useful for us for future
4 proposals as well.

5 CHAIR BAILET: I would ask other Committee
6 members to provide input on Bob's proposal. Len?

7 DR. NICHOLS: I want Tim back if we're not
8 voting. But I mean, really, if we're not voting, let's go
9 get Tim and see what he thinks about this matter. But,
10 look, I'm always in favor of learning more. What I'm
11 trying to figure out is what am I going to know that's
12 going to change the way I feel, and I'm not sure I get
13 that, because it seems to me -- I mean, maybe we should
14 just have a little bit of a discussion.

15 The promise here is amazing. The specificity is
16 lacking. I don't know that I can figure out anything from
17 two hours. I can imagine that a two-hour webinar can help
18 me have a more concrete vision of what the grouper does,
19 but it seems to me we ought to be more specific about what
20 we ask him to do. Okay? And I would submit part of what
21 some of us feel like we want -- at least I'll speak for
22 myself -- would be show me how it would work on a smaller
23 scale to start, and I don't know if smaller scale is one

1 set of conditions, one set of episodes, one set of -- one
2 geography. I will leave that to you all. But that to me
3 would be one thing.

4 And then the second thing would be, yeah, I'd
5 like to hear from CMMI, but I'm not sure -- they can't tell
6 us that, short of a two-month wait, because we don't meet
7 again until June, right? That's what I'm kind of feeling
8 like. If we're going to do the information session, let's
9 do it in the next 30 days and specify exactly what we want
10 them to show.

11 DR. BERENSON: Could I respond?

12 CHAIR BAILET: Please.

13 DR. BERENSON: I'm only asking for a postponement
14 until June, and the demonstration would have to happen
15 certainly early in that period. And I would absolutely
16 want it to be as effective as possible. I don't know
17 exactly what that implies. I don't know if we can run
18 claims through as one of the suggestions was. But I think
19 that the PRT in particular, but anybody else who can
20 contribute to that, can help figure out what we need.

21 And what was the other point? That was basically
22 the point I wanted to make. I would also like to hear from
23 -- now that this is -- well, no, that's fine. I'll leave

1 it at that.

2 CHAIR BAILET: Bruce.

3 MR. STEINWALD: First, I'd like to ask the staff
4 if there are any unintended consequences if we postpone
5 voting?

6 MS. STAHLMAN: Such as?

7 MR. STEINWALD: Does it create a hardship for
8 you? Does it somehow mess up the procedures that we've
9 laid out in a way that would --

10 MS. STAHLMAN: I don't think so.

11 MR. STEINWALD: -- cause a problem?

12 MS. STAHLMAN: Not that I can think of. I think
13 that if we wanted to put it on the agenda, the June meeting
14 is June 5th and 6th. So it's a Monday and a Tuesday. It
15 would probably be the Monday here in the --

16 MS. PAGE: Have to ask the submitters if they can
17 make that.

18 MR. STEINWALD: Well, hearing that, then I have
19 no objection to putting it off, and that's not quite saying
20 -- I don't know about the rest of you, but I know your
21 doctors are used to getting up when it's dark, but Len can
22 verify this. Economists generally aren't, so --

23 [Laughter.]

1 MR. STEINWALD: It might not be a bad thing to do
2 just for the quality of our deliberative conversation.

3 CHAIR BAILET: Thank you, Bruce. Harold?

4 MR. MILLER: I don't -- Bob may feel this way. I
5 don't personally feel that seeing a demonstration of the
6 grouper will in any fashion help me make a decision about
7 this. I am still troubled by the lack of specificity in
8 other respects that makes it difficult to approve a model
9 that is going to have PROs but we don't know what they are
10 yet, and that initially is just based on reporting quality
11 measures, not based on any actual performance on those
12 quality measures, with no minimum quality standard and the
13 potential of achieving savings by stinting. Those are the
14 things that concern me.

15 If the submitter said that they would be able and
16 willing to fill those things in by the next meeting for
17 enough specific things to argue how that would be an
18 initial test, and I think that would make to me a
19 significant difference in the way we would approach it.
20 But I don't personally feel that a demonstration of the
21 episode grouper would solve that problem. I mean, I think
22 I understand maybe because I think I understand how the
23 episode grouper works, and it's not clear to me that seeing

1 a demonstration of it answers any questions about that. I
2 think this may be a theme of mine, I guess, but I'm not
3 sure we will really know how the episode grouper works
4 until it's actually put into practice and you see how it
5 works in reality.

6 CHAIR BAILET: I think given the significance of
7 the proposal from Bob, maybe we could just go around to the
8 other Committee members and just provide input, if you have
9 any input. Len?

10 DR. NICHOLS: So I don't have input, but I have a
11 question. What did you ask that didn't get clarified, if
12 there was some specificity that you were looking for you
13 didn't get? I think that will help me understand what we
14 want them to do next time, if we want them to do anything.

15 DR. TERRELL: Sure. We and other members, I
16 think we asked things that would give us a specific
17 example, show us, you know, how this would work. They gave
18 us some examples in their original proposal that were
19 related to cardiology and CT surgery and that. They came
20 back with one that was specific, I believe, to colonoscopy.
21 But the thinking about it more as an ecosystem, if you
22 will, where there was a specificity around how the entire -
23 - how it would work with that as it related to how would

1 somebody come up with the way it actually impacted cost and
2 quality.

3 So what we've heard today is by virtue of having
4 access to information, it will naturally lead to
5 improvements in cost and quality because people will see
6 their data, and then they will make choices related to
7 that. And I believe what we were asking for was something
8 that would be far more specific with that. Okay, we can
9 provide this type of information. Some of that was
10 provided for us in tables. But the next pieces of it, sort
11 of the analog piece that's the final stages, if you will,
12 after all the digital stuff, we didn't quite get, at least
13 in my opinion. I don't know about the other two of you,
14 but that was my need.

15 MR. STEINWALD: Well, I'll say this in response
16 to that. First of all, it was only the three of us asking
17 questions, and now there's 10 people asking questions, and
18 they don't all have the same perspective that the three of
19 us had.

20 Having said that, though, we've already asked an
21 awful lot of this proposer, and I think they would be
22 within their rights to say, "You know what? We've done
23 enough."

1 On the other hand, they have had the benefit of
2 listening to the conversation over the last three hours and
3 might have a clearer idea themselves of what would be
4 responsive to the concerns that they heard expressed around
5 the table.

6 And so I guess I'm suggesting that before we
7 table the vote, we ought to ask the developer whether
8 they'd be willing to go one more round with us.

9 CHAIR BAILET: Let's hold that question. Paul
10 and Bob.

11 DR. CASALE: So as Bruce said, I wouldn't object
12 to it, but as Len said, I'm not sure seeing how the grouper
13 works would necessarily change my concerns, a lot of the
14 concerns that Grace just articulated. But if there are
15 other members of the Committee that would feel more
16 comfortable -- of course, getting more information is
17 always helpful, but I'm not sure it's going to allay some
18 of my concerns, again, that particularly Grace articulated
19 well.

20 CHAIR BAILET: Bob?

21 DR. BERENSON: Yeah, I mean, this is going to
22 involve asking a question of a couple of our former
23 presenters here, is to what extent what, Francois, you were

1 talking about as successes in New York and Tennessee, et
2 cetera, is using the same methodology as what ACS and
3 Brandeis are proposing, I mean, is it -- would we be able
4 to talk to some of the physicians who are being paid under
5 this method as a way of seeing how it functions in the real
6 world? Or is what they're proposing different enough so
7 that that would not necessarily be useful for us, I guess?
8 If I could ask both parties to comment on that.

9 DR. OPELKA: Well, I can't speak to the model
10 that Francois is talking about, so I have no knowledge of
11 contractually how those arrangements, those business
12 associate agreements are run, how the risk model works. So
13 I can't tell you that the detailed specifics are -- how
14 comparable they are, how comparable they are not. But from
15 the perspective of giving more information and answering
16 more questions, you know, I don't personally have a problem
17 with that. The more we can inform you about it, the
18 better. We don't want you uncomfortable in your decision
19 making process. We, too, feel this is very important and
20 giving --

21 DR. BERENSON: Do you think it's possible to do a
22 useful demonstration with Q's and A's in a few-hour period?
23 Is that something that is doable and useful?

1 DR. OPELKA: To the extent of the grouper?

2 DR. BERENSON: Yes.

3 DR. OPELKA: Yes. Now, we didn't really talk
4 about the different groupers that CMS has, and that was
5 part of the question that came up earlier, but it didn't
6 come up in our own discussion. This particular grouper,
7 the reason this grouper has so much value is it measures
8 all Part A, Part B. The other groupers that are out there
9 narrow things down to that which clinicians know they can
10 influence.

11 We want everything, so we would be showing you a
12 demonstration of what looks at all the possible costs we
13 can attribute to an episode, because we think that's --
14 when you're looking at APMs, we think that's the way to go.
15 When you're looking at MIPS, where you're trying to protect
16 people from penalties, that's a different world, and that's
17 a different grouper.

18 DR. BERENSON: Francois, were you just talking in
19 positive terms about the concept of condition-based
20 episodes, or were you talking specifically about a
21 methodology that is comparable, in some specific way, to
22 what you understand they are proposing?

23 MR. DE BRANTES: [Off microphone.]

1 CHAIR BAILET: It's not on.

2 DR. TOMPKINS: The logical features of the group
3 that Francois uses and the build-up of the episode
4 construction logic in the code specifications, they're
5 consistent. Are they identical? No. They're consistent.
6 So if the question is, can you give actionable information
7 to delivery systems of physicians so they feel more
8 comfortable about the cost world in which they're living,
9 through his lens it would be qualitatively similar to this
10 lens.

11 CHAIR BAILET: Did you want to make a comment, to
12 answer Bob's specific question?

13 MR. DE BRANTES: Yeah. Chris captured it. I
14 refer to it as not necessarily siblings but first cousins.
15 So it's qualitatively the same.

16 DR. BERENSON: I mean, if we did go to what I'm
17 suggesting, I think we would want to establish some
18 subcommittee or PRT with others who wanted to join, to
19 really figure out what would be the best use of the
20 extension. I don't think we could do that at this moment
21 here, but it sounds like there's things to be learned both
22 from a demonstration of the grouper and perhaps some
23 conversations with physicians who have been functioning

1 with the grouper in the states where it's in play. But I
2 think we would need to brainstorm a little bit.

3 CHAIR BAILET: Yeah, how best to do that, and we
4 also have our staff to help us guide us through the actual
5 appropriate process, but I would Kavita, and I saw Len's
6 card up, and Grace, but I also like Elizabeth. So, Kavita,
7 do you want to just make a comment real quick?

8 DR. PATEL: I, too -- I mean, so when Len asked
9 the question of what, like, what would change, honestly, I
10 would have a better sense of what this looks like. I mean,
11 I feel like I have read everything several times, and I'm
12 still -- maybe I'm the 10-year-old also. I just can't wrap
13 my brain around this. And so what it inclines me to do is
14 to default to what is currently the PRT's recommendation,
15 which is to not recommend, and they also made a comment
16 about not even recommending limited scale. I am calling
17 that into question, but in order for me to make the
18 decision about potentially advancing this to limited scale,
19 I feel like I need that extra piece of information.

20 I'll also say, that in the transcript, I didn't
21 see anywhere that we talked with anyone at CMS. I know
22 that several times it's been mentioned that it's just
23 sitting on a shelf, you know, not getting updated, not

1 getting used. I don't let my own decisions be influenced
2 by what the agency is thinking, but I'd like to understand
3 what have they done, just to get a sense of what is it that
4 they have done, because that has not come up. So I don't
5 care what their opinion is about it, but I would like to
6 understand that, and that will all help me make that
7 decision.

8 So I'm just being honest about what would change
9 my deliberation.

10 CHAIR BAILET: Thank you, Kavita. Elizabeth?

11 VICE CHAIR MITCHELL: Thank you. I actually
12 could support the postponement, and would participate in a
13 demonstration. I think I could get quite a lot out of it,
14 but would ask even more specific questions about the PROs
15 that are planned for use. I think understanding those
16 outcomes and how -- outcome metrics, and how they would be
17 integrated would be very helpful. And, additionally, if
18 there's time, just a bit more information on the data
19 access piece.

20 CHAIR BAILET: Len.

21 DR. NICHOLS: So I think we've graduated to what
22 do we want to learn, right, from the future. Okay. I'm
23 persuaded if folks want more time then I wouldn't mind

1 having more time either. I'm just always pushed back
2 because we've come so close.

3 So what I would like to know would include not
4 only how are current physicians, how they would view all
5 the implications of the allocations that you're proposing,
6 I'd like to know how, if you will, a fresh set of
7 clinicians, maybe from a multispecialty group, how they
8 would view it. Because here's what I'm worried about, two
9 things. Maybe they're both wrong, but one is, how do we
10 implement this without making it difficult to do anything
11 else in the same area?

12 Because what I remember reading quite a bit in
13 the proposal was a notion of free choice. We want every
14 doc to voluntarily join or not. Well, what if the surgeons
15 all love it, and what if the urologists all love it, but
16 what if primary care and six other specialties don't? Then
17 what have we got? That's what I'm having a hard time with.
18 How do you make it jive with this world of voluntary.
19 That's why I naturally, just simplistically, overly
20 simplistically gravitate to can we find one little corner
21 of Buffalo, or some darn place, to do it, you know, or
22 Tennessee or Arkansas, whatever. See what I'm trying to
23 say? I want to see how it would play out.

1 DR. OPELKA: Well, there's --

2 DR. NICHOLS: And so -- if I could just say one
3 more thing, Frank.

4 DR. OPELKA: The College of Surgeons is a finite
5 resource center. We are not a payer. Now I would take my
6 reserves out of my payer and go model this and mock it up
7 and do everything you asked, but there's only a limited
8 amount of services. And all these questions are great
9 questions, but who's going to finance it? If it doesn't
10 get off the dime, you're never going to get the answers to
11 these questions. We don't have the resources to gather in
12 an advanced delivery system all these questions. We're not
13 that body. So that's where the payer and the partnership
14 with the Innovation Center comes into play, but we can't
15 get there if you're not comfortable enough to get there.

16 The Innovation Center is ready to go. They keep
17 saying, "Let's get going." Well, now we're saying, "No,
18 it'll hold until March." No, now it's going to hold until
19 June. Once we go past June, it will hold until 2019,
20 because they've got to be working on the 2018 rollout. So
21 there's a part of this that says if you want to get going,
22 somebody's got to take the step. Someone's got to have a
23 little faith and make the move. But if you're not ready,

1 then we're backing up -- when we go to June, we're really
2 backing up to 2019.

3 DR. CASALE: So along those lines, are you
4 suggesting we look at the Prometheus experience as a
5 reflection of what would happen in your model, since it's
6 qualitatively similar, rather than you having to, you know,
7 sort of actually do the work within your own model, to look
8 at some real, live experience? I'm asking whether that --
9 if we looked at that, should we look at it as a corollary
10 to what would happen, or how physicians look at it or
11 respond to it?

12 DR. OPELKA: I don't have personal experience
13 with their model to tell you, so I can't answer it. I know
14 the grouper logic they use. I don't know the business
15 associate agreements that are used at the point of
16 implementation, and how that incorporates. So I can't tell
17 you if you're comparing grouper to grouper or you're
18 comparing apples to oranges.

19 CHAIR BAILET: Bob.

20 DR. BERENSON: Yeah, now I'm really confused. I
21 mean, Francois was telling a story that CMMI is so -- at
22 least the Obama CMMI was so sort of locked into ACOs and
23 didn't want to support any competition to that, and you're

1 telling me that CMMI is ready to go, and we're now the ones
2 who are the roadblocks. I'm confused about what your
3 situation is with CMMI. Why do you even need us if they're
4 ready to go, is my question.

5 DR. OPELKA: I can't speak for CMMI. I can tell
6 you that the Innovation Center has been involved and
7 engaged in this model since its inception. We've had many
8 meetings. Our own Q&A is very similar to the PRT walk, but
9 in a different sense they can give us technical support.
10 They can tell us how they want the model shaped. They can
11 help think about the implementation phases of this, and we
12 have been doing that with the Innovation Center for almost
13 a half a year.

14 DR. BERENSON: So you don't have that same
15 perception that Francois had, about their sort of bias?

16 MR. DE BRANTES: My answer was specifically to
17 Len's question, about why hadn't they done it to date, and
18 I think the -- to date is different today than it was a
19 year and a half ago. But, you know, that was the answer I
20 got from every representative from CMMI, when we asked the
21 question, "When are we finally going to get physician-
22 focused episode-of-care payment?" The answer,
23 systematically, was, "You're not because we don't believe

1 that that should be done outside of an ACO."

2 DR. BERENSON: That doesn't make any sense to me.
3 I mean, there --

4 CHAIR BAILET: Okay. So Grace and then Len.

5 DR. TERRELL: One of the things that I want to
6 make sure that the PTAC understands is that there's already
7 been a significant burden on the proposers. I mean, we
8 went through three rounds of questions and an interview
9 that was on the phone. We did have -- to someone's
10 question earlier -- a conversation with CMS. We just
11 didn't have it recorded. It was part of -- there's been a
12 lot of work on this.

13 And one of the other things that was pointed out,
14 to someone's question, is if you go back into your packet,
15 we did actually ask them, in one of those batches of
16 questions, "We are having difficulty understanding exactly
17 how you envision the model would work for you in an
18 individual case. We believe the most effective way to
19 address this would be for you to provide two detailed
20 examples of how all aspects of the model might be
21 implemented from one procedure and for one condition." And
22 then we proceeded to have A through K, I believe, of very
23 explicit information, which they provided.

1 So if we're going to ask them for a demo, which
2 we need to read this and determine what it doesn't do for
3 us. And I do believe a lot of the conversation today is
4 about there's something that's still -- it doesn't do for
5 us. But they did an enormous amount of work, trying to
6 answer our question. So I would just suggest that we think
7 through that.

8 CHAIR BAILET: Len.

9 DR. NICHOLS: So in the spirit of the PRT chair,
10 I would like to amend my previous remarks and say we should
11 make a decision today, and if we can't live with it, then
12 we can't live with it. But my gut says what we're talking
13 about here is what are the choices we have? We could say
14 no, forget it, good luck with CMMI and we wish you well.
15 We could say we think this should be explored on a limited
16 basis. We can say this should be implemented. We could
17 say it's high priority and we should erase all other
18 payment systems.

19 But I would guess we're going to end up on a cusp
20 between no and limited scale. That's where we are, and I'm
21 comfortable making that judgment. But maybe if other
22 people would rather wait, I'm not opposed to that. I just
23 think -- I think everything we need to know is in the

1 appendices and the answer and some other reports I just
2 found on the Web, so I'm not worried about not knowing.

3 CHAIR BAILET: I'd like to -- I think this is
4 important enough that we should -- Harold?

5 MR. MILLER: You can go ahead.

6 CHAIR BAILET: No, no. Please. Go ahead. I
7 didn't see your card up.

8 MR. MILLER: No. I just put it up. I was just
9 going to -- I agree with Len. I don't think we should
10 postpone. I think we should decide today. I am still
11 trying to think through to decide what, but I do think we
12 should be thinking about what we could recommend with
13 comments, and the comments, to me, have to say that the
14 structure is very promising but has some gaps in it, and
15 has some weaknesses. And just as we were doing with the
16 other models, I think the judgment has to be, in my mind,
17 are those gaps sufficiently fatal problems that we really
18 can't move forward, and have them filled in afterwards, or
19 not.

20 And I am leaning at the moment to say I think we
21 could specify, in comments, what would be solutions to the
22 problems that I have with it, such that we could say,
23 recommend limited testing, whatever, if the following

1 things are done. The PROs have to be specified, that, to
2 me, it can't be just pay for reporting initially. And CMMI
3 can decide what they want to do with that. CMS, the
4 Secretary can decide. But that would be what I would
5 recommend that we say, and we can debate whether not that
6 is a satisfactory recommendation.

7 But I don't feel, as I said earlier, if they
8 said, "Hey, we've heard what you said and give us two
9 months and we'll bring you all that stuff," I don't think
10 they're going to say that but we can ask them. But in the
11 absence of that, I don't think we're going to get any --
12 we're not going to get any information that, to me, is
13 determinative, that I don't have today.

14 CHAIR BAILET: Okay. Thank you, Harold. So my
15 opinion, as an n of 1, I have the submitters in front of
16 the Committee. I'm not hearing Harold, despite hearing
17 from the Committee members, that there is some level of
18 discomfort about the amount of knowledge that's been put on
19 the field, for us to consider. I'm not hearing that they
20 are going to rally, but I guess I'd give Frank one more
21 crack at that question, specifically. But I'm not hearing
22 that they are going to rally and that they have -- they are
23 in a position to have more information that they feel they

1 could present to us, to help compel or sharpen our
2 deliberations, substantively, beyond where we are today.
3 I'm not hearing it and maybe I'll pause and turn to Frank,
4 or Dr. Tompkins. If there's a magic bullet, we'd like to
5 hear it.

6 DR. OPELKA: I don't think there's a magic
7 bullet. From the point when this was submitted to today,
8 we've moved a lot further down in specifications of the
9 PRO. That's work that's ongoing, and it's due to be out in
10 the fall. It's not going to be here in June. It's going
11 through reliability and validity testing, and all sorts of
12 things that are required in PRO-based activities.

13 The episode-based measure framework has gone
14 through the CCSQ. We're still waiting for their final
15 approval, as are many other specialties, but that measure
16 framework has also been fully specified and turned in and
17 was included in the submission, so that information is
18 there.

19 The ability to give a detailed example is
20 something that we could provide. I don't know that it
21 would materially change where you are, but it can be
22 provided. And then the same with demonstrating the grouper
23 and how it works and being able to answer detailed dive

1 questions on the grouper. That can also be done.

2 My concern is getting this to the point where it
3 can move forward for 2018. Any pushback from today, and
4 we're into June, I don't know how the Innovation Center
5 could move forward and get this thing done, if we're
6 pushing back any further from today.

7 CHAIR BAILET: Okay. So to complete my thinking,
8 I would like to ask for a directional sense from the group,
9 from the Committee. I ask this question before every
10 proposal was deliberated on. Are we ready to vote? And so
11 I would like just a nod. Do we feel comfortable that we
12 are ready, based on the facts that have been presented, to
13 deliberate and vote, understanding that it is imperfect,
14 understanding that there are gaps, and understanding that
15 despite our best efforts, even in June, there will still be
16 gaps, based on what I'm hearing, relative to what we feel
17 we need.

18 So I see Harold, Bruce --

19 MR. STEINWALD: Can we hear one more time from
20 Bob? I would like for him to answer first.

21 DR. BERENSON: I don't get it. If you're down
22 the road, what do you need us for? I mean, if CMMI now
23 wants to proceed to 2018, I don't understand why you're

1 even here. So, that's a question.

2 DR. OPELKA: Well, again, I can't speak for CMMI.
3 If they're waiting for the PTAC in order for them to
4 proceed down the road, then that's why we're here. We've
5 not been given an indication one way or the other. CMMI
6 asked us to bring it to the PTAC, and if that holds up the
7 CMMI, that's their call. But they asked us to go through
8 the process and we're here under their direction.

9 DR. BERENSON: Okay. I didn't understand that.
10 Did the PRT understand that CMMI has directed them to come
11 to the --

12 CHAIR BAILET: No, but that's fair. That's
13 important to know. So we're going to go ahead and begin
14 our deliberative vote. You guys can step away from the
15 table as the Committee will go ahead and start the process,
16 going through the criterion. And again, for those who are
17 new to the process, we are going to go through each
18 criteria. It's a simple majority vote. We have an
19 electronic system, and let's just go ahead and start that
20 process now. There are nine of us who are actually in the
21 queue to vote, and it will show 10, and that's because of
22 the electronic support.

23 So Criterion 1, Scope of Proposed PFPM. This is

1 a high-priority item. The proposal aims to broaden or
2 expand CMS's APM portfolio by either (1) addressing an
3 issue in payment policy in a new way, or (2) including APM
4 entities whose opportunities to participate in APMs have
5 been limited. We're going to go ahead and vote now.

6 Ann?

7 MS. PAGE: For Criterion 1, zero Committee
8 members have voted 1 or 2, which means Does Not Meet; two
9 Committee members voted 3, Meets; two Committee members
10 voted 4, Meets; four Committee members voted 5, Meets and
11 Deserves Priority Consideration; and one Committee member
12 voted 6, Meets and Deserves Priority Consideration. We
13 have five votes. Since there are nine Committee members
14 voting, five votes constitutes a majority, so the Committee
15 has voted that this proposal Meets and Deserves Priority
16 Consideration for this first criterion.

17 CHAIR BAILET: Any comments from the Committee,
18 based on the output here.

19 [No response.]

20 CHAIR BAILET: If not, we're going to go ahead
21 and move to Criterion 2, which is Quality and Cost, again,
22 another high-priority criterion. The proposal is
23 anticipated to (1) improve health care quality at no

1 additional cost, (2) maintain health care quality while
2 decreasing cost, or (3) both improve health care quality
3 and decrease cost.

4 Any further comments before we vote?

5 [No response.]

6 CHAIR BAILET: Then we are going to go ahead and
7 vote.

8 CHAIR BAILET: Ann?

9 MS. PAGE: Zero Committee members voted 1, Does
10 Not Meet; four members voted 2, Does Not Meet; five
11 committee members voted 3, Meets; and zero Committee
12 members voted 4 or 5 or 6. Five members, the majority,
13 voted that this proposal Does Meet Criterion 2.

14 CHAIR BAILET: Thank you, Ann.

15 Any committee comments, based on the output?

16 [No response.]

17 CHAIR BAILET: We're going to move to Criterion
18 3, Payment Methodology, the last of the high-priority
19 criterion. Pay APM entities with a payment methodology
20 designed to achieve the goals of the PFPM criteria, address
21 in detail through this methodology how Medicare and other
22 payers, if applicable, pay APM amenities, how the payment
23 methodology different from current payment methodologies,

1 and why the PFPM cannot be tested under current payment
2 methodologies.

3 Comments before we vote?

4 [No response.]

5 CHAIR BAILET: Go ahead and vote.

6 Someone has to push it one more time. There we
7 go. Thank you.

8 MS. PAGE: Two Committee members have voted 1,
9 Does Not Meet; zero Committee members voted 2, Does Not
10 Meet; four Committee members voted 3, Meets; two Committee
11 members voted 4, Meets; one Committee member voted 5, Meets
12 and Deserves Priority Consideration; zero members voted 6.
13 The majority has voted that this Meets Criterion 3, Payment
14 Methodology.

15 CHAIR BAILET: Thank you, Ann.

16 Criterion 4, Value over Volume. The proposal is
17 anticipated to provide incentives to practitioners to
18 deliver high-quality health care.

19 Any comments before we vote?

20 [No response.]

21 CHAIR BAILET: Seeing none, let's go ahead and
22 vote.

23 MS. PAGE: One Committee member voted 1, Does Not

1 Meet; five Committee members voted 2, Does Not Meet; three
2 Committee members voted 3, Meets; and zero Committee
3 members voted 4 or 5 or 6. The majority of the Committee
4 has voted that this Does Not Meet Criterion 4, Volume over
5 Volume.

6 CHAIR BAILET: Thank you, Ann.

7 Any committee comments before we move on?

8 [No response.]

9 CHAIR BAILET: Next criterion then, Flexibility,
10 number 5. Provide the flexibility needed for practitioners
11 to deliver high-quality health care.

12 Let's go ahead and vote, please.

13 CHAIR BAILET: Ann.

14 MS. PAGE: Zero Committee members voted 1, Does
15 Not Meet; one Committee member voted 2, Does Not Meet; four
16 Committee members voted 3, Meets; and another four
17 Committee members voted 4, Meets; zero Committee members
18 voted 5 or 6, Meets and Deserves Priority Consideration.
19 The majority of the Committee has voted that it Does Meet
20 Criterion 5, Flexibility.

21 CHAIR BAILET: Thank you, Ann.

22 Seeing no committee comments, we're going to go
23 ahead to number 6 Criterion, Ability to Be Evaluated. Have

1 valuable goals for quality of care cost and any other goals
2 of the PFPM.

3 Go ahead and vote, please.

4 MS. PAGE: Zero Committee members have voted 1,
5 Does Not Meet; two Committee members voted 2, Does Not
6 Meet; six Committee members voted 3, Meets; one Committee
7 member voted 4, Meets; and zero Committee members voted 5
8 or 6, Meets and Deserves Priority Consideration. The
9 majority of the Committee has voted that this proposal
10 Meets Criterion 6, Ability to Be Evaluated.

11 CHAIR BAILET: Comments from the Committee?

12 [No response.]

13 CHAIR BAILET: Seeing none we are going to go to
14 Criterion 7, Integration and Care Coordination. Encourage
15 greater integration and care coordination among
16 practitioners and across setting where multiple
17 practitioners or settings are relevant to delivering care
18 to the population treated under the PFPM.

19 Please vote.

20 MS. PAGE: Zero Committee members voted 1, Does
21 Not Meet; one Committee member voted 2, Does Not Meet; five
22 Committee members voted 3, Meets; one Committee member
23 voted 4, Meets; and one Committee member voted 5, Meets and

1 Deserves Priority Consideration; one Committee member voted
2 6, Meets and Deserves Priority Consideration. The majority
3 of the Committee has voted that this proposal Meets
4 Criterion 7.

5 CHAIR BAILET: Thank you, Ann.

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

10 Please vote.

11 MS. PAGE: Zero Committee members voted 1, Does
12 Not Meet; two Committee members voted 2, Does Not Meet;
13 five Committee members voted Meets; two Committee members
14 voted 4, Meets; and zero Committee members voted 5 or 6,
15 Meets and Deserves Priority Consideration. The majority of
16 the Committee has voted that this proposal Meets Criterion
17 8, Patient Choice.

18 CHAIR BAILET: Thank you, Ann.

19 And we're going to go ahead and finish with
20 Criterion 9, and then we have Criterion 10. So 9 is
21 Patient Safety, how well does the proposal aim to maintain
22 or improve standards of patient safety.

23 Please vote.

1 CHAIR BAILET: There we go. Ann?

2 MS. PAGE: I'll summarize. One Committee member
3 voted 2, Does Not Meet; eight Committee members voted 3,
4 Meets; and the rest of the numbers are zero, so the
5 majority of the Committee has voted that the proposal Meets
6 Criterion 9, Patient Safety.

7 CHAIR BAILET: Thank you, Ann.

8 And last, Criterion 10, Health Information
9 Technology. Encourage use of health information technology
10 to inform care.

11 Please vote.

12 MS. PAGE: Zero Committee members voted 1 or 2,
13 Does Not Meet; six Committee members voted 3, Meets; two
14 Committee members voted 4, Meets; zero Committee members
15 voted 5, Meets and Deserves Priority Consideration; and one
16 Committee member voted 6, Meets and Deserves Priority
17 Consideration. The majority of the Committee has voted
18 that this proposal Meets Criterion 10, Health Information
19 Technology.

20 CHAIR BAILET: Thank you, Ann. So there will be
21 a small delay while they construct a summary slide, and
22 during that period I would just like to summarize where we
23 are, in our process.

1 The next phase is actually voting on the
2 recommendation of the proposal to the Secretary, and prior
3 to that we have the opportunity to comment, as a committee,
4 and I see Harold has a comment.

5 MR. MILLER: I'm wondering whether we don't need,
6 in this particular case, to be clear about what a comment
7 will be, in order to determine what it is we are voting.
8 So, in other words, if somebody is voting to recommend or
9 recommend limited testing or whatever, what is the comment
10 that goes along with that? Because people might have a
11 different opinion about what they're voting for if they
12 don't know what the comments are going to go along with it.

13 So I guess I'm just wondering -- we've kind of
14 added the comments later, but, in a sense, it's like, you
15 know, in an ordinary thing I might say, "I move that we
16 recommend X with the following conditions." We haven't
17 done that before but in a sense that's what's going to be
18 coming out, will be a recommendation with a bunch of
19 comments. So I just wonder -- we haven't really talked
20 through that, but at least in my mind, my feeling about
21 this is sort of connected closely to what the comments are,
22 you know, that -- how this is -- how that would be done
23 makes a difference to me.

1 CHAIR BAILET: Bruce.

2 MR. STEINWALD: I agree with Harold, and to take
3 it one step further, if we were to recommend something
4 other than full implementation, the choice, the steps down
5 for that, is limited-scale testing. But I'm not sure what
6 limited-scale testing means, with this proposed model.
7 And, I mean, I have a clearer idea in the other two
8 proposals that we already evaluated, but -- so my main
9 purpose is to agree with Harold, but I think if we're going
10 to talk about what we might recommend, we're going to need
11 to address this concept.

12 CHAIR BAILET: Well, let me just sort of distill
13 what I've heard sitting here for the last day and a half,
14 relative to this notion on limited-scale testing, and I
15 would ask that my colleagues jump in as well.

16 What I believe is that there is clearly the
17 category of it's a fabulous, innovative idea, but doesn't
18 have enough of a backbone fleshed out to warrant
19 recommending to the Secretary that there is additional work
20 to pursue, even if it's not full implementation. We've had
21 that with our earlier proposal today -- again, novel,
22 innovative concept, but we didn't feel there was enough
23 fleshed out where we felt we could get behind a

1 recommendation to pursue.

2 So in that gray zone, if we feel that there is
3 enough demonstrated here, that our recommendation would be
4 to provide CMMI with guidance that we support some form of
5 testing and evaluation, that it's worthy enough to pursue,
6 at that level, I think, frankly, that should give enough
7 guidance to CMS and CMMI our position, relative to feeling
8 that it merits -- it's valuable enough to the clinical
9 stakeholders and the patients that we should request that
10 they consider strongly pursuing some, and we leave it up to
11 them, to some degree -- we'll provide comments about
12 potential areas. Bob raised a few already. But we'll
13 provide some directional comments.

14 But, at the end of the day, we know that it's a
15 recommendation and then the Secretary has the ability to
16 distill that and respond to our recommendation.

17 So in my own mind's eye, it's either not strong
18 enough to recommend implementation of any kind, worthy of
19 exploration, or strong enough to recommend implementing --
20 and I'm not hearing a consensus around that at this point,
21 but we will know soon -- or that we feel it is meritorious
22 enough that we should take a position on further testing,
23 of some format, and we, frankly, haven't fleshed out what

1 that would look like, but we do know that we have made that
2 recommendation yesterday, with one of the proposals.

3 So, Harold, and then any other committee members.

4 MS. STAHLMAN: Kavita.

5 CHAIR BAILET: Oh, Kavita, you're first. Go
6 ahead. Sorry.

7 DR. PATEL: It did sound like the PRT, in some of
8 your comments, actually included something about a
9 potential for a revision. Now we heard from Dr. Opelka
10 that there is a time sensitivity. I'm going to put that
11 aside for a second and just say that it feels like there's
12 this kind of other fourth category of, if these thing were
13 present, and I'm looking at how the group voted, you know,
14 on all the high priority -- anyway, just having said that,
15 I agree with Jeff's assertion that you're either going to
16 do this or you're not. But it did seem like the PRT was
17 alluding to potential revisions that could be helpful, like
18 Harold said, with PROs, et cetera.

19 My own question about how this -- aside from the
20 examples that were included -- kind of what would this look
21 like in the eyes of kind of a smaller practice, or a set of
22 providers that were not tied to a facility. Those are the
23 kinds of things that it sounded like there would be a

1 revision, and I just want to make sure I read that, because
2 you read that in your PRT report.

3 So, for me, it might be, Jeff, that we're saying,
4 you know, do not recommend, but that the comment is because
5 these are the issues that would help to potentially be
6 revised -- or I think that was the word you used, was
7 "revised."

8 DR. TERRELL: Let me respond to that, Jeff --

9 CHAIR BAILET: Go ahead, please, Grace.

10 DR. TERRELL: -- just as a matter of -- so I
11 think that there's a logic problem or logic path that we've
12 set up for ourselves by this high-priority thing. Okay?
13 So if you don't make high priority on any of the three,
14 then, therefore, you can't recommend. So that probably
15 leads you to the path of thinking, even if you think
16 everything else is promising, or a lot is promising,
17 revision. Okay?

18 If you look at that, that's very different than
19 what we all just voted, where you see that had this been
20 the vote, if you will, of the PRT, we would have
21 recommended, by those criteria, to move forward, right, and
22 so we would have had a different set of recommendations.

23 So I'm not sure that what you're asking actually

1 is -- it may be relevant but it's not exactly the logic
2 path of the way that we would be thinking about it, and it
3 is relevant to the concept of even limited scale. I mean,
4 my -- just following the logic, I would say this says we
5 move forward with it, with massive comments, okay, even
6 though everything else that we've been talking about all
7 afternoon has been about limited scale.

8 So I'm just following the logic of the vote just
9 then, and there's going to be people out there who disagree
10 because we saw some 1s and 2s on practically every
11 category. But if you take the way we've set this thing up,
12 we had three PRTs that all say, "Uh-uh, not going forward"
13 because with information that we extracted, at least there
14 was one of the category 1 through 3 that said no.

15 We get to this. You know, the PTAC comes up with
16 another category, and then it's not going to be about
17 revisions, if we go by that. Had it looked like the PRT
18 had looked, then I think revisions would have been the
19 right thought process.

20 So my thought process is based upon this, if this
21 is what we truly believe, at least two-thirds of us, then
22 it would be moved forward with massive, massive, massive
23 comments, that we still have to articulate better than

1 we've done today.

2 CHAIR BAILET: Thank you, Grace. Len, Harold.

3 DR. NICHOLS: Let the record show this is not the
4 beginning of the massive comments, but I would -- a couple
5 of things just come to mind, that I have to say. One is
6 foolish consistency is the hobgoblin of little minds.
7 Look, this is how this thing worked out. That doesn't mean
8 that's how I feel.

9 [Laughter.]

10 DR. NICHOLS: But I would say, at the end of the
11 day, here's the deal. This one is above my pay grade, and
12 by that I mean, I could see how we could, if certain
13 circumstances were made available, we could deliver
14 technical assistance to the other two. We can't help these
15 people.

16 [Laughter.]

17 DR. NICHOLS: What we can do is tell CMS, or tell
18 the Secretary what we think he ought to do with this, and
19 that's where I would concur with the massive comments. But
20 I don't -- to me, limited-scale implementation, they can't
21 do this on a big scale. They could keep it alive, and
22 that's sort of where, I think, we are here.

23 CHAIR BAILET: Thank you, Len. Harold.

1 MR. MILLER: I'm in a slightly different place
2 but not necessarily an inconsistent place. I'm not sure
3 that I would argue for massive, massive comments.

4 But as I think about the options, it seems to me
5 that saying do not recommend, with comments, is not really
6 consistent with what we came up with up there and doesn't,
7 I don't think, give it kind of the sense that it deserves.

8 I don't think that this, in my mind, limited
9 testing of this, is consistent with the limited testing
10 concept that we've talked about for other areas. In other
11 areas, the idea of limited testing meant do this with a
12 small number of practices because a bunch of data and
13 measures and benchmarks have to be worked out and cannot
14 possibly be worked out in any other way than actually
15 putting it in the field. And I don't think that's the case
16 here.

17 What I see here is a model that has two
18 characteristics. One is it is not yet complete. All of
19 the pieces aren't -- but are in process. There's PROs in
20 process, et cetera, and it can't move forward without
21 those. So I would say it should only move forward where
22 those exists, but that doesn't mean that one waits for them
23 to be developed across the entire board to do it. So it

1 may be that it only gets done in a limited way, simply
2 because it's completed in a limited way.

3 The other comment that I would make is I do not
4 believe that it should move forward with a reporting-only
5 quality measure for something like this.

6 So my recommendation, I believe, sort of what is
7 fuzzily forming in my mind right now, is a recommend Level
8 3 recommendation but with a comment that says it should
9 only be implemented -- it can be implemented broadly, not
10 on our current limited version, in a few places broadly,
11 but only when the PROs are developed and only if there is
12 actual accountability for those PROs, not sort of a vague
13 transition reporting-only notion with tiers of quality.

14 So that's at least where I'm coming down, and
15 that's why I say if I thought that that's what 3 meant,
16 then I would be voting for 3. If I don't think that 3
17 means that, then I don't want to vote for 3.

18 So it's those caveats that to me make me able to
19 say a 3, and I don't -- and I'm just projecting that maybe
20 others feel the same. They may not agree with my
21 particular caveats, but the concern is I don't want to
22 first vote 3 and then discover that we're not going to
23 agree on the caveats that led me to vote for 3. That's the

1 problem, if you follow me.

2 CHAIR BAILET: Thank you, Harold.

3 So let's go with Bob and then Elizabeth.

4 DR. BERENSON: My frustration is that a number of
5 the items that Harold is now referring to, we never really
6 discussed. I actually am pleased that they're expanding
7 the quality measures beyond MIPS, that they have done PROs,
8 and it looks like it's in the right direction. But Harold
9 may be right that if it's simply reporting, that's not good
10 enough.

11 We haven't talked through that stuff. I mean,
12 there's a few other items also that the PRT had a problem
13 with, which we haven't talked about either, so that's the
14 frustration. But if that's where we are, I'll vote.

15 CHAIR BAILET: Elizabeth.

16 VICE CHAIR MITCHELL: Thank you.

17 I think we've been in this room too long because
18 I'm agreeing with Harold again.

19 [Laughter.]

20 VICE CHAIR MITCHELL: One of the reasons I'm
21 comfortable potentially moving forward is I don't see the
22 same risks that I've seen in testing some of the others. I
23 think it is hard to understand the risks of giving

1 physicians more information about who is getting what care,
2 at what cost. I see that as a good thing.

3 Where I am uncomfortable is with my lack of
4 understanding of accountability, so I'm exactly where you
5 are in terms of not being able to say yes without -- at the
6 pay-for-reporting level. So I would want to see some sort
7 of connection to payment linked to metrics.

8 PROs, if they're in development, that's great,
9 and if the timing doesn't work, I just think we need to
10 make sure that those connections are articulated.

11 So if there are ways to emphasize and clarify in
12 the comments that we expect some sort of mechanisms of
13 accountability that aren't entirely clear but have been
14 alluded to in the comments, then I'm really close to
15 comfortable to recommending.

16 CHAIR BAILET: Grace?

17 [No response.]

18 CHAIR BAILET: Okay. So --

19 DR. TERRELL: I move the question.

20 CHAIR BAILET: So I'm a pragmatist, and I have
21 struggled through the discussion because of a comment that
22 was made earlier relative to behavioral change and working
23 with physicians and trying to get them galvanized around

1 changing their care delivery models.

2 Having this kind of information does illuminate
3 and raise a lot of awareness, and once you have awareness,
4 then you can actually work with the clinical delivery arm
5 to try and modify the behavior.

6 The challenge I have with this model is that
7 there's a lot of migration in the construct of how it's
8 analyzed. So you have data that is attributable to
9 physicians who are not participating in the model but may
10 actually be part of the care team delivering substantive
11 care. That's just one example of a gap that I have
12 relative to how this could play through, and I think to
13 some degree, that's a different but perhaps similar
14 question that Bob was asking.

15 So I have significant concerns about how this
16 would play through trying to change physicians' behavior in
17 an environment that is not an ACO but is in more of a free-
18 form entity. There's a lot of moving parts, a lot of
19 flexibility, which I like, but still with that uncertainty,
20 I don't feel comfortable voting for implementation in the
21 true sense, even with comments, because I think there's a
22 difference between voting for implementation with comments
23 versus voting for small-scale testing with comments. I

1 think it allows more degrees of freedom.

2 And, again, this is a recommendation, and the
3 Secretary and CMS then can -- as someone earlier alluded to
4 on Day One, we could recommend moving forward or not moving
5 forward, and they could say too bad, so sad, we want to
6 move forward.

7 So I do think there's still the degrees of
8 freedom, but as the PTAC, I think we have to be comfortable
9 with the information that we have been given today -- and
10 up to today, I should say -- with our recommendation, and
11 we should just be mindful and thoughtful about the
12 implications and the ramifications between small-scale
13 testing -- support but small-scale testing versus support
14 implementation with some caveats.

15 So I just think I would like to close with that,
16 and then, Ann, you could just summarize for folks on the
17 phone where we are on the 10. It's pretty straightforward
18 and --

19 MS. PAGE: Harold had a comment, Mr. Chairman.

20 CHAIR BAILET: Thank you.

21 Harold, one more. One more time.

22 MR. MILLER: I want to suggest one more caveat on
23 at least Harold's list of Recommendation 3 caveats, which

1 is that it should move forward where some majority of the
2 members of the clinical affinity group, determined by the
3 episode grouper, are participating.

4 I am troubled still, and I should have said that,
5 not just the quality measures, but the notion that kind of
6 one or two people -- I think one of the key elements of
7 this notion is that it is a clinical affinity group.
8 That's one of the core concepts, but it's not required the
9 clinical affinity group participates.

10 And it seems to me that I would recommend that if
11 it's going to go -- when it goes out first, maybe that
12 might change later on, but when it goes out first, it
13 should have clinical affinity groups, sort of the majority
14 of them there, which will improve its evaluability. I
15 think it will improve its likelihood of success, and it
16 will then encourage the clinical affinity groups to, in
17 fact, form because if there's no way to have the thing
18 without having a clinical affinity group.

19 So it's kind of like halfway in between the
20 individual physician model and the whole ACO, where you've
21 got to have everybody there.

22 We could figure out exactly what the threshold
23 is, but I think one of the concerns we had as a PRT --

1 again, I won't speak for my colleagues -- was that there
2 was no minimum threshold really in terms of who had to
3 participate. So some higher minimum threshold would make
4 me a whole lot more comfortable with it.

5 Again, you may not -- that may not be enough
6 caveats for you, but that would be enough caveats for me.

7 CHAIR BAILET: Thank you, Harold. Well said.

8 Bob, your card is up. Is it just from fatigue or
9 you just couldn't put it down?

10 [Laughter.]

11 CHAIR BAILET: All right. Very good.

12 So we are at the precipice, if you will, of
13 voting, and I was asking Ann, please provide a quick
14 summary.

15 MS. PAGE: Sure.

16 The Committee voted on Criterion 1, the Scope of
17 the Proposed PFPM, to rate this as having high -- Meeting
18 the Criterion with Priority Consideration.

19 On Criteria 2 and 3, the Committee found that
20 this Meets the criteria.

21 On Criterion 4, Value over Volume, the Committee,
22 the majority, decided that it Does Not Meet this criterion.

23 And then for Criteria 5 through 10, the

1 Committee, the majority of the Committee, voted that this
2 Meets those criteria.

3 CHAIR BAILET: Thank you, Ann.

4 So are we ready to proceed with making our
5 recommendation and just to review the process one more
6 time? It is a voice vote only. We don't have the
7 technology.

8 A 1 is do not recommend the payment model to the
9 Secretary. A vote of 2 means recommend proposed payment
10 model to the Secretary for limited-scale testing; and 3,
11 recommend to the Secretary for implementation; and 4 is
12 recommend to the Secretary for implementation with a high
13 priority.

14 Unlike the last 10 votes we have taken, this is a
15 two-thirds majority vote, and I think -- I'm trying to
16 remember. We went -- I think we started with you last
17 time, Paul, so, Harold, we'll start with you and go for it.

18 MR. MILLER: Why don't we start with you, Jeff?
19 No. Kidding.

20 [Laughter.]

21 MR. MILLER: I vote for 3, with caveats. My
22 caveats are that I vote for implementation, not what we
23 called limited testing, with the caveats that it only be

1 implemented where PROs have been developed, where there is
2 actual performance accountability associated with either
3 the PROs or other quality measures, but not simply
4 reporting only.

5 And where a majority or some super majority or
6 whatever, but a significantly high proportion of the
7 members of the clinical affinity group that would be
8 determined through the episode grouper, as who were
9 participating these things, are actually participating in
10 the alternative payment entity.

11 CHAIR BAILET: Thank you, Harold.

12 Len.

13 DR. NICHOLS: I would say 2, with all of that.

14 CHAIR BAILET: Grace.

15 DR. TERRELL: 3.

16 MR. STEINWALD: I guess 3, although I'm not sure
17 we should call it -- "caveat" means to me that if you do
18 something, don't be surprised if something bad happens.

19 I think we need to call them "conditions" or
20 something like that.

21 MR. MILLER: Okay. I'll call them "conditions."
22 I think they're going to become comments for us, but to me,
23 they're comments in the form of a condition.

1 DR. TERRELL: Massive comments.

2 MR. MILLER: No, not massive comments.

3 CHAIR BAILET: I am in the camp of 2.

4 Elizabeth, I'm looking to you. You turned it on.
5 It's time for you to step up to the microphone, please.

6 VICE CHAIR MITCHELL: It is exactly what it was.

7 I guess I'm at the 3, with the comments.

8 CHAIR BAILET: Kavita.

9 DR. PATEL: I'm going to say 1, because the
10 massive comments or whatever -- caveats, massive comments,
11 to me are the very reason that I don't know how we can move
12 forward.

13 And we already said -- I just want to be clear.
14 We've already talked about how we can't really think about
15 how to do limited scale. So I struggled, just like Jeff
16 does, where that sounds like an attractive option, but I
17 just don't know how you do that because we've already heard
18 we don't really know where we would do that limited-scale
19 testing.

20 DR. BERENSON: I'm going to give it a 2 because I
21 want it to go forward, but I don't know what the model is.

22 [Laughter.]

23 DR. CASALE: Sorry. That was just a great

1 comment.

2 CHAIR BAILET: Paul.

3 DR. CASALE: Yeah. I vote 2, and in terms of the
4 limited scale, to me, when Kavita asked how will this
5 change the way care is provided and the answer was we're
6 going to change the payment and that will lead to change in
7 care, to me, that's a big leap of faith.

8 And so the limited testing to me is not doing 50
9 whatever, 54. Limited to me is a very small number of
10 surgical procedures, where, again, we talked about
11 appropriateness, and the answer was, well, we'll do goals
12 of care and PROs. Those clearly would have to be in place
13 for the surgical procedures that are going to be tested.

14 CHAIR BAILET: Kavita.

15 DR. PATEL: Can I ask a point of order? I know
16 we're not doing Robert's Rules, but the way Paul
17 articulated that limited scale would make me very
18 comfortable with a 2. Is that -- am I --

19 CHAIR BAILET: Yes. Yes.

20 DR. PATEL: Am I doing something illegal?

21 CHAIR BAILET: No. No. I was actually -- that
22 was where I was going to go, was to just sort of re-filter
23 people's perspectives to give them the opportunity to

1 modify their vote.

2 DR. PATEL: Because I was really scratching for a
3 way to do that, but I had heard Dr. Opelka say we don't
4 really have a geography or kind of a place.

5 But the way -- I think if we reduced and kind of
6 did a limited number --

7 CHAIR BAILET: I think there's a way. Yeah.

8 DR. PATEL: -- then that, to me, would feel much
9 -- I'm looking. I'm struggling, like could that be a way.

10 So I would respectfully revise my recommendation
11 to a 2 and just kind of echo that it would be for the
12 reduced number to have a little bit of a sense of what the
13 kind of boundaries are on the episodes.

14 CHAIR BAILET: So I turn to my DFO, Ann.

15 MS. PAGE: So, according to the Committee's
16 rules, a two-thirds majority vote of the nine votes would
17 be six, so we need six votes to determine the Committee's
18 decision.

19 We have four votes for limited-scale testing and
20 four votes for recommending. So, according to the --

21 MS. STAHLMAN: Five votes are limited --

22 MS. PAGE: I'm sorry. Five. Five. Sorry.

23 MS. STAHLMAN: Because Kavita --

1 CHAIR BAILET: Yes. Kavita changed her vote.

2 MS. PAGE: Sorry.

3 So, according to the Committee's rules, when we
4 don't -- we start at the top, high priority and then
5 recommend and recommend for limited-scale testing, and so
6 top-down, we acquire six votes at the point of recommend
7 for limited-scale testing, so that is the Committee's
8 recommendation.

9 CHAIR BAILET: Thank you.

10 Len and then Grace. Is this the -- we're going
11 to go to the comment period to support staff at this point?

12 DR. NICHOLS: Correct.

13 CHAIR BAILET: Thank you.

14 DR. NICHOLS: So I just wanted to say the reason
15 I was for 2 was because, to me, what we're talking about
16 here is a signal. It's just a signal to the Secretary and
17 CMMI, and I would just amend Paul's. I love the idea of
18 limited number, but I wouldn't limit it to just surgical.

19 I think one of the beauties of this thing is you
20 could actually do yearly management of a real chronic
21 condition by primary care. So, to me, I'd want a mix, but
22 I want -- at the end of the day, CMMI is going to decide
23 which ones, but I think it should be both.

1 CHAIR BAILET: Thank you.

2 Grace. And then we'll get Harold and keep going
3 around.

4 DR. TERRELL: I just want to make the remark that
5 from a process point of view -- or maybe it's just a
6 psychoanalysis point of view, the 3 -- 3 is that time where
7 the PRT members sit -- actually voted not to recommend.

8 CHAIR BAILET: I wasn't going to go there, Grace,
9 for obvious reasons, but --

10 DR. TERRELL: But it really ought to be thought
11 through as we're learning from this process because we did
12 a lot of work. We came to a conclusion based on under what
13 I think were constraints.

14 We saw stuff. We had discussion, and we got to a
15 different place. But nobody else did in the room right
16 now.

17 And so, as we're thinking through how to improve
18 this process, we really need to understand what that means.
19 I think it's significant.

20 And with respect to the comments, I think that
21 the types of things that were brought up in the PRT report,
22 either as comments on a 3 or how you create caveats for
23 what may be a larger category than limited scale, we may

1 need to have other language around that, that we would all
2 feel comfortable for.

3 It's probably been well articulated by the
4 process both here today and in writing, but we need to
5 think through our process in the future to get this a
6 little bit better.

7 CHAIR BAILET: Well, can I just make a comment to
8 your comment, Grace? I think it actually shows the
9 strength of the deliberation. Right?

10 DR. TERRELL: Mm-hmm.

11 CHAIR BAILET: Because the first proposal
12 yesterday was the PRT review team did a body of work and
13 came to a conclusion. The Committee had a differing
14 opinion. Today, the PRT had an opinion, the Committee had
15 a different opinion, and the PRT changed their -- so I
16 think this is an iterative process. Right. I think that
17 we're learning.

18 We clearly need, and continue to request,
19 stakeholder input and public input, which is also shaping
20 our thought process. So it's a very dynamic circumstance,
21 and I think we need to drill down and figure out why the
22 PRT -- potentially what triggered in this process, changed
23 unanimously your position. And that's for a later date,

1 but I do agree with you that it's material.

2 Harold.

3 MR. MILLER: While I agree with Len, I do not
4 think that this should be -- we should recommend limiting
5 it to surgeries for a couple reasons.

6 One is I think that it fails to address -- first
7 of all, that's where there are already some models. I
8 think what it fails to address is the issue of the concern
9 about the control of episodes, and it would fail to address
10 what -- I agree with -- Francois made the point that I had
11 been -- he and I both have been talking about for years, is
12 we need condition-based models.

13 So I think it's important to say that however
14 it's tested, it ought to be tried to be tested in a way
15 that actually deals with whole conditions.

16 The other thing I think I would like to see us
17 make the point, clarity, is that the limited-scale testing
18 here is a different concept than what we had been talking
19 about on the other things, and it's limited in this case
20 simply because of the scope of this particular proposal,
21 which is so broad -- and I'll see if everybody agrees with
22 me on this -- that what we're talking about limiting is --
23 that, in a sense, is too broad to be implemented, as

1 proposed, right away, which in a sense the applicant
2 themselves have acknowledged that it's not ready to be able
3 to have done that broadly.

4 And we're just saying we think it should be
5 somewhat more limited than even they said it was going to
6 be limited initially, but that's a different concept than
7 the limited-scale testing we described for other things.

8 And so I think to be clear about that category,
9 rather than creating a separate category, we ought to be
10 clear that this is kind of a different concept, my
11 proposal.

12 CHAIR BAILET: Thank you, Harold.

13 Bruce.

14 MR. STEINWALD: Yeah. I agree with that. This
15 is certainly different. The nature of the limitation is
16 different than what we had done before.

17 In response to Grace's comment that we were all
18 3's, I mean, my -- I thought the choice was between 1 and
19 3, and 2 was off the table. And it wasn't until Paul kind
20 of introduced the concept of --

21 DR. TERRELL: The new 2.

22 MR. STEINWALD: Yeah, the new 2, that I thought,
23 hey, you know, he's got something there.

1 But I agree that we -- the staff will be
2 challenged, but -- to articulate what we mean by limited.
3 And I certainly agree that it shouldn't be surgical
4 procedures, but conditions that, I guess, CMS would select
5 based on criteria that we are unable and probably not
6 qualified, actually, to identify ourselves.

7 CHAIR BAILET: Paul.

8 DR. CASALE: I would just say yeah, and I agree.
9 Certainly, it's in the area of conditions where we really
10 have no experience, and so there's the opportunity.

11 I guess part of my thinking was on the
12 stipulation around having the quality measures and the PROs
13 in particular where maybe there would be more around
14 surgical than clinical conditions, but certainly, if we lay
15 out what we think are the important conditions on the
16 quality measures and they're available and the condition
17 specific, then yeah, absolutely, that makes sense.

18 CHAIR BAILET: Harold, closing remarks?

19 MR. MILLER: Just to build on that very -- thank
20 you, Jeff. Just to build on that very quickly, I think, in
21 fact, by us saying that it will encourage that the PROs do
22 get developed more than just for surgery, which is why I
23 think it's important to say that otherwise there could be

1 something that turns out all or ends up having surgical
2 episodes.

3 CHAIR BAILET: Okay.

4 Is that a comment? Excuse me. Is that a --
5 Please, Ann, go ahead.

6 MS. PAGE: This is just a question. It's a
7 direction you want to give staff on one of the issues
8 mentioned in the PRT report, but I haven't heard it
9 discussed, and that's any direction around the proprietary
10 nature of the episode grouper. So we talked about that in
11 another proposal submission, but what, if anything, do you
12 want said in the report to the Secretary around that
13 proprietary nature of the grouper?

14 DR. TERRELL: Perhaps based on the conversations
15 we've had earlier, given the fact that we've advised this
16 one to move forward, our comments can be about scrutinizing
17 and understanding and making sure that it's meeting the
18 needs of the public.

19 There was a lot of questions that we ask, and
20 because we didn't completely get the answers in great
21 detail, a lot of what might need to be in the comments
22 would be -- this really needs to be investigated and
23 understood.

1 What we heard from the proposer yesterday was it
2 was about getting this done, and their proprietary wasn't
3 all that proprietary. This may not be the case in this,
4 and that could have implications.

5 We have had, however, somebody that has other
6 proprietary tools to basically also testify today in favor
7 of this, so that in and of itself also leads to the thought
8 process of how would CMS do this. Ought this to be
9 something that is CMS-owned, -operated?

10 On the other hand, Dr. Opelka's comment was quite
11 relevant that it needs to be curated on a regular basis,
12 and if that needs to be through a proprietary process, then
13 it needs to be fleshed out ahead of time.

14 CHAIR BAILET: Go ahead, Harold.

15 MR. MILLER: I'll just add to that. I think
16 Frank made it clear that they don't have the resources to
17 do sort of the continued development of this on their own,
18 and so it seems to me that if, in fact, CMMI decides to
19 implement it, then it is going to be something that they
20 have to figure out how to do. And I know that they are not
21 going to do something that is proprietary. It might be
22 secret, but it's not going to be proprietary.

23 So I think that -- but I think that we should say

1 specifically that we are not imagining that this be
2 something that would be a proprietary thing. It would have
3 to be, obviously, open source.

4 VICE CHAIR MITCHELL: I'm just going to agree.

5 CHAIR BAILET: Go ahead, please.

6 VICE CHAIR MITCHELL: That's what we have said
7 for the other models. This has to be something that is in
8 the public domain, and therefore, it's the functionality
9 that we are looking for.

10 I don't know that there are a lot of other things
11 out there that would have this functionality, so it may end
12 up being the only option. But I think we do need to be
13 quite clear about that and consistent.

14 DR. TERRELL: It could certainly have a vendor
15 role. Many things do for CMS.

16 CHAIR BAILET: All right. So I want to
17 personally thank the members of the Committee for their
18 stalwartness, if that's a word, and thank the public for
19 hanging in there with us over the last day and a half.

20 Staff, do you have what you need to complete the
21 process?

22 [No response.]

23 CHAIR BAILET: Then any other final comments

1 before we move? Do I have a motion to adjourn?

2 DR. TERRELL: So moved.

3 MR. STEINWALD: Let's thank the Chair and Vice
4 Chair, too.

5 DR. TERRELL: Thank you and staff.

6 CHAIR BAILET: Thank you. Thanks staff. Thank
7 you.

8 We're adjourned. Thank you.

9 [Whereupon, at 5:30 p.m., the meeting was
10 adjourned.]

11

12

13

14

15

16

17

18

19

20

21

22

23

1

2

3

4