PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

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PUBLIC MEETING

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Virtual Meeting Via Webex

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Monday, June 22, 2020

PTAC MEMBERS PRESENT

JEFFREY BAILET, MD, Chair
GRACE TERRELL, MD, MMM, Vice Chair
PAUL N. CASALE, MD, MPH
CHARLES DeSHAZER, MD
KAVITA PATEL, MD, MSHS*
ANGELO SINOPOLI, MD
BRUCE STEINWALD, MBA
JENNIFER WILER, MD, MBA

STAFF PRESENT

STELLA (STACE) MANDL, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
AUDREY MCDOWELL, Designated Federal Officer, (DFO), ASPE
SALLY STEARNS, PhD, ASPE

CONTRACTOR STAFF PRESENT

ADELE SHARTZER, PhD, (Urban Institute)
LAURA SKOPEC, (Urban Institute)

*Present via telephone (partial)

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10:01 a.m.

*** Opening Remarks by Chair Bailet and CMS Leadership**

CHAIR BAILET: Good morning and welcome to this meeting of the Physician-Focused Payment Model Technical Advisory Committee, known as PTAC. Welcome to our first ever virtual public meeting.

We've been working very hard over the last few months and chose to hold our meeting virtually rather than further delay evaluating submitted proposals. We will begin that work later on in our agenda.

But first, we are very excited today to be joined by the Administrator of the Centers for Medicare & Medicaid Services, Seema Verma.

In her role as the Administrator she oversees a trillion dollar budget representing about a quarter of the total federal budget, administers health coverage programs for more than 130 million Americans and oversees the quality and safety for all providers

participating in Medicare.

Nominated by President Trump on November 29, 2016—the seventh nomination by the President-elect—and confirmed by the U.S. Senate on March 13, 2017, she is one of the longest-serving Administrators in modern history.

Administrator Verma is a graduate of the University of Maryland and holds a Master's Degree in Public Health from Johns Hopkins University. Modern Healthcare ranked her as the number one most influential person in health care in 2019.

And with that, it is my pleasure to welcome Administrator Verma.

*** Seema Verma, Administrator, Centers for Medicare & Medicaid Services (CMS) Remarks**

ADMINISTRATOR VERMA: Thank you, Jeff. I appreciate the introduction and thank you all for joining us virtually today. I'm excited to kick off a new phase of partnership between CMS[1] and PTAC.

1 Center for Medicare & Medicaid Services

Before we get into value-based care, I'd like to take this opportunity to talk about CMS's response to the coronavirus pandemic and how we're responding in the context of value-based care.

First of all, I want to extend my sincere gratitude to everyone on the front lines of this crisis. Caring for both the physical and mental health is challenging in times like this, and America is grateful for our frontline workers and their service.

Those of you that have been working around the clock in that capacity deserve every ounce of support that we can muster. And that's why at CMS we've been working to provide health care workers with the tools that they need in this unprecedented time.

During the pandemic, CMS has expanded flexibility across the board. And the first and best example of this is telehealth. Telehealth has been nothing short of a lifeline.

It's allowed seniors to access care that they need without leaving their homes and

risking potential exposure to the virus. And it's also protected health care workers to preserve PPE[2].

We have increased access to telehealth visits, including by expanding the types of telehealth visits we cover, and never before has the health system adopted so rapidly any change, especially one that so dramatically transforms how care is delivered.

Since mid-March, nearly 7.3 million Medicare fee-for-service beneficiaries have used telehealth and that's up from approximately 136,000 from January to mid-March, an over 4,000 percent increase. And we continue to hear very positive feedback from both providers and patients.

And we've also removed regulatory barriers so that the health care workforce can practice at the top of their license consistent with state laws. This effort was ensuring that health systems across the country could have all hands on deck.

We've allowed physicians affiliated

2 personal protective equipment

with hospitals to provide care in places like skilled nursing facilities and inpatient rehab facilities, and we've also changed some of the requirements for nurse anesthetists.

Under the CMS' Hospitals Without Walls initiative, we have taken multiple steps to allow hospitals to provide services in other health care facilities and sites that aren't necessarily a part of the physical existing hospital and to set up temporary expansion sites to address patient needs.

For example, ambulatory surgery centers with capacity can register as hospitals for the duration of the emergency and receive comparable compensation. And we've also changed our testing policies.

So, we're allowing labs to go out to nursing homes to collect samples. And we've also expanded access to testing in pharmacies.

And finally, we have lifted scores of regulations across the board to help our health systems and provide more flexibility. Anything from just removing some of the reporting requirements to give our systems more

flexibility.

And we're also working hard to support states as they seek to use new tools available to them in order to respond to the pandemic. CMS has approved over 365 requests from states for waivers, amendments and flexibilities in Medicaid state plans. And most of these were done in a matter of days.

When it comes to our existing payment models, we have announced important flexibilities on implementation dates as well as data reporting requirements to ensure providers can focus on patients instead of paperwork during the pandemic.

We've also made adjustments to payment methodologies, including mitigating risks during the emergency and modifying cost targets and benchmarks to adjust for the response to the virus. So providers aren't at risk for costs solely due to this unprecedented pandemic.

And you're going to hear more about this from Brad Smith later on today. And of course, this just scratches the surface. We

continue to solicit feedback from providers, such as you, and we have ongoing meetings, weekly meetings with provider types across the board.

And as we reopen the country, we are considering the impact of these flexibilities and what should be a permanent part of our Medicaid and Medicare programs. And some of those changes will require Congress to act.

But we are looking at what we can do through our regulations as well. I've been very clear that I think that telehealth and flexibilities around telehealth should be maintained.

And as we assess the changes made to our programs, we will also be looking at the flexibilities we offer in Alternative Payment Models and how to continue to encourage value-based care.

This crisis brought to light numerous vulnerabilities in our health care system, including how a fee-for-service payment in a time of falling non-COVID[3] demand left many

3 The disease COVID-19, caused by the SARS-CoV-2 virus.

providers with serious revenue decline. By contrast, Alternative Payment Models such as population-based payment models may buffer such abrupt revenue losses.

And as you know, improving value is a top priority at CMS, a central plank of our agency-wide agenda. We want to deliver high-quality outcomes at the lowest cost.

A major component in the transition to value-based care is the models we develop and release. The process of crafting a model is complex and requires significant investment of time and resources.

PTAC plays a vital role in our development of these models by providing practical, well-vetted input and we are deeply grateful for that. And conversations with submitters who have gone through the PTAC process have informed and enriched our thinking on these issues.

Going forward, we want to continue to hear from stakeholders on what they believe to be care delivery issues and how they think

we can use value-based care to address those issues, especially after their experiences during the public health emergency.

And we want to leverage PTAC as a place to gather valuable public input on provider adoption of Alternative Payment Models. Boosting participation in our existing models and future ones that we plan to release is a top priority.

Right now the application for Direct Contracting[4] is open and the Primary Care First and Kidney Care Choices model applications recently closed. We expect that these new models will bring in many new providers to value-based payments and Alternative Payment Models when they begin next year.

And we look forward to providing additional opportunities as more models are announced. Again, this year we will be reviewing a lot of the models that started at the beginning of CMMI[5], are now coming to fruition in terms of their evaluations and

4 Direct Contracting Model
5 Center for Medicare & Medicaid Innovation

we'll be taking a long look at the results of these early models and try to apply lessons learned to the models that we develop in the future.

So, thank you again for being here. Your willingness to take time out of your busy schedules to serve the American people in its mission to improve the health and well being is invaluable. And so, thank you and have a wonderful conference.

* **Chairman's Update**

CHAIR BAILET: Thank you, Administrator Verma and welcome. My name is Dr. Jeff Bailet. I'm the Chair of the PTAC Committee and we're incredibly thankful to the Administrator for joining us and giving us her public remarks.

We appreciate you taking the time out of your very busy schedule to articulate your vision for this renewed sense of cooperation between PTAC and CMS, and we are here as eager and willing partners.

I would like to welcome members of the public who are participating today whether

it be Webex, phone, or livestream. Thank you all for your interest in today's meeting.

Should you have technical questions during the meeting or decide you would like to make a public comment on one of the proposals during the meeting, please reach out to the host via the chat function in Webex, or email, or call PTAC at the registration -- PTAC registration staff -- per your logistics email and your name will be added to the end of the preregistered list of commentators for the specified proposal.

You can also email ptacregistration@norc.org with any questions. Again, that's ptacregistration@norc.org.

We extend a special thank you to the stakeholders who have submitted proposed models, especially those who are participating in today's meeting.

We recognize that many PTAC stakeholders are directly involved in responding to the pandemic and we are grateful for your service to our communities across the nation, especially to those on the front line.

We are also thankful for the privilege of your time and attention today. PTAC has long been committed to supporting a submitter-driven process and we recognize that our stakeholders and potential future submitters may have their focus directed in other areas presently.

So, I would remind anyone who is considering submitting a proposal that PTAC accepts proposals on a rolling basis. So, you don't have to worry about submitting a proposal within a certain timeline.

In addition to the future, to the front-line providers, we also want to thank the multitude of other providers, support staff, caregivers, family members, and others supporting patients during this crisis.

This pandemic has highlighted many challenges within our health care system that we knew existed to varying degrees but really were brought to the forefront, the inconsistent resilience of our health care system and the many gaps that exist.

Some involve payment reform and

clinical redesign, work that is the focus of the models PTAC is evaluating and can play a significant role in addressing.

This public health emergency has taught us much about our current fee-for-service system and that value-based Alternative Payment Models, as the Administrator has said, can play a significant role in addressing those weaknesses.

In a fee-for-service system providers must rely on their patients' ability to present for appointments and procedures in order to support their financial business model.

The pandemic challenged this delivery structure with a sudden, staggering decline in revenue for many types of providers across the country. A variety of alternative payment methodologies such as capitation or value-based payments offer providers continued revenue in the face of declining patient visits.

Alternative Payment Models are an important part of healing the health care

system, accentuated during this crisis as are other key solutions that have played an important role in supporting patients and providers, such as telehealth.

Now is most certainly an important time for PTAC to ensure that our processes and approach to model evaluation are well designed to encourage stakeholders to engage with us to strengthen the resilience of our health care system.

In addition to submitting proposals for Alternative Payment Models, we are exploring new ways of sharing your ideas with the committee that will be announced in the coming months.

Although today's meeting is being held virtually, PTAC Members are actively engaged, participating from their various parts of the nation and eager to hear from our submitters today.

While our goal is for a seamless virtual experience, the potential exists for technical challenges such as sound delays or background noise. So, we appreciate your

understanding should such challenges arise.

I want to note that this is PTAC's tenth public meeting that includes deliberations and voting on proposed Medicare Physician-Focused Payment Models submitted by members of the public.

PTAC has been working hard since our last public meeting in September, and I would like to walk through some of that work before we begin our deliberations. First, I would like to introduce our newest PTAC Member as we begin.

Dr. Charles DeShazer was appointed by the U.S. Government Accountability Office in October of last year. He is an internist by training who joins us from Highmark Health Plan in Pittsburgh, and we are pleased to have him serving on the PTAC Committee. Welcome, Charles.

DR. DESHAZER: Thank you.

CHAIR BAILET: We are expecting three new appointments to PTAC in the coming weeks and we will be sure to welcome those new members at our public meeting, at our next

public meeting this September.

I would also like to take a moment to reflect on the work of PTAC and how it has evolved over time. PTAC was created within the Medicare Access and CHIP Reauthorization Act of 2015, known as MACRA.

The first phase of the Committee's work involved many public meetings where we sought public feedback about how best to design the Committee's proposal review process.

We also attended briefings about the government's work in the Alternative Payment Model space. The Secretary of HHS[6] then released the MACRA final rule which included the ten criteria we were to apply to our review of proposals.

In December of 2016, we began receiving proposals from the public for Physician-Focused Payment Models, moving us into the next phase of our Committee's work. We have received 36 models, delivering reports to the Secretary on 24 of them.

6 U.S. Department of Health and Human Services

Each report represents significant effort by the submitters drafting the proposal and the Committee in its subsequent review.

PTAC has been receiving models for three and a half years, long enough that we wanted to reflect on the different models we have reviewed, including evaluating who has submitted ideas, what payment and care delivery issues have they identified across the health care system, and what solutions have been proposed.

To this end, ASPE's contractor, NORC, has compiled two reports that summarize and provide an inventory of the proposals that have been submitted and the extensive evaluating reviews provided by PTAC. You can find these reports on the ASPE PTAC website at the top of the resource page.

The first report highlights themes and common elements across proposals regarding issues targeted and the proposed solutions. The second report describes patterns in how PTAC has assessed the proposals that have been submitted to the Committee.

Taken together, the reports provide a comprehensive look into breadth, objectives, and variation of Alternative Payment Models submitted by stakeholders and the findings derived from the Committee's analysis of the proposals relative to the Secretary's criteria.

I believe these reports synthesize the extensive evaluative work conducted by our Committee as we review the proposals designed to address important issues in health care delivery as raised by stakeholders in the field.

These combined efforts can inform stakeholders who may want to submit proposals to PTAC, policy developers, the PTAC itself, and the public at large.

Later today after we have voted on the two proposals, the contractor will offer a short presentation on these two reports that I think you'll find very interesting.

Looking to the future, we reflected on the history and the work of PTAC taking into account the tremendous and important stakeholder input on care delivery and

Alternative Payment Models.

We want to incorporate these reflections to further activate and encourage stakeholder engagement.

As we continue to evolve our work as a Committee, we drafted a Vision Statement to better communicate to the public how our work fits into the transition to value-based care. I would like to read that Statement now.

PTAC was created to contribute to a national priority to improve the efficiency and effectiveness of the U.S. health care delivery system.

We believe that proposed solutions from frontline stakeholders in our delivery system can substantially enhance quality, improve affordability, and influence policy development and system transformation.

PTAC provides a forum where those in the field may directly convey both their ideas and their concerns on how to deliver high-value care for Medicare beneficiaries and others seeking health care services in our nation.

PTAC is committed to ensuring our

stakeholders have access to independent expert input and their perspectives and innovations reach the Secretary of Health and Human Services.

PTAC will continue to submit comments and recommendations regarding Physician-Focused Payment Models submitted by stakeholders to the Secretary, as required by statute.

In addition, we will expand our communications with the Centers for Medicare & Medicaid Services, CMS, and stakeholders to identify our opportunities to further inform and prioritize the work CMS, including the Center for Medicare & Medicaid Innovation (CMMI) and other policy makers are undertaking to modernize health care.

This statement serves as the framework for our, for other changes you will see both today and in the future. We want to remain thoughtful and leverage collaborative opportunities that encourage stakeholders to provide their ideas on how to address care delivery challenges through expanding value-

based care.

We also want to broaden our knowledge foundation, including gathering information through public dialogue on various cross-cutting themes and topics raised across proposed models, such as telehealth. We believe such input will serve to better inform our recommendations to the Secretary.

Also, shortly we're releasing an updated version of our Proposal Submission Instructions that are designed to expand the number of and types of proposals that are submitted to PTAC.

We have found that while certain proposals may have strengths within some criteria and weaknesses in others, when evaluated as a whole, these proposals may raise important care delivery, payment, or policy issues.

Therefore, PTAC encourages stakeholders to submit Physician-Focused Payment Model proposals that address the innovative approaches in care delivery, regardless of the level of sophistication of

the payment methodology.

These updated Instructions reflect the Committee's vision to encourage engagement and to activate stakeholders who wish to convey care delivery and payment challenges along with proposed solutions.

We are eager to elicit real-time input to help inform the Committee about specific issues the stakeholders are experiencing in the field. We hope that these new Instructions will encourage more submissions.

As the Vision Statement expresses, submitting to PTAC is an opportunity to help inform the policy community about what you have experienced on the front lines and suggest potential approaches to address any issues.

In addition to these efforts, we are looking forward to having theme-based discussions during future public meetings to foster dialogue and insights on specific broad-based challenges whose impacts are not limited to a single proposal.

These discussions will occur in

addition to the current deliberative public process which happens after proposals on any topic have been reviewed by a PTAC Preliminary Review Team and then by the full Committee.

I want to be very clear that we will continue to accept all proposals on any topic at any time. PTAC is always open for business.

We are hard at work preparing for our first theme-based discussion which we are hoping to hold in September. This will be, excuse me, focused on telehealth.

Included in this session will be holistic reflections on previous proposals that included elements related to telehealth, tying together how alternate payment models and telehealth may play a more important role as features that can further transform our health care system.

We also intend to invite public input on this topic in the future as well as continue to evaluate submitted proposals that are ready for deliberation, as has been done in the past. As today's comments convey, your input is very important to us.

In addition to the efforts I just shared, at the end of the day we will pose some questions about challenges in care delivery, payment model design, and other important challenges members of the public are experiencing. A detailed list of these questions will be posted on the ASPE PTAC website.

Comments by email will also be accepted. Your input will inform our future work, and we will report out the comments received related to this inquiry at a future public meeting.

Together, all these efforts just described serve to further inform PTAC's work and help enhance our efficiency and effectiveness on behalf of the stakeholder community and the beneficiaries they support as we continue to evaluate alternative payment and clinical redesign models.

As a reminder, in order to receive updates about these various opportunities to engage with PTAC, please join the PTAC listserv, which you can find on the contact

page of the ASPE PTAC website.

Moving on, PTAC published a report to the Secretary with our comments and recommendations on the proposal entitled "ACCESS Telemedicine: An Alternative Healthcare Delivery Model for Rural Cerebral Emergencies," that we deliberated and voted on last September, which had been submitted by the University of New Mexico Health Sciences Center.

Our Preliminary Review Teams have also been working hard to review multiple proposals, two of which we are scheduled to deliberate and vote on today.

To remind the audience, the order of activities for review of a proposal is as follows. First, PTAC Members will make disclosures of any potential conflicts of interest. We will then announce any Committee Members not voting on a particular proposal.

Second, discussions of each proposal will begin with a presentation from the Preliminary Review Team or PRT charged with conducting a preliminary review of the

proposal.

After the PRT's presentation and any initial questions from PTAC Members, the Committee looks forward to hearing comments from the proposal submitters and the public.

The Committee will then deliberate on the proposal. As deliberation concludes, I will ask the Committee whether they are ready to vote on the proposal.

If the Committee is ready to vote, each Committee Member will vote electronically on whether the proposal meets each of the Secretary's 10 criteria. After we vote on each criterion, we will vote on our overall recommendation to the Secretary of Health and Human Services.

And finally, I will ask PTAC Members to provide any specific guidance to ASPE staff on key comments they would like to include in PTAC's report to the Secretary.

A few reminders as we begin discussions of today's first proposal. First, if any questions arise about PTAC, please reach out to staff through the ptac@hhs.gov email.

Again, that email address is ptac@hhs.gov.

We have established this process in the interest of consistency in responding to submitters and members of the public and appreciate everyone's cooperation in using it.

I also want to underscore three things. The PRT reports are reports from three PTAC Members to the full PTAC and do not represent the consensus or position of the PTAC.

Second, PRT reports are not binding. The full PTAC may reach different conclusions from those contained in the PRT report. And finally, the PRT report is not a report to the Secretary of Health and Human Services.

After this meeting, PTAC will write a new report that reflects input from the public as well as PTAC's deliberations and decisions today which will then be sent to the Secretary.

PTAC's job is to provide the best possible comments and recommendations to the Secretary, and I expect that our discussions today will accomplish this goal.

I would like to thank my PTAC colleagues, all of whom give countless hours to the careful and expert review of the proposals we receive. Thank you again for your work, and thank you to the public for participating in today's first ever virtual meeting.

* **Deliberation and Voting on Eye Care Emergency Department Avoidance (EyEDA) submitted by the University of Massachusetts Medical School**

Let's go ahead and get started. The first proposal we will discuss today is called "Eye Care Emergency Department Avoidance." This proposal was submitted by the University of Massachusetts Medical School.

* **PTAC Member Disclosures**

PTAC Members, let's start by introducing ourselves and at the same time, read your disclosure statements on this proposal. Because this meeting is virtual, I will prompt each of you.

I'll start. Jeff Bailet, CEO of Altais, nothing to disclose. Next is Grace.

VICE CHAIR TERRELL: Grace Terrell,

CEO of Eventus WholeHealth, nothing to disclose.

CHAIR BAILET: Paul.

DR. CASALE: Paul Casale, cardiologist and Executive Director of New York Quality Care, the ACO for New York-Presbyterian, Columbia, and Weill Cornell, nothing to disclose.

CHAIR BAILET: Charles.

DR. DESHAZER: Charles DeShazer, chief medical officer for Highmark Health. Nothing to disclose.

CHAIR BAILET: Kavita.

DR. PATEL: Kavita Patel, internist and fellow at the Brookings Institution. Nothing to disclose.

CHAIR BAILET: Angelo. Angelo may be on mute.

DR. SINOPOLI: Angelo Sinopoli, a pulmonary critical care physician and Chief Clinical Officer for Prisma Health, South Carolina.

CHAIR BAILET: Bruce.

MR. STEINWALD: Bruce Steinwald, a

health economist here in Washington, D.C. Nothing to disclose.

CHAIR BAILET: And finally, Jennifer.

DR. WILER: Jennifer Wiler, Chief Quality Officer, UCHealth, Denver Metro and professor at University of Colorado School of Medicine in Denver, Colorado. Nothing to disclose.

CHAIR BAILET: Thank you. I would now like to turn the meeting over to the lead of the Preliminary Review Team for this proposal, Dr. Paul Casale, to present their findings to the full PTAC, Paul.

*** Preliminary Review Team (PRT) Report to PTAC**

DR. CASALE: Thank you, Jeff. Before I get started on the presentation, I wanted to state that Harold Miller who, as you can see was a member of the PRT for this proposal, resigned from the PTAC on November 19, 2019.

He did participate in the PRT, and his input is reflected in the report that is about to be shared. Next slide.

So, just as a reminder about how PRT

works, the PTAC Chair and Vice Chair assign two to three PTAC Members, including at least one physician, to each complete proposal to serve as the PRT.

The PRT identifies additional information needed from the submitter and determines to what extent any additional resources or analyses are needed for the review. The PRT determines, at its discretion, whether to provide initial feedback on a proposal.

After reviewing the proposal, additional materials are gathered and public comments received. The PRT prepares a report of its findings to the full PTAC.

As Jeff already mentioned, the PRT report is not binding on PTAC. PTAC may reach different conclusions from those contained in the PRT report. Next slide.

So, some background on the EyEDA proposal. It's based on a Transforming Clinical Practices Initiative award assisting over 1,600 optometry practices across the U.S. to increase the number of patients with eye-

related symptoms who make visits to a practice rather than an emergency department for urgent eye conditions.

The submitter asserts this approach improved the quality of care for patients and reduced the cost for treating urgent eye-related conditions for both payers and patients because the payment for an office visit is significantly less than the payment for an emergency department visit.

The goal of the EyEDA proposal is to encourage treatment of selected eye-related symptoms through office visits with optometrists and ophthalmologists rather than visits to hospital ED[7].

The Alternative Payment Model entities are licensed optometrists and ophthalmologists as well as organizations employing optometrists and ophthalmologists. Next slide.

The core elements of the proposal: Financial risk is in the form of an eight percent reduction for all urgent care visits.

7 Emergency Department

These are identified by ICD-10[8] diagnosis codes relative to payments under the normal physician fee schedule.

Shared savings payment at the conclusion of the performance year is based on the participating provider or practice's number of qualifying urgent office visits relative to a target level and the reduction in ED visits in area hospitals for the same diagnoses relative to a base year period.

Performance on two quality measures are also taken into account: patient experience and patient safety. These area quality threshold in order to participate in the model and receive shared savings payments. Next slide.

The eight percent reduction for initial office visits will be for specified ICD-10 codes in the categories of ED avoidable conditions such as conjunctivitis, corneal injury, corneal injury with a foreign body, a stye, acute posterior vitreous detachment, eye pain, and other eye conditions.

8 International Classification of Diseases, 10th Revision

The submitter believes that the number of patients making urgent care visits to the practice instead of the ED will increase by educating patients about the desirability of receiving urgent eye care from optometry or ophthalmology practices and by expanding the office hours for those providers.

The proposed model does not, however, require that participating practices use any specific approach to encourage these visits. Next slide.

In terms of the payment model in order to receive shared savings bonus payments, providers must meet minimal thresholds on the two quality measures. They include patient experience, assessed through a patient survey, and patient safety, which is defined as the seven-day adverse event rate for the ICD diagnosis codes for which they were seen.

Adverse events include unscheduled ED visits, hospital admissions or observation stays, blindness, or permanent visual impairment or death.

The target number of visits for each

participating practice or provider would be developed based on historical volume of visits for these conditions, which would then be increased by some percentage.

Practicing, sorry, participating practices or providers could receive shared savings payments if there were a reduction in ED visits for the proposed urgent eye-related conditions.

The proposal does not specify the percentage of the savings that would be shared or the method for identifying the service area.

Each participating physician or practice would receive a share of the savings for distribution based on the increase in urgent care visits at that practice as a percentage of the total increase in urgent care visits across all participating practices. Next slide.

The experience with the TCPI[9] program provided technical assistance, as I mentioned, to over 1,600 optometry practices nationwide.

9 Transforming Clinical Practice Initiative

From October 2017 through May of 2019, optometrists enrolled in TCPI reported more than 330,000 visits to the ED were avoided through same day office-based appointments and after-hours triage. These reports were based on ICD-9[10] codes for office visits rather than tracking of changes in ED visit rates.

Feedback from TCPI provider participants indicates that many of these optometrists would participate in the EyEDA model.

So, to summarize, the PRT review is seen here. And what I'll do rather than walking through this slide I will go through each of the criteria in detail. Next slide.

The key issues identified by the PRT. The eight percent reduction in fees for urgent care visits may discourage participation and cause problematic financial losses for practices that cannot successfully meet targets for increased number of visits.

Payment is still fee-for-service based on office visits, with no flexibility in

10 International Classification of Diseases, 9th Revision

payment to support different approaches to services. Payment reductions and visit targets tied to specific diagnosis codes could result in undesirable incentives to code incorrectly.

The model does not attribute patients to practices. The methodology for determining shared savings and attributing the savings to participating providers is not clearly defined.

The proposed model does not require or encourage care coordination with primary care providers or other specialists. And many of the problems with the payment model arise due to challenges that the submitter faces in trying to craft a model to meet the requirements that CMS has established for an Advanced APM[11]. Next slide.

So, for Criterion 1, scope, which is a high priority, the PRT conclusion was does not meet. This was a majority conclusion.

In reviewing this criterion, no Alternative Payment Models in the CMS portfolio specifically address eye-related conditions or

11 Alternative Payment Model

focus on care delivered by eye specialists. So, that was one of the considerations in regard to scope from a provider point of view.

Specialty participation in APMs is important but should broaden existing opportunities. The particular clinical issue of urgent eye visits might be appropriate in a broader risk-based model such as an ACO[12] or Bundled Payment Model as opposed to a stand-alone model.

The model narrowly focuses on changing the site of treatment for one particular set of health problems rather than taking a more holistic approach to the patient's needs.

And finally, ED visits for eye-related conditions occur primarily among those under age 65. It's not clear if practices would be able to increase their provision of urgent care in the office if the model is not implemented for more payers beyond Medicare. Next slide.

Criterion 2, quality and cost, also

12 Accountable Care Organization

a high-priority criteria. The conclusion from the PRT is that it meets this criterion. This was unanimous.

Treatment of patients in an office-based setting for the proposed eye conditions rather than an ED when appropriate would reduce costs for both payers and patients.

Increased access to care in the most appropriate setting would potentially improve health care quality. The model includes two quality measures designed to ensure that urgent conditions receive high-quality care in an office setting.

However, the proposed measures have limitations that may not adequately ensure the highest quality care. Patient satisfaction does not necessarily ensure that a condition was treated in the most appropriate way.

The patient safety measure captures only adverse events that occur within seven days, and only those related to the same ICD-10 diagnosis as the original office visit. The rate of adverse events is unlikely to be a statistically valid measure for small

practices.

And finally, some conditions may not represent urgent needs but instead are emergencies that cannot be safely treated in an office setting. Next slide.

Criterion 3, payment methodology, also a high priority. The PRT conclusion was that it does not meet the criterion. This was unanimous.

The proposed payment model would provide a strong financial incentive to increase the number of urgent care visits for eye conditions. However, the approach to setting performance targets raises concerns.

It would penalize practices whose patients already come to them for urgent care needs. And small practices could have a low or a high baseline rate based on random variation.

The proposal does not require any mechanism to document the nature of the presenting symptom or to identify the reason the visit should be deemed urgent.

The shared savings calculation is based on a reduction in ED visits without

attributing the reduction to participating practices. The proposal does not specify how adjustments would be made when eligible patients in the service area change over time.

And finally, the proposal does not provide any upfront payments to support the ability of participating payments to deliver more and better urgent care. Next slide.

Criterion 4, value over volume. The PRT concluded that it meets this criterion and was unanimous.

The proposal creates an incentive for optometry and ophthalmology practices to encourage patients to come to their office for urgent care needs, which would likely decrease ED visits for eye-related conditions.

The proposal includes a measure indicating whether the ocular problem was resolved and also tracks satisfaction of adverse events. However, the small size of many practices will make statistically appropriate assessment of adverse event rates problematic.

Payments for urgent care services and targets are still tied to office visits

with the physician. The practices would not have the ability to address urgent needs through phone calls, emails or non-physician staff.

Finally, the model forces practices to increase the number of office-based visits in order to offset payment cuts and meet visit targets, even if more visits are not needed. Next slide.

Flexibility, the PRT conclusion was that it met the criterion for flexibility. And this was a majority conclusion.

The proposal would reward optometrists and ophthalmologists for changes in their care delivery processes in order to better respond to patients with urgent eye conditions, without dictating how the practices should do this.

However, the proposal does not fundamentally alter the fee-for-service structure of payment for eye visits.

Providers would be paid only for office visits, not for phone calls, emails with patients, even if those services could resolve

the patient's needs, and not for care management or other education activities that would help patients avoid developing eye problems.

The eight percent reduction in visit payments and an uncertain shared savings payment would make it more difficult for practices to provide services that do not qualify for fees. Next slide.

Criterion 6, ability to be evaluated. The PRT conclusion was that it met it this criterion. And the conclusion was majority of the PRT.

The proposal's primary performance measure is quantifiable and could be compared with other providers. The information is systematically collected through claims across providers and over time.

The proposal uses standard ICD-10 codes to identify urgent visits, so the same definitions of eligible visits could be used for non-participating providers.

The adverse event metric could also be determined from claims for participating

providers and compared with non-participating providers.

To compare patient experience and satisfaction between participating providers and non-participants, patient survey data would have to be collected from a comparison group of patients who see non-participating providers.

The lack of attribution of patients or ED visits avoided to participating providers could make it difficult to evaluate whether changes in ED visits were different between participating and non-participating providers. Next slide.

Criterion 7, integration and care coordination. The PRT conclusion was does not meet criterion. And this was a unanimous conclusion.

The submitter reported that eye care specialists informally make referrals among themselves and to other providers to ensure appropriate care.

However, participating providers would be encouraged to see patients for urgent care needs, even if they are not the most

appropriate provider to treat the condition.

There are no formal methods for integration with primary care physicians or other providers who may be initiating treatment or treating a patient. Next slide.

Criterion 8, patient choice. The PRT conclusion was that it meets this criterion. And the conclusion was unanimous.

The proposed model would make it easier for patients to receive appropriate treatment for urgent eye conditions outside of a hospital ED.

It is possible that a beneficiary might not realize that they have the right to seek care in another setting, such as an ED, even if their optometrist or ophthalmologists presents them with access in the office setting.

Next slide, patient safety. The PRT conclusion was it does not meet this criterion, and it was a unanimous conclusion.

The proposed measurement of adverse event rates and patient satisfaction scores would help to ensure that eye problems are

being addressed appropriately during the urgent care visits.

However, the proposed diagnosis codes cover a broad range of eye conditions, some of which are much more clinically serious than others. Patients do not know their diagnosis when they seek care for an eye condition, only their symptoms.

The same symptoms -- such as eye pain, impairment of a visual field, or redness -- can result from conditions across a wide range of clinical severity, not all of which are appropriate for care by an optometrist or in an office setting.

As a result, patients who need care in the ED may not receive it, which has the potential to harm patient safety. Next slide.

The final criterion, Criterion 10, health information technology. The PRT conclusion was that it met this criterion and the conclusion was unanimous.

The TCPI project on which the proposal is based led providers to use electronic health records more extensively. If

implemented well, the proposal could encourage providers to use technology to a greater extent to inform care.

There is potential for providers to incorporate telehealth services to expand access and achieve the proposal's objectives. However, the proposed model does not explicitly require or encourage enhanced use of health information technology. Next slide.

So, with that, Jeff, I thought I would turn it over to Kavita for any additional comments she may have on the discussion amongst PRT.

DR. PATEL: Thanks, Paul. It's Kavita.

I just wanted to just reinforce kind of the process that we used because, as Paul mentioned, we had three of us on the Preliminary Review Committee and found our interactions with the submitters and all the deliberations kind of back and forth on the Review Team very engaging.

And despite it being kind of pre-COVID, I feel pretty confident that we can have

a great conversation now and wanted to thank Paul for leading the PRT, as well as acknowledge Harold's important input and the submitter's time to take, to propose this important model, and hopefully we can answer any questions for the Committee as well.

*** Clarifying Questions from PTAC to PRT**

CHAIR BAILET: Thanks, Kavita, and thank you, Paul, for leading the PRT. Before we have the submitters provide their statements and make themselves available for questions, I just wanted to turn it over to other Committee members that may have questions of the PRT, Kavita or Paul, or clarification prior to bringing up the submitters. All right.

VICE CHAIR TERRELL: I've got a question, Jeff. This is Grace.

CHAIR BAILET: Go ahead, Grace.

VICE CHAIR TERRELL: My question is related to some of the commentary back, in fact some of the criticism back that was, I believe from one of the associations related to emergency physicians, where they were concerned about many of the types of diagnoses that were

listed as being ones that were appropriate within the setting of an urgent care.

And I was wondering if there was any work done either with the background information that was done by our contractors, or otherwise, to look into that as being something that was a concern that needed to be taken into account or not?

Because there was a huge number of diagnoses that were listed as being potentially appropriate that looked appropriate to me as far as I could tell. But there was some concern from some of the outside public.

And I'm just wondering how you all thought through that.

DR. CASALE: Yes, we did have a discussion around that, and I'll ask Kavita to comment as well. And I think, yes, it is a very long list and many of them appear appropriate for the office setting.

I think some of the concern was that there are within that group of conditions some that require, obviously, emergent care in that the patient may not be in the position to

distinguish that.

And that for some of those particularly time-sensitive conditions, being seen in an office setting rather than an emergency room may lead to adverse outcome.

DR. PATEL: And the only thing I would add, Grace, there wasn't any, we just basically had kind of a more transparent discussion. I believe, it's probably somewhere in our transcription minutes with the submitter.

But just to emphasize that part of the acknowledgment of this was because of this work starting in the TCPI program that there was definitely kind of a more, I would say hub and spoke model so that there was kind of an academic hub with spokes.

You know, this wasn't just kind of the idea where this kind of started from came from having kind of ED physicians and also having kind of urgent care and ophthalmologists and having an interdisciplinary approach.

And that was something that we brought up that while that seems like an

incredibly robust model that was kind of worked out through TCPI that may not necessarily scale.

However, it would be something I think in our comments to the Secretary's report, no matter what the voting is, that looking at that model would be critical because it did offer something that was valuable to training, you know, in the setting of ED physicians as well as urgent care physicians.

MR. STEINWALD: This is Bruce. I have a question.

CHAIR BAILET: Go ahead, Bruce.

MR. STEINWALD: I'm curious about the proportion of emergency events that could be addressed through the model in the physician's office as opposed to emergency room.

The proposal states that the patient invitation of extended hours is going to be the principal means of encouraging patients to see providers in their office. And yet a lot of these events occurred in evening hours and weekends.

And I guess I'm curious as to what

proportion of those events, like a foreign object in an eye, I have heard actually be seen in the office when these events often occur during times when there is most unlikely to be office hours.

DR. CASALE: Well, I think we would look at the experience they had in the TCPI model in which they, you know, they saw over 330,000 visits.

I don't believe and maybe I don't really believe there was data around, you know, the time of day for those visits that I recall. But you're right.

I think we recognize that as one of the concerns in terms of the education and expanding hours. I mean, expanding hours will certainly help, education might.

But as you said, when, even if these happen during the day, having easy access -- it would be critical. But to your original question, I don't remember if there, I don't recall we had data around the time of day that these occurred.

DR. PATEL: I don't, either. It would

be good to ask the submitters that.

CHAIR BAILET: I had a, this is Jeff. I had a follow on question, Paul. It sort of follows onto Grace's initial point.

The Academy of Ophthalmology made reference again to the long list. And I think that is something that is in the process of being reviewed and potentially pared back.

But there was also some comments just about the safety. You know, creating or conveying a message to patients that for some of their eye complaints, urgent eye complaints, that they could be seen in an office rather than present to an emergency room.

And there were, you know, there were some strong statements both from the Ophthalmology Society and also from even the Optometry Society as well. I'm just, I saw some back and forth in the responses from the submitters to your PRT.

Where does that sit? And we can get a further clarification from the submitters themselves?

But there seemed to be a reference

that sort of contention between those two bodies had sort of got ironed out between the submitters. Is that in fact true, Paul?

DR. CASALE: It's not clear to me that it's been ironed out. I think they would turn to the TCPI project and, you know, sort ofthe experience they had there.

As, and again I would be interested to hear directly from the submitters because particularly from an ophthalmology letter also raised this question of safety.

But again, I think from the material, from the TCPI project, and from the experience they had there, there were, again I think the submitters felt that this model was safe for the, you know, overwhelming majority of patients who come, present with eye symptoms.

DR. SINOPOLI: Paul, this is Angelo. I'm sorry.

CHAIR BAILET: No. Go ahead, Angelo.

DR. SINOPOLI: Was there any discussion during this around the potential for some virtual real-time triage to make sure

patients got directed to the appropriate level of care?

DR. CASALE: Well, we brought that up in terms of our concern that really it's all office-based fee-for-service in terms of how this payment model would potentially work with a sort of focus around office-based.

So, you know, I think we had some discussion around it. But we didn't, other than some suggestions as we put in our report, that both from a triage and management point of view, virtual care would potentially offer some benefits.

But that I think was the extent of our discussion.

CHAIR BAILET: Great. Any other questions from the Committee?

DR. DESHAZER: Yes, this is Charles. I just wanted to follow up with that too because it wasn't clear to me, is there -- are there strategies embedded within this model to kind of get, I think to Angelo's point as well, to get to a more proactive approach in being a more flexible way of interacting with the

patients because I do see that as being part of the challenge also.

And a part of this is going to be changing care-seeking behaviors of the patient. And I just wondered if there were thoughts around how you would, you know, create that within the model and how that would support that.

DR. CASALE: Yes, again I think that would be a good conversation with the submitters.

I think again, because the payment model is really based around the shift from ED visits to office visits again, so that sort of -- so to your point and Angelo's point and certainly in the current era that we are in where we're seeing, you know, back when we first reviewed this or looked at this back in September, virtual care was in a very different place.

But having that been, even with that said, you would see that there would be opportunity here. But again, I think ultimately the payment model was focused more around

office visit, ED visit.

CHAIR BAILET: Anyone else from the Committee have any questions before we move on? Okay. Hearing none, let's go ahead and have the proposal submitters join us.

We have three representatives from UMass[13] joining us via Webex. If you guys could introduce yourselves.

I know you want to make some opening comments, which will be limited. We'll limit those to ten minutes, and then we'll open it up for questions. So, thank you all for being here.

*** Submitter's Statement**

DR. POLAKOFF: Thank you. We'll go in order as presented on the slide. This is David Polakoff speaking. I led the TCPI team.

I'm an internist and geriatrician by background and a professor of population and quantitative health sciences at the University of Massachusetts Medical School.

DR. SCOTT: And I'm Clifford Scott. I'm an optometrist and a consultant to the

13 University of Massachusetts Medical School

UMass Medical School and President Emeritus of the New England College of Optometry.

MR. FLANAGAN: I'm Jay Flanagan. I was the program director for the TCPI project under Dr. Polakoff.

CHAIR BAILET: Welcome. You guys want to start with your opening remarks?

DR. POLAKOFF: Thank you. This is David Polakoff and I'll deliver the opening remarks. But we will all as a team be available to the PTAC for questions.

First, I want to thank PTAC for hosting us and offering us this opportunity to present, as well as express our gratitude and appreciation to the PRT for the very careful review and the process we went through during the PRT review. It was helpful and very, very thoughtful.

So, by way of background in 2015 UMass was awarded one of the 29 practice transformation networks by CMMI under its Transforming Clinical Practices Initiative or TCPI.

The goals were to promote a broad

set of aims including improving the quality of and access to care provided by 140,000 clinicians across the U.S. and specifically assisting those clinicians in moving toward and into successful value-based care arrangements.

The UMass network included more than 1,600 optometry and ophthalmology practices representing almost 4,000 individual clinicians. One of CMS's explicit goals for the program was to facilitate the entry of enrolled clinicians into advanced alternative payment models or APMs.

Because there is no APM available for these eye care specialties, UMass, with CMS encouragement and approval, developed the APM under consideration here today.

The Committee Members have reviewed and analyzed the model, and I won't present the model in detail during this short ten minute presentation. However, at its core, as has been noted this morning, the model is very simple.

It encourages and financially incentivizes eye care professionals to have a conversation with their established patients

about the availability of urgent care services for ocular symptoms in the office or in the clinic setting.

It further encourages the professionals to expand the availability of those services by expanding hours of service, by enhancing after-hours availability, and telephonic triage.

Finally, this model takes an approach to reducing the use of emergency departments for non-emergent services that is far friendlier to patients and families than other interventions that have been recently publicized such as retrospective denial of payment for unnecessary ED use or triage models that redirect patients after they have arrived at the emergency department seeking care.

I'll note that the one published reference that assessed the epidemiology and scope of the issue that this model addresses, ED use for non-emergent eye conditions, is based on data that are 10 to 15 years old.

In the process of developing the model, we performed a very similar analysis to

Channa et al. using the most recent years available from the same data set, NEDS[14], and found that there have recently, in recent years been approximately three million such visits each year representing charges of about $3 billion annually for the five conditions covered by the model: conjunctivitis, corneal injury with or without foreign body, hordeolum, acute posterior vitreous detachment, and eye pain.

This is not a small scale or uncommon issue. I would also like to emphasize that this proposal is based on our experience in TCPI with over 1,600 eye care professionals.

In that program we were able to monitor the impact of these practices implementing the care model without any benefit from the financial incentives of a payment model.

Now, even without any such incentives, the majority of the participating practices were able to implement the care model with minimal or no up-front investment of

14 Nationwide Emergency Department Sample

resources and were able to demonstrate increases in urgent care visits that averaged 20 to 25 percent over baseline over the first year after implementation.

Again, this was accomplished without the benefit of incentives. While the scope of the model is indeed limited to two specialties we observed in the TCPI implementation secondary impacts that widen its scope.

Optometrists have long sought and struggled to integrate their services more closely with primary care providers. Primary care providers are in many cases already engaged in more holistic value-based payments systems such as ACOs and capitation models.

And through those systems the primary care providers are incented to control unnecessary costs. After reduction of hospital days, reduction of the utilization of emergency departments for non-emergent care is a prime target for such cost reduction.

The ability of eye care professionals to contribute to the larger cost goals at ACOs and other networks serves to

align and integrate these professionals more closely into the medical neighborhood and has a secondary effect of improving coordination of care.

While difficult to measure, we did anecdotally observe this impact in the TCPI practices. Some of the concerns that have been voiced regarding this model relate to the level of risk assumption by participating clinicians in the form of the discount on fee-for-service reimbursement for urgent visits.

These concerns have run in both directions. Comments from some individual clinicians and from professional societies have suggested that the eight percent discount is excessive.

Comments from the PRT questioned whether it is sufficient to truly meet the criteria for an advanced APM. In the spirit of Goldilocks, perhaps that suggested we found the proper middle ground.

However, we do acknowledge that if the model is broadly appealing that the discount level might be subject to further

actuarial analysis and adjustment by CMS or other interested payers.

In other words, the specific level of discount is a variable feature of the model and is subject to modification by any adopting payer.

PRT Members and public comments, including some of the discussion just minutes ago, reflected some concerns regarding the rather lengthy list of ICD-10 codes that are included within the model.

We want to emphasize that this long list in part reflects the nature of the ICD-10 classification system. When we began model development, claims were still being submitted under ICD-9 and the list was actually much, much shorter by almost a factor of ten.

But the diagnosis codes are used to reflect the payer perspective. We fully recognize that patients present for evaluation and treatment based on symptoms, eye pain, red eye, blurry vision, et cetera.

For this reason we began our development process around the five common eye

conditions that I've already listed. However, in order for payers to be able to effectively administer any such model, they need to be able to analyze claims based on diagnosis codes.

And so, we convened an expert panel of eye care professionals, chaired by Dr. Scott, who can answer questions about the panel. And that panel cross-walked the five conditions to the ICD-10 codes.

The expert panel was instructed to include only those codes that are clearly and unequivocally within the scope of practice of both optometry and ophthalmology, and also unequivocally amenable to initial evaluation in an office setting.

It was recognized there were some instances these conditions might require referral to an ophthalmologist for surgical intervention or even to an emergency department for emergent treatment.

It was also a criterion that even in such event a code would not be included if the additional step of initial evaluation in an office setting would introduce a delay that

would pose a risk to the patient.

In other words, the expert panel was instructed to exclude any code where the model might create a risk to patient safety. Codes were only included when the five member panel unanimously agreed that the code met the criteria.

We would like to emphasize that it is standard practice for optometrists to refer patients who present with conditions requiring surgical intervention to ophthalmologists. And as such, interventions are just not within their scope of practice.

The typical practice makes such referrals multiple times every week. And the design of this model would not penalize them for doing so.

If anything, the model provides incentives for eye care professionals to triage patients and provide or refer for appropriate care earlier in the progression of disease. And without a need for a more expensive visit to an emergency department to get that referral.

The financial incentives are modest and are hardly sufficient to motivate a clinician to jeopardize their licensure by withholding a referral or exceeding their scope of practice.

So, in closing, this model is designed to accomplish several goals which have been proven to be accomplishable in a large scale pilot test of the care model: to provide a vehicle for specialty practices to participate in value-based care, to reduce unnecessary use of emergency departments for non-emergent services, and to provide eye care professionals with new tools to facilitate closer alignment with the medical neighborhood and improve care coordination.

While this model is specific to two specialties and a limited set of conditions, it is not difficult to envision its replicability for other conditions in other specialties. Eye care is hardly alone in the overuse of emergency departments for non-emergent care.

This overuse has been the subject of extensive discussion in recent years in both

medical literature and in the broader media and is receiving a great deal of attention from private payers.

We believe we have presented a relatively simple, novel, and elegant solution which above all is patient-centered. Just before I, and I would like to say that there are several things that came up a few minutes ago in the discussion between the PRT and the other PTAC Members.

And we would be happy to respond to some of those in the question period.

CHAIR BAILET: Great. Thank you, Dr. Polakoff.

I think what I would like to do now is open it up to the PTAC Committee members who would like to ask questions, and we can revisit the questions that we asked amongst ourselves, as you suggested.

Each of the Committee members, if you could just direct your questions to Dr. Polakoff, then he'll determine who on his team is best to go ahead and answer those questions.

And just please, it might be a

little awkward, but we'll see if we can make this work. So, I'm going to go ahead and open it up to the Committee members.

DR. SINOPOLI: Jeff, this is Angelo. I have a question, if I may.

CHAIR BAILET: Please.

DR. SINOPOLI: So, one point of clarity and one question. So, one is I think I heard you say that the patients were limited to established patients of the practice, and therefore would not be taking patients who otherwise might be considering the emergency room and would call an office instead.

Is that correct?

DR. POLAKOFF: Thank you for that question. It's not so much that we limited it to established patients. But that is the only way that it was being promoted.

The promotion of the model essentially was a communication between the participating clinicians and their established patients.

Essentially, to make this very concrete they, the practices, provided flyers

that were set on the reception desk and posters that were posted in the office that essentially said, "Did you know that we also treat urgent eye conditions?"

"If you have an urgent issue, please call us. Here's our phone number." That in a nutshell is the promotion of the model. So, while it is not closed to new patients, it's not promoted to them.

DR. SINOPOLI: Thank you for that clarification. And my question around that is then in the payment construct, how do you differentiate, or do you have patients that would have been coming to your office anyway for a number of these minor eye issues and would not have been considering the emergency room to begin with and therefore really not decreasing in emergency room visit?

DR. POLAKOFF: In the TCPI model we counted as an urgent visit only those visits where the patient called and requested same day or within 24 hours of the call service. It was based on the patient's identification of the need for urgent service.

DR. SINOPOLI: Thank you.

MR. STEINWALD: Can I follow up on that?

CHAIR BAILET: Bruce, you have a question. Go ahead.

MR. STEINWALD: Yes. It's the same question I asked earlier and to follow Angelo's. And so, I think we have a better understanding now of the population of patients that might change their behaviors.

My question is still what happens when the event that leads to the potential visit to the emergency room and is late at night or the weekend?

Is there still the potential for that patient to receive office services or does the timing of the event really dictate where the patient will receive the care?

DR. POLAKOFF: Thank you for that question. There is still potential for that patient to be seen in the office.

And to some extent that depends on the individual practice's willingness to expand their services. Many of the practices that

participated in our TCPI project were very small offices in small towns.

The average practice size was 1.6 clinicians. So, in those instances sometimes the doctors are willing to take the call in the middle of the night and come into the office or they'll say, you know, we open at 7:00 a.m.

If you can be there at 7:00, I'll see you first thing at 7:00. But it really is up to the individual practice to determine just how broadly they want to open this up.

In general, there is an element of telephone triage in many of these visits, both during normal office hours and even after office hours.

And so, you know, it could be that the patient reaches the doctor directly or through an answering service. And the doctor ends up saying, you know, I think you need to go to the ED for that.

MR. STEINWALD: Thank you.

CHAIR BAILET: Grace. You might be on mute, Grace.

VICE CHAIR TERRELL: Can you hear me

now? In a former life I was, I ran a large multi-specialty group that had ophthalmology and optometry in it.

And I know that from that experience quite often one of the things, as you mentioned, in your proposal is true that the equipment is actually better in the office than in many emergency departments such that it's actually superior care, not just less expensive care.

And quite often when I've done urgent care work in the past and spoke to an optometrist or an ophthalmologist, they would want us to, they would meet with the patient in their office and would not want to see somebody in the emergency room.

So, I perfectly understand where you are coming from with respect to this being potentially much better care.

My bigger concern or questions are around the actual payment model itself because this is essentially fee-for-service which you have available now.

And so, I'm really more interested

in understanding the barriers to why this type of urgent service is not being provided now by eye care clinicians because essentially you could do this now.

I mean, you could have extended hours. You could create some, you know, word of mouth. You could partner with primary care that were in ACOs to make sure that this which is just a site of service issue and probably a more appropriate site of service in many instances were done.

So, my biggest question for you is if this is superior, which it quite often would be, what's preventing eye care clinicians from providing that service now?

DR. POLAKOFF: So, I'll give an initial response. Thank you for that question. And then I'm going to ask Dr. Scott to comment as well.

My distinct impression from interacting with these thousands of optometrists through the TCPI program is that it's more of a business issue related to their, the business model of their practices.

And that's what we seek to interrupt with, by providing new payment methods. We should set optometry and ophthalmology apart in this part of the discussion because the services they provide are different, and they're often reimbursed different.

But for the typical optometry practice, their revenue is a mix of clinical revenue and retail revenue from the sale of eye glasses and contact lenses. And in most practices the clinical revenue is actually a minority.

And the reimbursement rates for fee-for-service visits, to be perfectly blunt about it, aren't sufficient to incentivize them to want to expand their hours, come in, in the middle of the night to see patients for urgent visits.

They're more focused on the other side of the house. And so, one of the things we were hoping to do is to, in a very modest way, disrupt those incentives and provide an incentive to enhance the clinical services they offer. Dr. Scott.

DR. SCOTT: Thank you. I agree, Dr. Terrell. I think is a, it's a transitional time right now between fee-for-service and other payment methods that would be much more efficient and better quality for the patients.

It exists already in certain venues. The VA[15], I spent a good part of my career in the VA, and it's exactly how it worked.

Emergency rooms actually would, when they had patients who had eye conditions that weren't easy to manage, would call us in the middle of the night and either we would go in to see them, or if it was a condition that could be managed, it was done that way.

One of the interesting things that's happened recently is the acceleration of triage, electronic triage, telemedicine, telehealth, telephone that COVID has produced. And I have some data that wasn't available when we submitted this.

And that came from surveys that were done. New England College of Optometry and the, one of the large ophthalmology practices in

15 U.S. Veterans Administration

Boston, put together an ongoing continuing education weekly seminar for managing COVID, and it was available to optometrists and ophthalmologists.

It became very popular. It was every two weeks. But the way they kept people interested in staying on the calls were they had surveys.

And two pieces of information came out that I was unaware of. One, was a question about during the pandemic, "have you provided care to patients through, that required referral to a PCP[16]?"

And 102 people out of 400, give or take, actually did that. And it sort of points to the value of triage. Instead of seeing somebody who has an eye symptom that manifests a systemic condition, the patient did get triaged correctly.

And then the other one was for impact: "During the pandemic have you provided care for a patient?"

And that meant either telephone or

16 primary care provider

more likely seeing the patient in the office of someone who would have gone blind if they hadn't come in? And it was about 100 out of 400 people who responded to that survey.

So, I think there is a reality check, that desire to provide that kind of care is there.

I would not have wanted to have been on the, you know, the panel reviewing this because of the complexity of it. I mean, it's very convoluted how you can incentivize people to do it.

And I realize that having all of the ICD-10 codes has created a lot of confusion in the people reviewing it and the people observing it.

CHAIR BAILET: Thank you, Dr. Scott. Grace, did that answer your question? Can we move on? Yes.

So, my question is trying to wrestle with the issue of scope. I commend the submitters for trying to get the eye care specialists on the field of value-based care delivery.

I think it's a great effort on your part and appreciate all the time that you've put in to developing this proposal.

In the back and forth communication with the PRT, I saw that the TCPI program and just sort of the global collective of practices you were working with, the urgent care visits that occurred in that initiative that qualified within the construct of this list were somewhere between, as you said and this was all payers and correct me if I've got it wrong, but zero to one was a lot of variability.

But zero to one over 25 what were classified as urgent care visits in a month. And that was with all payers.

My concern or question is, a) is that in fact correct? And then if you look at this from a Medicare beneficiary standpoint, would there be sufficient numbers of members having these events that would make this a worthwhile effort for the eye care specialist to want to participate?

DR. POLAKOFF: That's a great question. And I think that you've correctly

identified the TCPI that, while sponsored by CMMI, was an all-payer initiative and the instructions of the program were to collect data on an all-payer basis, and so we did.

I think the model becomes more viable the more different payers participate. And whether there would be sufficient Medicare only patients in a practice to make the model viable and both statistically and financially is somewhat of an open question.

I think it will be highly variable among practices. It just depends on the patient base of the particular practice.

I will say that part of that range of, you know, zero to one patients per month to 25, and by the way that is per clinician and that's not per practice. It's per clinician in the office.

Some of that depends on the level of interest of the practice in expanding urgent visits. You know, most of our practices implemented the model.

But they did so with varying levels of enthusiasm. And, you know, so some of it is

just who their patients are and, you know, who turns up and asks for care.

Some of it is how active and engaged is the practice in promoting the model?

CHAIR BAILET: That's helpful. Again, if you really drill down and try and extrapolate the volume clearly, you would want a model that would have sufficient numbers of events that would, as you said, sort of captivate the interest of the clinicians to make it worth their while especially if you're talking about after hours or, you know, weekends, et cetera, non-traditional hours.

There would have to be sufficient volumes to make it worthwhile especially if you're talking about a reduction of the magnitude of eight percent. And again, I understand that's only for the visits in this particular category.

But if there isn't enough volume and enough dollars attributed to that it's going to be challenging to get the physicians and the clinicians activated to want to participate.

So, that's just a thing that you

guys are, you know, will have to, that will have to have further evaluation and be addressed. And obviously, as you said, more payers that can participate the higher the value of a model like this getting implemented.

DR. POLAKOFF: If I may just add one other point. One of the things we found was that the, just anecdotally, was that the incentives that the participating practices said motivated them were not solely financial.

The other motivation that came across as very powerful in talking to the clinicians and the owners of the practices was that it provided an opportunity for them to start to demonstrate how they create value in a value-based health care system.

It allowed them to change their conversation somewhat in both the setting of negotiating managed care contracts because they now had data on how they were creating value and in developing their care coordination and referral relationships with primary care physicians.

Once again, they used these data to

demonstrate how they provided value, which was something that previously they were really stuck and stymied. Everybody around them is engaged in a value-based care world and they felt they couldn't participate in the conversation.

CHAIR BAILET: Great point. Thank you. Charles, do you have a question?

DR. DESHAZER: Yes. And actually, I want to build on the last comment because you alluded to this model in the context of the medical neighborhood.

And I'm just wondering are, and you kind of alluded to that point there, but, I guess, is this model more effective in a bigger context of a, you know, value-based organization or, you know, are there ways that it would be enhanced by that context?

I'm trying to think about how, you know, being a part of the medical neighborhood that this model would maybe be more, you know, more effective or more enhanced. What are your thoughts around that?

DR. POLAKOFF: Well, I can offer at

least one illustration from the TCPI program. The TCPI was a broader program than just getting clinicians into value-based payment models, or APMs.

It also, you know -- we also worked with the practices on improving quality, improving outcomes, and a whole range of other care coordination and care integration and patient-centeredness strategies.

In the context of eye care practices, one of the ways that played out is that they do most of the eye exams that are measured in some quality measures, such as the diabetic eye exam measure, right?

They do those measures. But primary care clinicians are accountable for those measures.

And so, we assisted these practices in their ability to electronically transfer data back to referring primary care clinicians that allowed the primary care clinicians to get credit for the eye exams that the optometrists had done.

In so doing, that builds the

relationship of the medical neighborhood. A lot of these clinicians previously were in a world where they were sending a consult letter back by old fashioned snail mail to the primary care doc reporting on the eye exam.

It never made it into the EHR[17]. And as a result, the primary care physicians were reporting really poor results on their diabetic eye exams. We helped them fix that. That facilitates the relationship.

Then we add on top of that this reduction of costs for unnecessary ED use. And the ability of the optometrist to display that back to the primary care physician is a way they're creating value.

These things integrate in a more holistic way and start to enhance the medical neighborhood and, essentially, to bring eye care into the care team for the patient.

I hope that addresses the question, Dr. DeShazer.

DR. DESHAZER: Yes, that's helpful definitely. I see that capability in terms of

17 electronic health record

the integration and coordination to support overall value-based strategies.

CHAIR BAILET: Thanks, Charles. Seeing no further questions, I'd like to personally thank the submitters for their time today, and more importantly for their efforts to try and create a model for the Committee to review and potentially be implemented.

I'd like to just ask them to go back -- and they'll be moved back from the participant panel to the general audience and they can return to a listening mode to continue with the meeting.

*** Public Comments**

We have two -- actually we have two public commenters who are signed up. And I'm going to go ahead and work with the operator to call them up.

The first is Dr. Steven Eiss. He's an optometrist from the American Optometric Association. Dr. Eiss?

DR. EISS: Hi, yes. Can you hear me?

CHAIR BAILET: Yes, we can.

DR. EISS: Okay, yes. Thank you.

Thank you for the opportunity to provide comments today. Again, my name is Dr. Steven Eiss. I'm a practicing optometrist in southeast Pennsylvania.

And I'm representing the American Optometric Association as a volunteer Chair of the Third Party Center Committee. As background, the AOA represents approximately 39,000 doctors of optometry, optometry students, and paraoptometric assistants and technicians.

Doctors of optometry serve more than 10,000 communities across the country and counties that account for 99 percent of the U.S. population. Recognized as Medicare physicians for more than 30 years, doctors of optometry provide medical eye care to more than six million Medicare beneficiaries annually.

In support of evidence-based health care and to serve the needs of the American public, the AOA develops clinical practice guidelines that meet the National Academies of Science, Engineering, and Medicine Health and Medicine Division, or NASEM, evidence-based

standards.

The aim of the PTAC proposal, how doctors of optometry can help reduce unnecessary hospital visits for eye emergencies is such an important focus. As primary eye care providers, doctors of optometry have long played a role in serving their communities by providing emergency eye health care.

This role for doctors of optometry in the health care system has proven to be even more impactful over the past several weeks, as our country has been faced with the COVID-19 public health emergency.

According to data collected by the AOA, during the public health emergency 79.2 percent of doctors of optometry surveyed were providing emergency care through the public health emergency.

These doctors of optometry estimate that nearly 60 percent of patients they treated during the crisis would have sought care in emergency department or other urgent care settings had they not been available to provide care.

During the pandemic reducing strain on overburdened hospitals was even more critical to our health system and to slowing the spread of the virus.

However, even outside of the extenuating circumstances of the past few weeks, doctors of optometry can increase efficiencies in our health care system by caring for patients with emergency eye injuries to avoid unnecessary emergency room visits.

Recent analysis has shown that an estimated 8.3 billion is spent each year on emergency department care that could be provided in another location. Additionally, nearly 40 percent of all ED visits were for non-urgent medical conditions, according to a 2013 study.

Unfortunately, many patients are seeking care in EDs for ocular conditions that could be treated in an office-based setting. A 2017 study found that nearly one-quarter of enrollees who visited the ED for an ocular problem received a diagnosis of a non-urgent condition.

Better educating and incentivizing patients to seek care for non-urgent ocular diseases in an office-based setting could yield yet considerable cost savings, without adversely affecting health outcomes, and could allow EDs to better serve patients with more severe conditions.

Further, a JAMA[18] Ophthalmology 2019 analysis of data from an electronic records system found that patients with non-emergency eye concerns would save $782 in charges and 5.75 hours in visit duration by choosing same-day outpatient care rather than an emergency department visit.

It is clear that doctors of optometry can play a key role in achieving these types of cost savings.

Additionally, the AOA's Health Policy Institute, or HPI, recently conducted a descriptive epidemiological analysis of the diagnosis codes reported nation-wide in emergency department encounters and determined that although urgent, most eye related

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conditions reported in the emergency department may be treatable in an outpatient optometry clinic or office.

The Agency for Healthcare Research and Quality, AHRQ, sponsors the Healthcare Cost and Utilization Project, HCUP, a family of health care databases and related software tools and products.

The nationwide emergency department sample is contained in the tool called the HCUPnet, useful for identifying, tracking, and analyzing national hospital data.

Using the select set of eye and vision related diagnosis codes, HPI queried the HCUPnet tool and identified a rate of 4.5 visits per 1,000 persons, totaling 1.45 million eye ED visits in 2016.

The CDC[19] reports a national rate of 458 per 1,000 persons in 2016. So, eye visits represent approximately one percent of all emergency department visits in 2016.

Potential savings by transitioning eye emergencies to optometry offices and

19 U.S. Centers for Disease Control and Prevention

clinics should be of key interest of health care payers and policy makers. Most especially, those shown by these data, who bear the brunt of unavoidable eye-related emergency department visits and charges.

These payers include private insurance, which is about 29 percent, Medicaid which is about 40 percent, and Medicare which is about 12.5 percent.

For example, a 2013 study of 475,941 patients found that 91.5 percent of total cost, totaling 18.4 million, could be saved by diverting eye emergency department care to optometry offices and clinics.

While we fully agree with the University of Massachusetts that patients are better suited to seek care for ocular diseases and conditions in an outpatient, office-based setting with a doctor of optometry, we have concerns with certain aspects of the proposal.

We fully recognize that as part of the alternative payment model, physicians must take on some financial risk. However, we are concerned that doctors participating in the

model are required to take a discount of at least eight percent applied to all fee-for-service rates on the emergency care-related visits.

We know from previous research that are significant cost savings when patients do same-day outpatient care, rather than an emergency department visit. We believe a more equitable model would require doctors to pay an eight percent payment penalty on pertinent visits in the year following the performed care if the savings were not truly realized.

The care that doctors of optometry provide is valuable care, and we believe an up-front payment discount devalues that care.

We are also concerned that the list of diagnosis codes meant to assist in identify - identification of visits that would be considered in the EyEDA model, was too broad.

The 2019 JAMA Ophthalmology study indicated that the top four ophthalmologic diagnosis for ED patients were conjunctivitis, corneal abrasion, iritis, and vision loss. We recommend that the pertinent diagnosis code

list for the proposed payment model be further revised and limited.

We also believe for this payment model to be successful and equitable, there would need to be additional policy incentives in place. The policy proposal authors have rightly noted that patients lack awareness of the existence of alternatives to the ED for urgent eye care conditions.

Hospitals lack incentives to dissuade or redirect patients with non-emergent conditions away from the ED.

CHAIR BAILET: Dr. Eiss, I don't mean to interrupt. But you are - you're running a bit long. I've given you some added time. But if you could please close it out, that would be greatly appreciated. Thank you.

DR. EISS: Okay. I'm just about to finish. Thank you.

CHAIR BAILET: Super.

DR. EISS: We request that payers have a 24 [hour] phone line support service for questions for beneficiaries, and we believe the EDs themselves should be part of the effort to

encourage patients to seek care with optometry offices.

Without the engagement of other players in the health care system, the payment model would in practice target a single health care provider which we believe may not meet the goals of PTAC.

I also have a little exception with the characterization that optometry is very retail focused. Obviously, market forces have really pushed optometry away from that, to where many, many of the practices are much more medical care.

And as a care provider, you know, we just want to take care of our patients. You know, our incentive is to see our patients to provide the care they need.

We don't want to see them go to the emergency room and get, you know, care that may not address exactly what they may need or be in their best interest.

So, again thank you for your time. I apologize for running a little long, and I'll be glad to answer any questions related to

care.

CHAIR BAILET: Thank you, Dr. Eiss. I'd like to go ahead and turn it over to the next commenter and that's Dr. Lori Grover, also from the American Optometric Association. Dr. Grover?

DR. GROVER: Good morning. Can you hear me?

CHAIR BAILET: Yes, we can.

DR. GROVER: Thank you, Dr. Bailet, and thanks to the Committee for letting us comment today. I'm speaking a bit more today from a 30-year clinical background as a doctor of optometry, formerly with Johns Hopkins and I also have doctoral training in health services research and health policy.

I currently am the Director of the Center for Eye and Health Outcomes at Memphis. And I wanted to just share with you that we understand and support the importance of the role of APMs in improving health care deliveries.

I do want to emphasize I think it's important to view the eye care delivery role of

the doctor of optometry as a parallel to that of family physicians within the health care arena, especially when you're taking into account the complexities, the stakeholder incentives, payments, and delivery of quality patient centered coordinated care; there is much to think about in that role.

Doctors of optometry provide almost 80 percent of the primary care in the United States. And we understand the recognition of emergency eye care delivery as an area where cost savings certainly can be achieved.

We recognize that primary care is really a primary access point to the health care system, and hence why I wanted you to have that perspective of us as a parallel to our physician colleagues in primary care.

The observations made earlier regarding the suggested lack of clinical care volume and the delivery of primary eye care misrepresents the scope of the continuum of care that is delivered by doctors of optometry in the United States.

And I think that's just because of

observations limited to a small and narrower network that isn't really representative of current national continuum of eye care delivery, especially with Medicare beneficiaries.

So, aside from the data that supports this, I also can support this with personal experience. I've treated chronic vision impairment and have always served a larger, older adult population.

So, we embrace the area of emergent and the urgent care not only as part and parcel of what doctors of optometry deliver but also as an area of great potential for transformational approaches.

We support and appreciate the recognition of optometrists and their important national role in eye care. We value that greatly and we feel it's time that we can help to take our place with our colleagues in that arena.

The details that are proposed here unfortunately do require additional refinement and collaborative input.

And ultimately we aim to ensure that a wide range of clinicians, that includes not only, as was mentioned earlier, both existing ACO and other network models in which doctors of optometry are engaged but also can include small practices in rural areas, where we can participate and have doctors benefit, have the patients that are served benefit, and have care delivery transformation that can be equitable and efficient.

So, thank you for letting me comment.

CHAIR BAILET: Thank you, Dr. Grover. I'm just going to check with the operator; is there anyone else who signed up for public comment?

Hearing none, I turn back to the PTAC Committee. Are we ready to vote? It sounds like we're ready to vote.

*** Voting**

So, since there's no other comments I would just like to review a few of the voting system parameters, which haven't changed. We're simply using an online version of the

same technology that you've seen us use in typical meetings.

We appreciate your patience as we use this tool virtually for the first time. It may take a minute or so to make the transitions and get people connected to the technology.

But I just want to review some of the parameters of voting. We vote on -- first electronically on the 10 Criteria. Member votes roll down until a simple majority has been reached.

A vote of 1 or 2 means does not meet. A vote of 3 or 4 means meets. Five (5) and 6 means meets and deserves priority. If there's an asterisk that means it's not applicable.

After we vote on all 10 Criteria, we will proceed to vote on our overall recommendations to the Secretary. We will use the voting categories and process that we debuted in December of 2018. We designed these more descriptive categories to reflect our deliberations for the Secretary.

So, first we will be voting using

the following three criteria -- or three categories. Not recommended for implementation as a physician-focused payment model; or recommended; or referred for other attention by HHS. We need to achieve a two-thirds majority of votes for one of these three categories.

With a two-thirds majority vote to recommend the proposal, we then vote on a subset of categories to determine the final overall recommendations to the Secretary.

And the second vote uses the following four categories, or subcategories, if you will. The proposal substantially meets the Secretary's criteria for PFPM[20]s, PTAC recommends implementing the proposal as a payment model.

Next, PTAC recommends further developing and implementing the proposal, as a payment model as specified in PTAC comments.

The third category is PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.

20 physician-focused payment model

And lastly, PTAC recommends implementing the proposal as part of an existing or planned CMMI model. We need a two-thirds majority vote for one of these four categories.

* **Criterion 1**

So, now let's go ahead and vote for the first criterion, which is scope, which is considered a high priority item.

So, scope, aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio, or include APM entities whose opportunities to produce -- to participate in APMs have been limited.

Please vote. Audrey? It looks like we -- can you go ahead, Audrey, and summarize for us what you see, please? You're on mute. Audrey, we're not hearing you, you're on mute.

MS. MCDOWELL: Okay. Can you hear me now?

CHAIR BAILET: Yes, we can.

MS. MCDOWELL: Thank you. Zero members voted 6, meets and deserves priority

consideration. Zero members voted 5, meets and deserves priority consideration.

Zero members voted 4, meets. One member voted 3, meets. Six members voted 2, does not meet. One member voted 1, does not meet. Zero members voted 0, not applicable.

So, we need a majority, which is five votes. And so, the majority has determined that the proposal does not meet Criterion 1.

*** Criterion 2**

CHAIR BAILET: Thank you, Audrey. Let's go to Criterion 2, please, which is quality and costs, which is also a high priority designation.

Anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing costs, or both, improve health care quality and decrease costs.

Please go ahead and vote.

Go ahead, Audrey.

MS. MCDOWELL: All right. Zero members voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration.

One member voted 4, meets. Seven members voted 3, meets. And zero members voted 2 or 1, does not meet. And zero members voted 0, not applicable.

So, the majority has determined that the proposal meets Criterion 2.

* **Criterion 3**

CHAIR BAILET: All right. Thank you, Audrey. We're going to move on to Criterion No. 3, which is payment methodology which is also a high priority designation.

Pay the APM entities with a payment methodology designed to achieve the goals of the PFPM criteria.

Addresses in detail, through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the physician-focused payment model cannot be tested under current payment methodologies. Please vote.

Audrey?

MS. MCDOWELL: Are you ready?

CHAIR BAILET: I am ready, Audrey.

MS. MCDOWELL: All right. Zero members voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration.

Zero members voted 4, meets. Zero members voted 3, meets. Four members voted 2, does not meet. Four members voted 1, does not meet. Zero members voted 0, not applicable.

So, the majority has determined that the proposal does not meet Criterion 3.

*** Criterion 4**

CHAIR BAILET: Thank you, Audrey. Let's go on to Criterion 4, which is value over volume.

Provide incentives to practitioners to deliver high quality health care. Please vote.

All right, Audrey, please continue.

MS. MCDOWELL: Okay. Zero members voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration.

One member voted 4, meets. Six members voted 3, meets. One member voted 2,

does not meet. Zero members voted 2 -- excuse me, 1, does not meet. And zero members voted 0, not applicable.

So, the majority has determined that the proposal meets Criterion 4.

*** Criterion 5**

CHAIR BAILET: Thank you, Audrey. Criterion 5 is flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care. Please vote.

Audrey?

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration. Two members voted 4, meets. Six members voted 3, meets. Zero members voted 2, does not meet, or 1, does not meet, or zero, not applicable.

So, the majority has determined that the proposal meets Criterion 5.

*** Criterion 6**

CHAIR BAILET: Thank you, Audrey. We'll go on to Criterion No. 6, which is ability to be evaluated.

Have evaluable goals for quality of care, cost and other goals of the PFPM. Let's go ahead and please vote. Here we go.

Audrey?

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Seven members voted 3, meets. One member voted 1 -- excuse me, 2, does not meet. Zero members voted 1, does not meet. Zero members voted 0, not applicable.

So, the majority has determined that the proposal meets Criterion 6.

*** Criterion 7**

CHAIR BAILET: Thanks, Audrey. Let's go to Criterion No. 7, which is integration and care coordination.

Encourage greater integration and care coordination among practitioners and across settings, where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM. Let's go ahead and vote, please.

MS. MCDOWELL: Zero members voted 6, meets and deserves priority consideration. Zero members voted 5, meets and deserves priority consideration. Zero members voted 4, meets. Three members voted 3, meets. Two members voted 2, does not meet. Three members voted 1, does not meet. And zero members voted 0, not applicable.

As we have indicated, we need a majority, which is five votes. So, in this case a majority has determined that the proposal does not meet Criterion 7.

* **Criterion 8**

CHAIR BAILET: Thank you, Audrey. Let's go to Criterion No. 8, patient choice.

Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients. Please go ahead and vote.

Audrey?

MS. MCDOWELL: Zero members have voted 6, meets and deserves priority consideration. Zero members have voted 5, meets and deserves priority consideration. Two

members have voted 4, meets. Six members have voted 3, meets. Zero members have voted 2, does not meet; 1, does not meet; or 0, not applicable.

So, the majority has determined that the proposal meets Criterion 8.

* **Criterion 9**

CHAIR BAILET: Thanks, Audrey. And we'll go ahead to Criterion No. 9, which is patient safety.

Aim to maintain or improve standards of patient safety. Please vote.

Audrey?

MS. MCDOWELL: Zero members have voted 6, meets and deserves priority consideration. Zero members have voted 5, meets and deserves priority consideration. One member has voted 4, meets. Zero members have voted 3, meets. Five members have voted 2, does not meet. One member has -- excuse me, two members have voted 1, does not meet. And zero members have voted 0, not applicable.

So, the majority has determined that the proposal does not meet Criterion 9.

*** Criterion 10**

CHAIR BAILET: Thank you, Audrey. And the last criterion, Criterion 10, which is health information technology.

Encourages the use of health information technology to inform care. Please vote.

Audrey?

MS. MCDOWELL: Zero members have voted 6, meets and deserves priority consideration. Zero members have voted 5, meets and deserves priority consideration. Two members have voted 4, meets. Five members have voted 3, meets. One members has voted 2, does not meet. Zero members have voted 1, does not meet, or 0, not applicable.

So, the majority has determined that the proposal meets Criterion 10.

CHAIR BAILET: Thank you, Audrey. Audrey, could you just summarize where we fell out on the ten criteria, please?

MS. MCDOWELL: Yes. The Committee has found that the proposal meets six of the ten criteria. And that is Criteria 2, 4, 5, 6, 8

and 10.

And the Committee voted that the proposal does not meet the remaining four criteria, and that consists of Criteria 1, 3, 7 and 9.

*** Overall Vote**

CHAIR BAILET: Thank you, Audrey. We are now ready to move into the next section of voting, which is the overall recommendation.

So, you see here we have not recommended for implementation as a PFPM; recommended, which would require two-part voting; or referred for other attention by HHS.

Those are the three categories. We're going to go ahead and vote. Audrey?

MS. MCDOWELL: So, seven of the Committee members have voted not recommend. Zero Committee members have voted recommend. And one Committee member has voted to refer for other attention by HHS.

In this case you need a super majority, which would be six. And so, the recommendation of the Committee is to not recommend this proposal for implementation as a

PFPM.

CHAIR BAILET: Thank you, Audrey. And in light of the vote not to recommend there is no requirement to have the second stage of voting here.

*** Instructions on Report to the Secretary**

So, I think at this point we would like to have the individual Committee members make comments that can be embedded in the Secretary's report.

And so, what I'd like to do is, because it's virtual, I'm going to go back to the list of Committee members as we used in opening for folks to introduce themselves and disclose any conflicts.

So, the first person on that list is Grace. And then we'll just go through the list, finishing with myself. Grace, if you want to --

MS. MCDOWELL: Excuse me, Jeff?

CHAIR BAILET: Yes?

MS. MCDOWELL: I just want to confirm that as they do that, that they're going to indicate how they voted.

CHAIR BAILET: Correct. Thank you, Audrey.

MS. MCDOWELL: Thank you.

VICE CHAIR TERRELL: So, I voted to not recommend. And mostly it was not about the care model, but it was about the payment model, which I did not think was adequate for the appropriate aims that they were bringing forward.

I do believe that the ability to have extended hours and getting people out of the emergency department when there is a non-emergent but urgent eye problem is appropriate. And it was thoughtful many of the ways that they put together their proposal as it relates to that.

I did not think that the payment model that was proposed would get them there. And so, I think there's some others that might be thought through, which is about other ways of motivating people to have increased access.

Part of my concern was the need based on numbers for it to be about more than just Medicare. And I like the idea in the

original CMMI, it was an all-payer access.

But I wonder if care and coordination fees, other types of bundled payments, many of the other types of payment models that are out there would actually achieve their aims better than a discount for volume.

And so, that's sort of where I voted, and why I voted the way I did.

CHAIR BAILET: Thank you, Grace.

Paul?

DR. CASALE: Yes, hi. Yes, I also voted to not recommend. Similar thinking to Grace, I mean, it was really the payment model, I think was where -- I think was most challenging.

I do think that, as Grace just said, increasing access at appropriate sites of care that are lower cost, better equipment in the office, all those would achieve higher quality.

But I think that the payment model as currently described being sort of office-based payment, I don't think -- I think there are other ways of doing that. And I still

struggle with the scope.

I mean, I understand that, you know, the eye care physicians haven't specifically had a model. But it seems to me that this is one that can be embedded in broader models, effectively, and I would see that coordination with primary care would benefit both, and of course benefit the patient.

CHAIR BAILET: Thanks, Paul. We've got Charles next.

DR. DESHAZER: Yes. I would just echo the statements of Paul and Grace in that the elements that I struggled with were the scope and the payment model and those are two high-priority criteria for us, which this model fails on.

But again, I think that there are elements that if you embed it within, you know, a bigger context could be of value in terms of the role of this strategy. So, I voted to not recommend on that basis.

CHAIR BAILET: Thank you, Charles. We have Kavita followed by Angelo. Kavita?

DR. PATEL: I voted to not recommend.

And the only thing I would add to be included in the Secretary's report is some comment regarding how best to carry forward outside of a CMMI model what was learned and gained from the TCPI program, in particular because of the ability to demonstrate this type of practice transformation is important to find a home for within, kind of, the HHS enterprise.

CHAIR BAILET: Thanks, Kavita. Angelo?

DR. SINOPOLI: Yes. I'll echo a lot of what's been said. I did vote not to recommend. And my main concerns were the scope and the number of diagnoses automatically listed there, and also very much the payment model.

And I would also echo, I think there's a lot of value otherwise in this model, in terms of being able to provide high-quality care outside the ER[21]. Sometimes there is actually much better equipment that may be better suited to be integrated into more of an integrated model with a delivery system and a

21 emergency room

robust triage or referral system.

CHAIR BAILET: Thanks, Angelo. Bruce followed by Jennifer.

MR. STEINWALD: I agree with the comments so far, especially about scope and the payment model. But I was the one person that voted to refer, because I like to be different.

But the reason I did that is because I was persuaded by some of the comments about telemedicine and the potential for telemedicine to be a source of both triage and referral and care coordination for the population.

And since that's a high priority that Secretary [sic] Verma[22] mentioned, I thought this obviously could be covered in the discussion section of the report. But to identify this as a potential good area for the application of telemedicine.

CHAIR BAILET: Thank you, Bruce. Jennifer?

DR. WILER: Yes. I too voted not to recommend. It's obvious the current payment models don't encourage broad access to sub-

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specialty eye care, as was described.

And the TCPI project had impressive results. However, given the current proposal, I too shared the concern that the payment methodology would not garner participation of providers or participants as currently described, which then directly impacts a high-priority area of scope.

The other thing I would add that has not come up in this conversation is the issue with regards to patient safety.

And my comment would be that the patient safety metrics described in this proposal are ones that don't appear to cross-walk to what is standard complications related to these ambulatory-sensitive conditions.

Specifically, those of observation, inpatient visits, and deaths. So, it appears that those quality metrics are a mismatch to what's being described.

And I agree with one of the previous speakers, that a global period that extends far beyond seven days, if this were to be considered, is more appropriate. Thank you.

CHAIR BAILET: Thank you, Jennifer. And I also voted not to recommend, and agree with the comments that have been made.

The only other comment I would make is an earlier observation about the numbers of encounters that qualify. When we were looking at a small number of zero to one per doc, per clinician, per month that would qualify, I'm just concerned that there would be insufficient scope.

I do commend the submitters for trying to engage and get the optometry community into the value-based world. I commend that effort and think that more thought needs to be placed on how to get a model out that this specialty could participate in to get into value-based care delivery more than they are today.

So, that was closing out those comments. I think it would be good, Audrey, if there could be a read back of comments that the Committee made just to ensure that we were articulate and that those were captured to go ahead and embed those comments into the

Secretary's report.

So, someone on the team want to summarize what they heard, or ask any clarifying questions? Yes.

MS. MCDOWELL: We'll turn that over to Sally.

CHAIR BAILET: Right, thank you.

DR. STEARNS: Okay. So, let's see. To summarize what I want to do is start with some of the positive points that were made, especially about the care model.

That historical data show that a large proportion of ocular-related visits to the ED often could be appropriately treated in an office-based setting. And in particular, offices may be, in many cases, better equipped than EDs for some of the ocular problems.

Also, the report will emphasize the TCPI experience showed interest and ability of many practices, including small practices, to expand their clinical services for the five categories or conditions identified.

And also, the COVID experience over the last few months, although not part of the

proposal, has further emphasized the value of virtual and office-based services for ocular conditions that can be appropriately treated in an office-based setting.

However, the report is also going to pay particular attention to the concerns on the four areas where the voting did not support the model. That would be scope, payment, integration and care coordination, and patient safety.

And some of the specific comments there include the fact that the payment model -- - that the PTAC does not feel that the payment model will get them to the point of being able to really encourage practices to move these services.

But there is a need for other ways to get people to do this. And including attention to broader models, such as ACOs, or alternatives such as bundled payments.

Some of the other points and concerns include, Jennifer mentioned some patient safety concerns. And the broader problem that the current payment models from

CMMI often don't encourage broad participation by optometrists, but simply that something broader is needed.

And I will also fall back on some of the comments in the PRT report on those specific four areas, where the voting was not supportive of the model.

CHAIR BAILET: Thanks, Sally. If there are no other comments from the Committee members, we have completed the first deliberation of the morning session.

We are reconvening at 12:45. We at that point will have Brad Smith from CMMI provide some opening remarks.

I am on the second PRT. So, I am going to turn the gavel over to Grace at that time, so that I can fully participate as a member of the PRT.

So, we are going to end this session.

I want to thank the commenters. Also, more importantly, want to thank the submitters for their time and attention developing this proposal working with the PRT

and providing their input today, and also all of the members and stakeholders across the country who have participated in the session this morning.

We're going to go ahead and adjourn until 12:45. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:19 p.m. and resumed at 12:45 p.m.)

VICE CHAIR TERRELL: Okay. It's 12:45. So good afternoon, and welcome back to this PTAC meeting. I want to extend a special welcome to anyone who has just joined for the afternoon.

I'm Grace Terrell. I'm the Vice Chair of PTAC. I will be handling some of Jeff's[23] facilitation duties this afternoon because he's on the PRT for the proposal that we're going to discuss this afternoon.

But before we do that, at this time, we are honored to be joined by a member of the HHS leadership.

I'm excited to introduce Brad Smith,

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who's the Senior Advisor to Secretary Azar for Value-Based Transformation, a Deputy Administrator for the Centers of Medicare & Medicaid Services, and the Director for the CMS Innovation Center.

Mr. Smith joined HHS in January 2020 after serving as the Chief Operating Officer of Anthem's Diversified Business Group. He brings with him extensive experience innovating in the care delivery and value-based care spaces.

Mr. Smith co-founded and served as the CEO of Aspire Health, a health care company focused on providing home-based palliative care services to patients facing serious illnesses.

And with that, it's my pleasure to welcome Mr. Smith. I think you're on mute there, Brad. Not hearing you.

CHAIR BAILET: Grace, I don't think he knows, I don't think he's hearing anybody. Someone's going to have to text him and tell him he's on mute.

VICE CHAIR TERRELL: Yes. So can somebody text him, please?

*** Brad Smith, Deputy Administrator and**

Director of CMMI Remarks

MR. SMITH: Okay. Can you guys hear me okay? Sorry about that.

VICE CHAIR TERRELL: You were on mute until just this instant, so --

MR. SMITH: Yes, okay. I was talking to myself. It's like when you're on the call, except you can see yourself, so it's even more confusing, but I'll kind of, kind of start over. So you know, again, thank you guys for having me. I deeply understand how important the work of PTAC is, and just to give you guys a little bit of background, prior to coming into the administration, I was running a health care company that did palliative care, and we were part of a coalition of folks who brought a model through C-TAC[24] to PTAC.

And through that process, you guys gave us really helpful feedback. We refined our model a lot, and as many of you may remember, you also approved another palliative care model around the same time.

You know, and then CMMI, before I

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was ever there, took those two models that came up from PTAC, other ideas they were hearing, and put together the SIP model, the serious illness population model, that they've recently announced.

So I've had the opportunity to firsthand see the importance of PTAC, see the way that it can make participants and folks who are bringing models to improve their models, and then seeing how CMMI can use that information to roll out a model for the whole country.

And so I just want to start by saying I deeply understand how important your work is, how important it can be for providers across the country, and how important it can be from, for CMMI and CMS, in informing everything today. I'll start just by talking a little bit about sort of my time so far. So as you guys know, I joined in January, and I spent the first two months going through all of the models that we have done.

It's about over 45 models now, and trying to understand the impact that they had

had and lessons that we had learned.

Over the past few months, I have obviously been holding to the COVID work, almost working full-time on it in March and April, but now I'm probably about 70 to 80 percent back to my CMMI job, and excited to dig back in with the folks from PTAC, with the CMMI team.

As we think about the next, the rest of this year and going forward, maybe I'll highlight a couple of areas that we're thinking about, and some of the things that may be helpful for your all's conversation.

So one piece is that as we went back and reviewed all of the models, I think we had a bunch of really important lessons learned.

So we've learned a lot about how to think about benchmarking, the importance of, for example, back-testing benchmarks on data to make sure that they're fair and accurate, both to participants and to the government.

We've learned a lot about operations, how to make sure that we're implementing our attribution really well, how

to make sure that we're being thoughtful about the investments we're making, how to measure quality metrics.

And I think one of the things that you're going to see us focused on the rest of this year is really operationally making sure that we're supporting participants well, that we're making sure all the existing models that we have are successful, and by successful, I really mean driving one of two outcomes: either one, helping lower costs, or two, helping increase quality. The other piece is we, of course, are going to be thinking about the things that have happened as part of COVID and some of the flexibilities we've gotten generated.

I know Administrator Verma probably talked about this earlier today. The way from the CMMI perspective that we're thinking about those COVID flexibilities is that we'll start by CMS reviewing them and deciding which of those flexibilities makes sense to continue as part of the core Medicare program, and then of the other flexibilities that they're not

planning to continue, we will then evaluate those for potentially incorporation into our CMMI models, and especially in models where participants are taking capitated risk or two-sided risk, those are models we're going to look to give participants as much flexibility as possible.

Just talking a little bit more about PTAC, and I think the ways that we can work together, you know, number one is the kind of feedback that you all have provided on models to providers and participants has been extraordinarily helpful. And I think you all continuing to do that, us sharing lessons that we're learning around benchmarking, some of the challenges of adverse selection, et cetera, I think would be, would be really helpful, and potentially maybe we could even come back and even share some of those lessons learned with you all at some point.

I think a second piece will be helping us think about new areas that we should consider launching models. As an example, you know, to date, we haven't done anything in the

behavioral health space.

We've done a few things, but we want to do more in the social determinants of health space. We've done a lot around post-acute bundles but want to do even more there. And I think being able to hear from you all, and hear from providers across the country, ideas they have, models they've tested, that will be extraordinarily helpful, and what we're committed to is anyone that you all recommend, you know, we want to meet with them.

We want to understand their recommendation. Where appropriate, we want to incorporate that with everything else we're hearing from across the country to roll out models.

So overall, I just want to thank you all for being great partners. We are here to work with you. We are highly committed to value-based care, hopefully as you saw in the model flexibilities that we had, and look forward to building a great partnership with you all.

With that, I don't know if anyone

has any quick questions, but just appreciate being able to be here.

VICE CHAIR TERRELL: Thank you, Mr. Smith. Any questions?

CHAIR BAILET: Thanks, Brad. I look forward to working with you. It's Jeff.

MR. SMITH: Thanks, Jeff.

VICE CHAIR TERRELL: All right. Well, thank you for providing those remarks, and hearing nothing from anybody else, I hope you'll continue to listen in this afternoon, but let's proceed with the proposal that we're scheduled for this afternoon.

So to remind the audience, I'm just going to reiterate the order of activities for our review of a proposal. First, the PTAC Members will make disclosures of any potential conflicts of interest, and then we will announce any committee members not voting.

Second, we will have a discussion of the proposal that will begin with a presentation from the Preliminary Review Team, or PRT, charged with conducting the preliminary review.

After the PRT's presentation, and any initial questions from the PTAC Members back to the PRT, the committee looks forward to hearing comments from the proposal submitters and the public, and then we'll deliberate on the proposal. And then we'll vote.

I'm not going to go into the details of, with how we do that, with respect to that, as we reviewed that this morning, and I want to make sure that we've got time for our deliberations this afternoon.

So with that, let's just go ahead and proceed forward with the proposal that we have in hand this morning --

CHAIR BAILET: Grace.

VICE CHAIR TERRELL: -- or this afternoon, which is the thing. Yes?

CHAIR BAILET: I didn't mean to interrupt, but I just wanted to make sure, I think I saw Jennifer had a question -- just circling back. Jen, it may have, the time may have passed, but I just wanted to make sure --

VICE CHAIR TERRELL: Yes, sorry.

CHAIR BAILET: -- to give you an

opportunity.

VICE CHAIR TERRELL: You handed with, for, so for whatever reason, it's been slow to show you when you have questions on our, because I think that happened to you this morning. Was that for Brad Smith? Okay. All right.

I apologize. Is he still available, where we could get him back on? If not, my apologies. Okay. All right. Well, Jeff, just stop me quicker next time, okay?

CHAIR BAILET: Okay. Sorry, Grace.

*** Deliberation and Voting on the Patient-Centered Asthma Care Payment Proposal submitted by the American College of Allergy, Asthma, & Immunology**

VICE CHAIR TERRELL: Okay. So the proposal that we are now getting ready to discuss is the *Patient-Centered Asthma Care Payment*. It was submitted by the American College of Allergy, Asthma, & Immunology, or ACAAI.

*** PTAC Member Disclosures**

VICE CHAIR TERRELL: So let's now go through and read in, or declare any conflicts of interest or disclosure statements. And just as Jeff did this morning, I'm just going to go, since it's virtual, I'm just going to go through and prompt you one at a time.

So Grace Terrell, CEO of Eventus WholeHealth, and I have nothing to disclose. Next is Jeff.

CHAIR BAILET: Jeff Bailet, CEO of Altais. I have nothing to disclose.

VICE CHAIR TERRELL: Paul?

DR. CASALE: Paul Casale, New York-Presbyterian, nothing to disclose.

VICE CHAIR TERRELL: Charles?

DR. DESHAZER: Charles DeShazer, CMO of Highmark Inc. Nothing to disclose.

VICE CHAIR TERRELL: Kavita?

DR. PATEL: Hi, Kavita Patel, Brookings Institution. Nothing to disclose.

VICE CHAIR TERRELL: Angelo?

DR. SINOPOLI: Angelo Sinopoli, Chief Clinical Officer of Prisma Health. Nothing to disclose.

VICE CHAIR TERRELL: Bruce?

MR. STEINWALD: I'm a health economist in Washington D.C., and have nothing to disclose.

VICE CHAIR TERRELL: Jennifer?

DR. WILER: Jennifer Wiler, Chief Quality Officer, UCHealth, Denver, and professor at University of Colorado School of Medicine.

VICE CHAIR TERRELL: Nothing to disclose?

DR. WILER: Nothing to disclose.

VICE CHAIR TERRELL: Okay. All right. Thank you all, and I'm going to now turn the microphone to the lead of the Preliminary Review Team for this proposal, Angelo Sinopoli, to present the PRT's findings to the rest of us on the full PTAC.

*** Preliminary Review Team (PRT) Report to PTAC**

DR. SINOPOLI: First, welcome to the afternoon session, and big thanks to my fellow PRT committee members, Jeff Bailet, and Bruce Steinwald.

If we could flip to the next slide, and we're going to review the PRT composition and roles, then the proposal overview, and then the summary of the PRT review, identify and discuss some key issues, and then we'll go through each of the 10 criteria. Next slide.

So in terms of the team composition and role, we did review some of this this morning. So the PTAC Chair and Vice Chair assigns two to three PTAC Members, including at least one position to each complete proposal to serve as the PRT.

One of the PRT members has to serve as the lead reviewer. PRT identifies additional information needed from the submitter, and determines what extent, if any, additional resources and/or analyses are needed for the review.

Assistant Secretary for Planning and Evaluation, ASPE staff, and contractors support the PRT in obtaining these additional materials. The PRT determines, at its discretion, whether to provide initial feedback on a proposal.

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

Important to know that the PRT report is not binding on the PTAC. The PTAC may reach very different conclusions than those contained in the PRT report. Next slide.

We'll briefly review the proposal. So background, asthma across the United States affects about 26.5 million people including about 3 and a half million Medicare beneficiaries.

The submitter estimates that Medicare spends about 454 million on asthma-related emergency room visits and about 1.1 billion on asthma-related hospitalizations.

If correctly diagnosed and managed, asthma does not have to be a life threatening and costly disease. The goal of this proposal intends to give physicians specializing in

asthma care, primarily allergists and immunologists, the resources and flexibility they need to better diagnose and manage patients with asthma.

The proposal seeks to save costs and improve quality by avoiding unnecessary hospitalizations and ED visits with better diagnosis and management of patients with asthma. Alternative payment model entity, and they describe an asthma care team consisting of an asthma specialist, such as an allergist or an immunologist, a primary care provider, as well as other providers, as needed. Next slide.

The core elements of the program are dividing asthma care into three categories for varying levels of care. These are needed for treatment stage, disease severity, and therapy.

Number one is diagnosis and initial treatment for patients with poorly controlled asthma. The next phase would be continued care for patients with difficult to control asthma, and the third would be continued care for patients with well-controlled asthma.

Beneficiary eligibility and payment around, excuse me, amounts from participating ACT[25]s differ in each category. The PCACP excludes asthma patients with certain comorbidities, such as COPD[26] and lung cancer, and additionally, participating asthma patients are excluded from all performance assessment measures if they fail to stop smoking, obtain certain prescription, or fail to obtain prescription medications or attend scheduled appointments.

Performance on service utilizations, spending, and quality is assessed relative to other participating ACTs, with adjustments to the PCACP payments based on performance.

ACTs must meet minimum quality standards to receive the bundled payments in Categories 1 and 2. The next slide.

We'll go into a little bit more detail about the various categories. The category one is defined as the diagnosis and initial treatment for patients with poorly-

25 Asthma Care Team
26 chronic obstructive pulmonary disease

controlled asthma, and eligibility for this criteria is a new patient with asthma symptoms without a diagnosis in the last year, or those with poorly-controlled asthma, or are on treatments that are not consistent with the current guidelines, or, and are enrolled by physicians at the initial visit.

Payment, bundled monthly payments for up to three consecutive months, replacing some fee-for-service billing for evaluation and monitoring in E&M[27] codes for asthma-related clinical services and collective tests.

Payments are stratified in this particular category, and up to five levels based on patient risk. Initial adjustments and payment would be up or down five percent, payment based on performance increasing to up or down nine percent over time.

Performance measures would include care quality, percent of patients with improved asthma symptoms, improved spirometry measures, reduced ED or urgent care visits, and ratings on practice access.

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Service use and spending, the average number of months to diagnosis of asthma, the price-standardized average total per patient spending on allergy testing, asthma medications, urgent and ED visits for asthma symptoms, and asthma-related hospitalization. Next slide.

So the next category was care for those, continued care for patients with continued difficult to control asthma. The eligibility here, beneficiaries who do not have well-controlled asthma after medication trials are those taking certain essentially high-risk medications or with recent severe symptoms or hospitalizations or significant comorbidities.

The payment, again, is a bundled monthly payment replacing some fee-for-service billing in E&M codes for asthma-related services and selected tests.

The payment in this category is stratified into four levels based on patient risk. Initial adjustment, again, is similar to the previous phase, up or down five percent, or increasing to up or down nine percent over

time.

The performance measures here are care quality, as it relates to improved asthma control, decreased control, and rating of active access.

The service utilization and spending performance measures are assessed using the price-standardized measures, as outlined previously in category one. Next slide.

Category three is defined as continued care for patients with well-controlled asthma, and eligibility here, patients with well-controlled asthma who were previously enrolled in categories one or two.

From the payment perspective, monthly supplemental payment that covers non-face-to-face visits and communication between physician. The performance measures here around quality and just a percent of patients with decreased or worsening asthma control, percent of patients rating access to physician practice as very good or excellent. Service utilization and spending measures use price-standardized average total per patient spending on allergy

testing, asthma medication, urgent and ED visits for asthma symptoms, and asthma-related hospitalizations as described in categories one and two. And that is a very high level review of the proposal.

As we walk into the summary of our PRT review, I would like to start out by saying that there was a great appreciation of this submitter trying to move us forward with our first specialty-oriented APM, and there's clearly a lot of attention to detail in this submission, particularly related to sticking to well-known asthma guidelines from a clinical stratification model that was very detailed.

The PRT committee did find some key issues that influence our thoughts as we review the criteria, so if we move on to the next slide, we'll be starting to go through some of that.

So just at a high level, some of the key issues that we identified was that the proposed model lacks sufficient scope for implementation as a stand-alone APM.

We'll talk about that in a little

more detail as we move forward. With three separate phases, diagnosis, difficult to follow, and controlled follow up, each having monthly evaluation and within each having four to five different payment levels in each phase, determined the patient clinical stratification, we thought that this was a highly complex model. The program includes the potential to maximize bundled payments through patient selection, because the patients are selected at the end of the month after, or at least assigned to a payment model, after the month of care.

The proposal also falls short in its approach to care coordination. In regards to its lack of focus on social determinant, the transportation, copayments, et cetera, in a Medicare population who is known to have more comorbidities, and debility and needs support than most other younger patients might need. Next slide.

The proposal does not clearly identify how the Medicare fee-for-service payment system, as it exists today, causes

failures and ability for a doctor to make an accurate diagnosis, and throughout the document, refers frequently to a focus on the need for increased fee schedule rate.

And next, the proposal may overstate the possibility of saving, citing a 50 percent reduction in ED visits and hospitalization in this Medicare population.

Inclusion of some tests, but not all tests, increases complexity and could further reduce potential savings. Allocation of the payment from the specialist to the primary care physician in the second phase was left unspecified and not clear as to what specific changes in activity this would aim to improve. With that, we'll go into the individual criterion. Go to the next slide.

So scope, the PRT committee felt that from a scope perspective, this did not meet [the] criterion, and the decision there was unanimous. We did agree that no APM and CMS today specifically addressed asthma, and it is a chronic condition with a high prevalence in the general population.

However, looking at various data sources, as you look at patients above 65, the CDC, for example, estimates that from an ER visit standpoint, that there may only be 126,000 visits a year, with about 24,000 admissions, and that the cost of those was somewhat less than we suggested in the proposal.

Also, with the exclusion of certain cohorts from this asthma population, like those that also have concomitants such as COPD would significantly decrease the number of patients eligible for this model, and then some of the data discussed above 60 percent of all asthma patients above 65 reduce the cost of care have concomitant COPD.

Also, taking into consideration, this age population who may already be enrolled in Medicare Advantage or other models, which may also exclude them from this model, continues to push the number of eligible patients even lower. And patients with asthma and, it also participates in other APMs like ACO, where those models were available. Next

slide.

So from a quality and cost standpoint, again, the proposal recognizes the need to facilitate physician engagement and emphasized shared decision making between the patients and provider.

However, the potential Medicare savings, we felt, could be significantly overstated by assuming that effects on improved asthma care in this particular population would be comparable to that in the younger population. Most of the data was around younger populations, and there was most specific data related to the Medicare population. Furthermore, using the submitters numbers of about $1.5 billion of total spent for the ER and hospitalization, even if they were able to decrease those costs by 50 percent, that would result in $750 million in savings, all covered before you removed the patient with COPD, and if only achieved a 20 percent, 25 percent improvement would bring that down to 375 million. Even previous discussions we had with Adam Boehler and CMMI on our goal of trying to

obtain a scale of $10 billion -- that was a significantly lower number than we thought would hit that goal.

And again, the model does not contain provisions to address social determinants of health, as mentioned before. And the model also, again, did not delineate how the care between the primary care and the specialist would look, and what that specifically was trying to insinuate. Next slide.

Criterion 3, the proposal model is, in our opinion, highly complex with multiple tracks assigned by provider assessment within the three main categories, and this is then on a monthly basis.

We felt like this complexity could make it difficult for providers to participate, and particularly for payers to administer. The proposed payment models are based on a monthly risk model, yet a participating provider has discretion to determine which patients are included at the end of each month.

No attribution or assignment is

preferred. Recent improvements in the Medicare physician fee schedule are intended to support these types of care in the PCACP's proposal.

The proposal does not identify, and we felt that this was a significant question, as the proposal does not identify how the present Medicare fee-for-service payment system causes failure in a physician to accurately diagnose asthma or prevent them from ordering the tests or prescribing the medication that a patient needs to successfully manage their asthma. Next slide.

The value over volume, PRT unanimously felt that this does not also meet criteria. The proposed model, sorry, the proposed model provides a payment amount to enable providers to tailor services to patient need, certainly.

The monthly framework and the ability [to] potentially enroll patients that would be financially beneficial to the provider reduces accountability of the sole provider.

The mechanics of the proposal seem insufficient to consistently drive more value

than is what's currently available in the standard fee-for-service model.

The proposed model does not clearly address major known drivers of improved health among Medicare patients, again, determinants of health. Next slide.

Flexibility, we did feel like it met the criteria for flexibility. The proposed payment model would give participating providers and patients flexibility to provide a broader range of services that could be beneficial in diagnosis and controlling asthma, although once the patient commits, the patient is limited to receiving all of their care from that particular specialist during that time period.

However, it is still unclear how the patient's primary care provider and asthma care specialist would work together to improve the flexibility and benefit to the patient. Next slide.

Ability to Be Evaluated. The PRT committee did not feel like this made the criteria, met the criteria. The proposed model

recognizes the importance of evaluation and notes that the types of data that would be available for model participant, including claims, patient-reported outcomes, and EMR data. However, the complexity of the proposed model is that the five payment levels within each phase, and potentially one-month intervals, during each, along the entire course of patient care could make it difficult to evaluate.

It would be hard to determine whether or not the proposed model saves money, given the proposal does not have a present benchmark. Proposed evaluation comparison is to performance by other ACTs, which don't exist today, but even if they did, controlling, comparing ACTs to another ACT, rather than to standard asthma care, we thought was somewhat problematic. Next slide.

Integration of care coordination, we felt like this does not meet criterion. The model emphasizes co-management between primary care, yet does not specify how care would be coordinated between primary care physicians and

asthma specialists beyond what happens, or should be happening today, and how this is improved on. The model does not elaborate on care management outside the office, other than an occasional contact by respiratory therapists. Some practices, such as phone calls to coordinate with other providers, we felt were expected under current standard care.

The proposal also does not address how care coordination might evolve over the course of the model, such as when a patient moves from a difficult to control phase to a well-controlled phase.

Without clear guidelines, the negotiations between the PCACP, payments between providers in each circumstance could be burdensome to providers and practice, and may hinder the coordination.

The model does not identify specific innovations in care delivery or approaches to improve care for patients with asthma that would be included beyond tools already available in a fee for service model. Next slide.

We did believe that patient choice, that that criterion was met. The proposal notes that this enhances patient choice by providing an additional option and desirable services for patients.

On the other hand, patients would be required to commit to receiving all asthma services during the month covered by the payment, which could hinder patient choice from that aspect. Next slide.

Patient safety standpoint, we did believe that it met criteria. The submitters expect that this model would promote early and accurate diagnosis, encourage timely development of care plans, educate patients, facilitate identification of asthma exacerbations early.

The proposal also notes that the proposed minimum quality standard would protect patients from under treatment. The emphasis on provider/patient conversations determining decision making is a strong element of the proposal. Next slide.

From a health IT standpoint, we felt

that it met criteria The proposal indicates that regular electronic communications between specialists and primary care would be required, and the payments in the proposed model could be used to support outreach and remote monitoring through the technology that helps manage asthma and patient compliance.

So again, I would say in summary that our biggest concerns were the scope of the complexity of this payment model and the concerns around how the present fee-for service-model prohibits accurate diagnosis and management of asthma patients today. That's my presentation.

VICE CHAIR TERRELL: Thank you, Angelo. Any comments from either of the other two members of the team, where we ask any about the rest of this if we've got questions for you.

MR. STEINWALD: This is Bruce. I was going to emphasize what Angelo did emphasize in his final remarks, is that we don't, we won't deny that there are certainly some Medicare beneficiaries whose asthma won't be better

controlled over this model.

But I just want to condense that the extent of the problem warrants in a larger model this complexity and it's difficult to evaluate that, and that's clearly the big picture, a problem.

CHAIR BAILET: Yes. And so Grace, this is Jeff. I just wanted to say that I think it's noteworthy that the submitters are trying to get a specialty-based model for allergists and pulmonologists into the field.

I also think that their approach on building out a model that really emphasizes team-based care is important, and I think that Angelo's summarized our overall assessment of the, of the proposal, and I'll save the rest of my comments to address with the submitters. Thanks.

*** Clarifying Questions from PTAC to PRT**

VICE CHAIR TERRELL: Okay. So I've got, I received a message, and, during this from the team that Dr. Kavita Patel lost video and is on the phone.

So since I can't see a tent, I see nobody else that's right now asking questions. It looks like Paul has one. Jennifer, it seems I keep missing you. Are you sure you don't have one? But let's make sure that Kavita also is able to communicate with us if she's got one or not.

DR. PATEL: Thank you. I'll save my question for the presenters.

VICE CHAIR TERRELL: Okay. Paul, do you have a question for the PRT?

DR. CASALE: Yes. Just one of the, one of the issues highlighted here was the complexity, and well-described, and I just wondered, in your communications with the submitter, the submitter, I'd be interested in their thoughts as well. But in your communications with the submitter as you evaluated with it, with them, was there any thoughts around, or is it better, did you obtain a better understanding of why it has to be so complex?

I wasn't sure I clearly sorted that out by reading the material. Is there a way to

simplify it, I guess?

DR. SINOPOLI: Yes, I think that's a great question, and we'd be interested to see how they respond.

In our communications with them, I think their focus was that, from their viewpoint, this seemed to be simpler than the present ICD-10 criteria that doctors have to document today, and so that was, that was their rationale.

VICE CHAIR TERRELL: I'm not seeing any other questions. If you had some, flap your, flap your name. I don't see any. Okay.

Well, hearing or seeing no others, then at this point, we're going to introduce and move on to our actual presenters themselves. So we have three new presenters from ACAAI join us by Webex.

I would like all of you to introduce yourselves, and you have 10 minutes to make opening comments, and then we're going to open it up for questions for all of the PRT members to ask you for clarification of different things about your proposal, and I want to thank

all of you for being here.

So we have three individuals that are, that are going to be presenters. Dr. James Tracy, Dr. James Sublett, and Bill Finerfrock. So I'm going to just turn the mic over to you all and let you have the 10 minutes to tell who you are and tell us about your proposal.

*** Submitter's Statement**

DR. TRACY: Thank you.

(Telephonic interference)

DR. TRACY: My name is James Tracy. I am the --

(Telephonic interference)

CHAIR BAILET: You've got, if you could, if you could mute, just make sure that you are, others on the phone, so you might be getting some feedback from other folks. It looks like, it looks like Bill is lighting up, so he needs to mute. Thanks.

DR. TRACY: Thank you. Are we good?

CHAIR BAILET: Sounds good.

DR. TRACY: All right. Thank you. The, I'm Jim Tracy. I am in private practice in Omaha, Nebraska. I'm an Associate Professor of

Pediatrics at the University of Nebraska, and Associate Professor of Internal Medicine at Creighton University, and Dr. Jim Sublett's also on the call. Jim, could you introduce yourself, please?

DR. SUBLETT: I've got to unmute myself. I'm Dr. Jim Sublett. I've been in practice 41 years, still see patients in our multi-site practice.

I'm the past president of American College of Allergy, Asthma, & Immunology, was Chief of Allergy and Immunology at the University of Louisville for 20 years, before stepping down a couple years ago.

I've been long interested in asthma disease management, and some of the questions and discussions we're having today date back probably 30 years, when that first emerged in the early '90s. We'll explain some of our complexity issues later as we go along today.

DR. TRACY: Bill Finerfrock?

MR. FINERFROCK: I'm Bill Finerfrock. I work as a consultant to the college and the advocacy council on this project and a number

of other issues, and I've been involved in health policy for about 40 years. Thank you.

DR. TRACY: All right. Thank you very much. As, on behalf of American College of Allergy, Asthma, & Immunology, I thank you for the opportunity to discuss our patient-centered asthma care payment proposal.

In my 40 years of practice in medicine, I've been amazed by the number of patients of all ages that come in to me believing that they have a disease, and yet really having that condition often due to misdiagnosis.

Or conversely, patients who do not know that they have a condition or disease, and opportunities are missed. This is true to the case with asthma.

In about 20 percent of the patients labeled as having, as having asthma do not come, do not actually have the diagnosis of asthma. And about the same number are not properly recognized as asthmatic.

In either case, the outcome can be costly in terms of dollars, and of course

quality of life. Asthma is a condition that spans all age groups.

It does not leave the elderly untouched, and the consequences of missed treatment or overtreating can be considerable. The College's proposal is a novel APM, and the first condition-based model designed to support the timely and accurate diagnosis of the chronic condition.

This model is designed for collaboration between patients' primary care physicians and asthma care specialists, holding the asthma care team accountable for both outcomes and costs.

And just as there are consequences with a particular course of treatment, such as cost or side effects, there's also similar consequences in not taking the necessary course of treatment.

Accurate diagnosis is critical, and a necessary step impacting both the outcome and the cost of this disease. This is the cornerstone of the PCACP. The model is designed to achieve multiple objectives.

The first, to ensure accurate diagnosis of asthma, also to promote local delivery of health care, and promote the mechanism by which specialists most able to care for the difficult to control asthma patient are involved in their care.

Improve overall outcomes including decreases in premature death, ER[28] visits, and hospitalizations, obviously reducing overall costs, and finally, to provide a value-driven, integrated asthma care team held accountable for meeting quality and cost measures --

(Telephonic interference)

DR. TRACY: -- specialist, primary care provider, and community-based services. The PRT and the review of January 20, 2020 reported that the PCACP did not meet criteria in six of the 10 criteria specified by the Secretary.

Three were specified as, quote, "high priorities", those being scope, quality, and cost, aim of methodology, and we'd like to address those briefly right now.

28 emergency room

The PRT notes that the limited scope and applicability of asthma in Medicare populations is about seven percent in 2018. We do believe that, although the numbers can vary between 3.5 and 4.4, this number is not a trivial number.

The PRT suggested COPD should've been included in our model. Yes, COPD is common in this population, especially when considering the overlaps combining asthma and COPD, thus making the diagnosis of asthma even more critical.

We chose to focus on asthma and would be happy to discuss our reasoning during the Q&A. As an example, just ask one of my patients, Susan D. She is a 69-year-old retired U.S. Air Force colonel, both underdiagnosed and undertreated for well over 30 years. In her case, she was part of a large integrated health care system where the cost of care and accessibility of care were clearly no obstacles to care.

It was not until being evaluated and managed by a small and attentive allergy

practice that adequate diagnosis and treatment were achieved. Now, at 69 years of age, she's actually able to be more active, sleeps through the night, and has nearly normal lung functions. In addition to a broad scope in authorizing physician-focused payment model(s), Congress specifically instructed CMMI to test innovative models that are, quote, focused primarily on physician services, by physicians who are not primary care practitioners, and to focus on practices of 50 or fewer professionals.

Existing models, such as ACOs, are geared towards large integrated practices or health care systems that have a primary care focus. Many small practices around the country simply do not have the opportunity to participate in these programs.

As Congress suggested, the PCACP model is focused on physician services that will be attracted to small single-specialty medical practices, small multi-specialty groups that may not be a part of an ACO or other large health care system.

Under quality and cost, one of (the) PRT's objections was that our APM probably overstates the potential savings in the Medicare asthma population by assuming the effects of improved asthma care would marry utilization, spending, and savings reported for non-Medicare asthma population.

However, there is no evidence that improved asthma care would be any less benefit for older individuals than for younger adults. In fact, the environmental scan produced by PTAC states that individuals aged 65 and older have the highest rate of asthma-related hospital stays, and that the diagnosis of late onset asthma among the elderly can be a challenging problem and is often delayed.

This suggests potentially even greater cost savings in the Medicare population than with younger adults. Another PRT-stated weakness is that most of the studies cited in the proposal are for younger patients that may not control for the fact that if a patient is involved in a management program, say, due to an exacerbation event, that their expenditure

may subsequently decline regardless of the, of the treatment program that was implemented.

We'd like to point out that most studies of health care interventions for all types of diseases have the same issue. There are no randomized control trials that support current CMS APMs, so it's unreasonable to criticize this proposal on that basis.

The PRT also states that the program's quality measures could be improved by adding objective measures of quality. This model includes objective measures of quality, including spirometry, fractional exhaled nitric oxide, emergency room visits, and hospitalizations. But also note, its subject measures such as patient satisfaction and perception of improvement are appropriate outcome measures even in the MIPS[29] program.

Another weakness per the PRT is that the PCACP does not address payment and care management and how care and payment will be coordinated between the primary care providers and the specialists.

29 Merit-based Payment Incentive System

The proposal explains that patients with well-controlled asthma would be managed by a primary care provider with support by the asthma specialist, and the difficult to control asthmatic patients would be managed by the asthma care team, assisting either of the specialists or the primary care providers with specialist support.

As more care is moved from the specialist to the primary care provider, the PCP would receive a larger share of the bundled payment, although we do not believe it's appropriate to be more specific, as divisions of care may differ based on individual practice and coordination arrangements.

Using evidence-based guidelines, our model seeks to link stratified payment methodology with shared risk, achieving cost savings through fewer or no, preferably, ED visits, hospitalizations, sick care visits, and more efficient use of medications, as well as to improve the quality of life for our patients.

We want to acknowledge the PCACP

would be the first APM that explicitly requires the team-based approach for the management of a chronic condition. This shared team approach would also include levels of shared risk, making this approach especially appealing in Medicare or any other carrier that we, and we believe both specialty, primary care members of, and primary care members of the team.

The PRT was critical of the PCACP's payment model as being overly complex because of three components of care. For those of us that actually take care of these individuals, this is the reality.

In point of fact, many patients do not present with a chief complaint of asthma. Often, it is something else, such as coughing, or wheezing, or shortness of breath. And unfortunately, many who come in with a diagnosis really don't have asthma at all, but they have something else.

Therefore, this appropriate diagnostic issue is really a challenge, and most challenging first step, and it allows for cost savings by correct diagnosis. It's

noteworthy that there are approximately 26 ICD-10 codes for asthma, but there isnearly 52 codes that may be presenting symptoms eventually leading to the correct diagnosis.

We believe that the PCACP is the type of model, the exact type of model that Congress specifically wanted to see implemented when it had enacted the model.

For that reason, we were surprised that when critiquing our model that the PRT suggested on more than one occasion that properly managed ACO could perhaps achieve what we were proposing through this model.

We do not believe that this should be the benchmark against which the physician-focused models are to be judged. We believe that there are many weaknesses identified in the, in the PRT are actually strengths in this model.

Are there things that can be improved that would increase the likelihood that our proposal can add to the quality of life for asthma patients and save even more money to the system? Of course, but these

improvements will, we believe, evolve organically as we learn the lessons of this model and make adjustments and refinements.

But we cannot achieve this until we put this model through a field test to make adjustments where appropriate. Therefore, it's our hope that you will see a sufficient merit in this proposal to recommend the PCACP to the Secretary for testing, so that we can learn from it, make adjustments, [and] refine the process.

We certainly appreciate the opportunity to present our model today. It was a very challenging format, and of course we welcome questions. Thank you.

VICE CHAIR TERRELL: Thank you. And you were right on time with 10 minutes, so I don't know if you've practiced that or not, but that was awesome.

DR. TRACY: We don't practice.

VICE CHAIR TERRELL: Anyway, thank you, Dr. Tracy. At this point, I'm going to open up the questions from my colleagues who would like to ask them, and since we are in

this challenging virtual format, I'll be calling on each of my colleagues who indicate that they have a question or a comment. I'm getting some text here, as is Jeff, to help us state, to make sure we get anybody, because I know we've missed at least Jennifer once in the previous conversation. I'm just going to ask my colleagues that if I say anymore, that you go ahead and get off mute and just interrupt if I miss you. And Dr. Tracy, we're going to actually direct all the questions to you, and then you can determine from your team who you think best ought to answer it.

So with that, I'm going to look and see what we've got going on. I've just heard Jen is number one, so Dr. Wiler.

DR. WILER: Thank you very much. Forgive me, but I have two questions. My first question is based on some of the comments from the PRT, so I would like to give you the opportunity to respond.

The first is the concern around patient selection, and this balance of garnering patient engagement versus what could

be described as risk profiling that's favorable to the provider, but not ultimately to the patient.

Obviously this is an issue we see often with regards to APMs, and that's patient selection, and this balance of feasibility of the payment model to be successful, and then also adequately taking on risk.

That's my first question. And then my second question is with regards to the concern around scope. Obviously, asthma, large problem in the United States, but when we're thinking about payment models that may be specific to Medicare beneficiaries, you addressed this, but I'm curious, why not expand it to other respiratory conditions, including COPD.

And what I'm wondering is, is it because of this concern of taking on risk for a patient population where the outcomes may be more challenging versus that of an asthma population? Thank you.

DR. TRACY: Yes. Thank you. I'll go ahead and get started, then I'll pass it off to

my colleagues. One of the disadvantages of being in this virtual setting, if we were actually in one of these committees, as I am with the FDA[30], I could just kick him under the table.

So I can't do that today. So kind of, I'm going to start with that first question, and there's no doubt that cherry-picking can be an issue, and it's certainly not, as you've pointed out, limited to the APMs with asthma.

One of our, one of our hopes were that we would have already tested this model before we came to you and kind of work out some of those details.

And so no, we recognize that that can happen, and how we control for that is a kind of, was actually a bit of a work in progress. Circling back to the COPD, we looked, before we chose asthma as the diagnosis that we were going to work on the APM, we looked at a number of disease states, and the problem is that as you add complexity, how you measure

30 Food and Drug Administration

success also becomes more complex, so we wanted to take a disease, in this case, asthma, that had fairly decent outcome data with it, and also some fairly stringent issues as far as stratifying between mild, moderate, and severe.

Every time you throw in something else into the mix, you could, you increase that complexity. We, one of the big deals that we faced was that there are a lot of conditions presenting as asthma, for us as immunologists, including ABPA[31] and certainly bronchiectasis. Those are fundamentally different.

They behave differently, both in the clinical sense but also in the practical sense. Dr. Sublett, would you like to kind of comment on the other points that she raised?

DR. SUBLETT: I'd like to make a couple of comments about COPD and asthma. You know, we mentioned that they're, and we've recognized certainly that overlap as a problem.

But the reports of this is, we often will see the Medicare age group come in as diagnosed as COPD but they're actually not

31 allergic bronchopulmonary aspergillosis

COPD, they're asthmatic.

I think there's a tendency for primary care, urgent care, emergency rooms, et cetera, when they see an elderly patient, or an older patient with a chronic lung problem like this, they immediately jump to COPD.

I'll give you an example. I have a lady who I'd followed for a number of years. Came in when she was 88 years old, had a lung history of allergy, and her daughter brought her in because she had been diagnosed as having COPD. A non-smoker.

She had been homebound for a number of years, and I saw her at 88, and was on only albuterol brochodilator nebulizations, PRN[32]. We'd done an evaluation in the office.

Her lung function in the office first day I saw her showed nearly a 40 percent improvement. Fast forward six months later, she was up at 70 percent. Fast forward two years later, 100 percent.

She was not COPD. She was asthma, and we see countless patients like this. But

32 When necessary, from the Latin pro re nata.

contrary to that, and this lady, by the way, lived until she was 103 years old, 15 years after I initially saw her with appropriate asthma management, allergy management, et cetera.

Contrast to that, COPD, the time they hit the Medicare population are usually pretty much fixed obstructive lung disease, and they generally, as we all know, are on a pretty much downward track.

And one of the unfortunate things we see many times is that the people who have been mislabeled are just expected to go on that track, and we can change that. The other thing that I'll comment on, the complexity of asthma is by nature of the disease, and that's why our plan is complex.

The way we look at this, when we first see these patients, as Dr. Tracy mentioned during his presentation, they come in and we're often sorting out various parts of what's going on with them.

Some, about 20 percent wind up not being even asthmatic, and those will not stay

in this APM. They would be moved back over, outside the APM, and hopefully treated for their underlying disease.

What we call laryngotracheal reflux, or vocal cord dysfunction, are frequently misdiagnosed as having asthma, and they can present as fairly severe asthmatics because they're not recognized as having that underlying problem.

So these patients will not remain in the APM. Once they're in the APM, if they're poorly controlled and we get them well-controlled, we'll shift them over to the well-controlled.

And I think that, as Dr. Tracy mentioned, that is one of the key issues, is these are not, we expect a number of these patients to either, after the first phase, to move over and out of that asthma track entirely, and then the ones who do need aggressive management will be on the poorly controlled sector.

We get them controlled. We often will be able to move them over. The other thing

I wanted to mention was the issues, or that you asked for.

So we do have a number of these patients, and by the nature of allergy practices, that we deal with some of the issues around indoor environments, smoking, et cetera, as part of our practice, so that was probably one reason we didn't emphasize that enough maybe in our original proposal. And I'll turn this over to either Jim or Bill, if they have any other comments.

DR. TRACY: Bill, it's up to you.

MR. FINERFROCK: Thank you. I think that, to go back a bit to the, what in essence is the cherry-picking issue, and I think Dr. Tracy referenced this, and it's a common problem with many of the models, but fundamentally, it stems from the fact that the models don't appropriately take into account the comorbidities or the social determinants of health that impact the outcome of the patient and create the incentive on the part of providers to try and select patients that are most likely to have the most positive outcome.

I think what's different here, and has been referenced, is that the front end of it, I'm trying to make sure that we have the appropriately diagnosed patient, and also that they get categorized into the proper area in terms of the model, and the incentive to move the patient from poorly managed to well-managed and adjust the payments to take that into account.

And if they're not managing it, if that's going on, then they get penalized. So I think those are important parts, and as Dr. Tracy said, things that we see as strengths of the model, the PRT seemed to think were weaknesses, but we think if you think of it differently, you'll agree with us that these are actually strengths.

VICE CHAIR TERRELL: All right. I'm going to move us along, because we had two other questions that I see here, and I want to make sure that we've got time to answer everyone's, that you had time to answer everyone's questions. So the next one is Dr. Kavita Patel, I believe is next.

DR. PATEL: Mine's a simple one, and I just, well one, I wanted to thank the submitters. As one of those internists who has gotten a diagnosis wrong myself, and made the COPD diagnosis only to learn it was asthma, yes, I do believe that there's some need for an element of this somewhere.

I also struggled with some of the things pointed out by the PRT. Question I had, and I apologize, because I had a video crash, so I missed about five minutes.

This could be for the submitters, but anybody else in the PRT, if they have the answer. Has there been aspects of this adopted by private payers in any form? Just, we've been talking about the Medicare population.

I could see, because of the prevalence of asthma in commercial populations, has this been something that has been adopted in other places, and could you speak to how that adoption has gone as a payment model?

DR. TRACY: I'll speak to that, Dr. Patel. And then the other committee members --

(Telephonic interference.)

DR. TRACY: The, I -- the short answer is, not that we're aware of. When we crafted this, we actually started developing this with that in mind that this wouldn't be just a Medicare model, but this could be extrapolated at a much broader scale.

But when we look back at it, we can't find anything that blends in the shared responsibility piece along with risk stratification.

Kind of circling back to that cherry-picker question, well so if we risk-stratify our situation, and we, and we have individuals who are going to be sicker, okay, we, they're not going to be -- that will be accounted for in your payment model.

So there's less incentive to cherry-pick with this model because you're stratifying it for the sicker patients. To be frank, we want to take care of the sick patients.

We think we could do a good job, but we also feel like there's a place for stratification so that you don't cherry-pick. Thank you. Anybody else can chime in here.

VICE CHAIR TERRELL: I'm going to move us along, because I think you answered her question. So I think Dr. Jeff Bailet is next with a question.

CHAIR BAILET: Thanks, Grace. Again, I want to compliment the proposed, the proposal submitters for coming up with a specialty-focused physician model, and again, compliment the team-based approach, which I think is one of the cornerstones of how the specialty and primary care community can address better serving patients.

My question, I'm trying to understand the scope. You guys are, have already clearly articulated why you didn't include COPD, and when I looked at the senior population, which this model is targeted for, about 61, almost 62 percent of those folks have COPD and asthma.

And then you also excluded lung cancer, and that's another 3.5 percent. So just on the math, about 65 percent of the population of Medicare folks with a diagnosis of asthma also have exclusion criteria.

In addition to that, there are folks who get eliminated if they are smokers and they don't cease to smoke. And just, again, in my back of the napkin, and you guys can confirm this, but from what I could be, what I could ascertain about 18 to 20 plus percent, 20 percent, let's say, of seniors who have asthma are smokers, and of those smokers with asthma, it looks like -- the literature looks like about 20 percent of those actually quit within the first or quit and have quit by one year.

So I'm just trying to understand, what is the universe of patients at the end of the day that this model would apply to? Thank you.

DR. TRACY: Dr. Sublett, you want to take that?

DR. SUBLETT: Well I've already mentioned the high rate of misdiagnosis. I expect that some of those 61 percent of COPD-ers are actually asthmatic.

My work over the years with disease management, and I worked with a large managed care company two years back, and they were

working on COPD, and I met with the group, and I brought up the fact of overlap, and actually that some of them were asthmatic, and there was this deer in the headlights look, that it's not even considered.

And I think that the numbers are probably, you know, my feeling is they're not accurate. I think as we get into this, we'll find a lot more asthma that are not COPD-ers than people realize.

As I mentioned already, a lot of the diagnosis probably comes from primary care, who don't have facilities in their practice fulfilling the spirometry. The use of fractionated nitric oxide has really helped in determining whether patients, including those who are smokers, and may actually be asthmatic.

I think the other thing, we're seeing an aging population, and we know that the numbers are actually probably pretty, I've looked at the recent CDC data, and you can just about roughly say that about 10 percent of the general population are asthmatic.

Pretty much across the board, the

numbers fluctuate up and down a little bit year to year, but if you look at the overall numbers. So as we expect the Medicare population to increase over the next few years, we're going to see more and more likely patients that are asthmatic.

The issue addressing smoking cessation, that's been built into the practice of allergists. That's what we do every day when we look at patients, is their triggers, and I've actually spent most of my career working on things like small particulates, diesel particulates, pollution, et cetera, that affect asthma.

That's something we'll counsel patients on. We're not going to give up on them. I think, I think the issue in general was non-adherence, and that's an important factor in any kind of line of disease management, or whether you keep beating your head against the wall of people that are non-adherent.

We'd expect that number to be fairly low in this kind of population management approach. Bill, you may have some additional

information on the population we except to see.

MR. FINERFROCK: Not of any great amount. I mean I think your point was the one I would've made, which is that, you know, we're going to see a dramatic increase in the number of Medicare beneficiaries, and there's no indication that asthma is going to be any less prevalent.

And so as those numbers go up, I think it's going to be an even more significant population, and the opportunities for savings moving forward, not just looking at what we see today, and looking in the, looking in the past, but projecting forward that this is something where there's a real opportunity to achieve a different way of providing care, or provide savings to the Medicare patient, and improve the quality of life and the quality of care to that population.

DR. TRACY: And I'll just, I'll just add too that a lot of these issues, such as smoking, we talked about this briefly, compliance would be, we believe it would be better in the integrated plan that we're

suggesting.

VICE CHAIR TERRELL: I have some questions, but I want to make sure that Charles and Paul and Angelo don't have any. I didn't get any message that you did. Angelo, do you have any questions? Somebody's telling me I'm supposed to ask you that.

And we're not hearing you if you're -- you may be on mute.

DR. SINOPOLI: Hello?

VICE CHAIR TERRELL: Hi.

DR. SINOPOLI: Can you hear me?

VICE CHAIR TERRELL: Yes.

DR. SINOPOLI: Okay. What I'd like the team to comment on is how they feel this Alternative Payment Model would solve what sounds like an inability of the present fee-for-service model to allow a doctor to make an accurate diagnosis, and what about the fee-for-service model impedes that accurate diagnosis?

DR. TRACY: Well there's several things. First of all, and I should tell you, this was kind of pre-COVID a little bit here, but we, when we looked at this, a lot of the

things that we sort of feel should be a critical element, which would include, by the way, telemedicine, those really are not, again, pre-COVID, were not particularly compensated well for by Medicare.

And a lot of the other things that we believe are part of the team, really although some of them are technically included, the practical reality is that the reimbursement was pretty tough. And plus, there was a fair amount of fragmented care.

I mean we hope that this will kind of get to that point, but in any time when you're having a fee for service, you're incentivizing to see the patient perhaps even more than you were before, and doing things that you may not necessarily need to do or want to do. Dr. Sublett, do you want to comment on that at all?

DR. SUBLETT: I think, I think looking at this from our standpoint of patients we see, the fee-for-service discourages, especially primary care from having the time to spend with these patients for counseling.

We're talking about smoking cessation, but one of the big factors is avoidance of triggers and that sort of thing that we can counsel.

Medication adherence, actually some allergists actually have the ability to do detailed environmental assessments, and now that we have, you know, telehealth available, that would be one aspect we could incorporate.

We talked about a lot of these things theoretically, but I think it's -- Jim just mentioned telehealth. In this, in the, you know, the populations that we deal with, there's a much higher rate of African Americans who wind up in the hospital, who die from this disease, about four times the rate of the general population.

Those kind of patients, with some of the other additional benefits of counseling and so forth we bring to the table in our practices would benefit, and working with primary care.

You know, primary care is interested in this disease, but I think their time that they can spend with the patient is so limited

that, especially in the difficult to control patients, we're able to bring that to the table, and working as a team results in much better service than standard fee-for-service that we see now.

VICE CHAIR TERRELL: Thank you. Any questions from Paul or Charles? You don't have to have any if you don't want to.

DR. CASALE: I don't have any questions. Thank you, Grace.

VICE CHAIR TERRELL: Okay.

DR. DESHAZER: And no questions from me. Thank you.

VICE CHAIR TERRELL: All right. I have just a very quick question, and that's related to the fact that this is very specific to allergy and immunology and primary care, but at least in my experience as an internist, asthma involves other specialists quite often as well, such as ENT[33] gets involved sometimes as it relates to hoarseness or vocal cord dysfunction.

Certainly, the pulmonologists take

33 Ear, Nose, and Throat Specialists

care of a lot of asthma in my community, and the gastroenterologists certainly do as a result of the fact that 60 to 80 percent do have GERD[34], at least in certain statistics, as well as things like eosinophilic esophagitis.

So I guess my question is, by limiting it to one specialty, which is really intentional in that you're looking for a specialty primary care-themed basis, my question is: what is the role for the other, rest of the team members that potentially may need to be involved in the care, or in certain communities, would be involved in the care of patients with asthma?

DR. TRACY: You know, I am so glad you asked that question. So when we started this modeling, in your, in the initial comments, when they were kind of going through the model, I think we've talked about allergists and immunologists.

So our starting point when we started this thing was that it wasn't going to be, even at the specialty level, just

34 gastroesophageal reflux disease

allergists and immunologists. It's asthma care specialists.

Somehow pulmonologists got left off the slide, but I want to make it really clear that we include pulmonary in this. Basically, in order to get CMS to buy off on this, which would be our goal obviously, we have to, this has to be attractive to all the stakeholders.

So when we looked at this, we looked at it, so what would be attractive for allergists and immunologists? Well that's what we are, so we knew that was pretty straightforward.

Definitely pulmonologists, for sure, depending on where you are in the country, but also to family doctors, pediatricians, and internists. So that's the big picture. So let's circle back to the other guys. So in GI[35], it's definitely an issue. That's something that's going to evolve with time. Clearly, that's relevant. There's no doubt the ENT, and it's not just with vocal cord dysfunction.

Sinus disease is probably even a

35 Gastroenterology

bigger player and very expensive. We actually considered looking at sinus disease as one of our APMs.

The complexity is colossal, and as challenging as asthma is you start blending in a surgical and a non-surgical specialty with those two stakeholders, then you've got conflict on you.

So we recognize that they're there. How that actually evolves in the models, should it be implemented, is definitely a work in progress. Thank you.

*** Public Comments**

VICE CHAIR TERRELL: Okay. Well, thanks, thank you, and if there are no, I'm going to assume there's no other questions from our commissioners, and we have four individuals from the public who have signed up for public comments, and I am going to open it up to each of them in order.

And because of our time constraints, I'm going to be pretty strict about this three-minute rule here. And so I'm going to start with Harold Miller, President and CEO of the

Center of Healthcare Quality & Payment Reform, and look forward to your comments, Harold.

MR. MILLER: Thank you, Grace, and thank you everyone for the opportunity to talk. I sent you all a lengthy letter several months ago, which I hope you had an opportunity to read. I'm going to focus today just on a couple of areas. At the very beginning of your meeting, Administrator Verma talked about the important role that telemedicine has been playing over the past several months.

I think the broader lessen is how dramatic the change in care delivery can occur when CMS changes the payment rules. And it also shows how Medicare, in fact, can lead when everybody wants to know if the private sector has done something first.

In this case, Medicare did it first. The concern now is how do you actually continue some of those services after the pandemic? And you have a proposal here that specifically allows telehealth as part of the payment model.

I was really disappointed to see that the PRT report didn't even mention that

fact. And Administrator Verma and Jeff, at the beginning of the meeting, talked about the negative impact on physician practices with the loss of office visit revenue.

This proposal has a monthly payment model that would actually provide more predictable revenue to the specialist, and the PRT report, again, is actually inaccurate, describing that aspect of the payment model.

The traditional concern about telemedicine has been that it will increase costs by creating yet more fees for services. The concern about monthly payments has been that they're too simplistic, and that they'll actually decrease access for high need patients.

So this proposal I think actually does a really good job of trying to address both of those things. Unlike any other model the CMS has, under this model, there is no payment at all if minimum quality standards aren't met, and there's a clinically nuanced risk stratification. I think it's very unfair to criticize as overly complex something that's

trying to be nuanced and patient-focused and is actually less complex than most of the other existing CMS models are.

Finally, you know, there are very few APMs for any specialist. Certainly none for allergists or pulmonologists, and none specifically for asthma, yet the PRT is encouraging people to simply do this through existing primary care medical home models and ACO models, even though those models are generally focused on trying to encourage PCPs to keep patients away from specialists.

The APMs that specialists submit are typically criticized because they fragment care. This is the first APM ever that actually proposes payments specifically designed to focus specialty care on a subset of patients who need it and to support coordination with PCPs.

It could certainly work inside of ACOs, but it can also work very well for small practices in rural areas that don't have the opportunity to participate in ACOs, or for patients who don't need anything more than good

asthma care.

Jeff, at the very beginning, described your vision as being a focus on front line providers and their ideas. In this case, that happens to be allergists that brought it forward, a model focused on asthma, but I think this model could be adapted to many other specialties.

So I think the only way though we're going to know really how it will work is to try it, and we've seen what a dramatic change there has been in the way carriers deliver recently when we actually tried to do something differently.

So I hope that you will actually recommend doing that here, that CMS try this so we can see how well it works rather than simply speculating about that. Thank you.

VICE CHAIR TERRELL: Thank you. Thank you, Mr. Miller, and I'm going to move now to Sandy Marks, Senior Assistant Director of Federal Affairs at the American Medical Association.

MS. MARKS: Thank you. Good

afternoon. I'm Sandy Marks, and I'm pleased to be making comments on behalf of the American Medical Association. More than 25 million Americans have asthma, including 4 million aged 65 or older.

Every year, there are more than a million emergency department visits, and more than 100,000 hospital admissions due to asthma. Medicare is spending more than $1 billion per year on asthma-related hospitalizations.

Many of these ED visits and hospitalizations occur because people with asthma are not correctly diagnosed and treated. Black and Latino people are disproportionately affected by asthma.

Our Surgeon General, Jerome Adams, has spoken eloquently about his own asthma and the inequities in treatment for minorities. Five years ago, the American College of Allergy, Asthma, & Immunology began developing a patient-centered approach to asthma.

They wanted to see asthma specialists and primary care physicians working together in teams to correctly diagnose

patients with asthma-like symptoms, and then treat them in the most cost effective way.

They wanted more complex patients to receive more intensive services in order to reduce hospitalizations and mortality. They found it impossible to deliver this patient-centered approach under fee-for-service, so they developed an APM to remove the barriers to better asthma care.

The APM is designed to work for diverse practices, large and small, and rural and urban. We were disappointed that the PRT failed to recognize the significant benefits of this approach.

Most PTAC reports have been more balanced, assessing strengths and weaknesses, determining if the benefits outweigh any concerns, and suggesting what could be done differently.

The AMA[36] believes that proposed care delivery model is exactly what is needed for patients with asthma, and that similar approaches are needed for other chronic

36 American Medical Association

conditions.

Several major advantages of the proposed APM were not recognized in the PRT report. The APM is specifically focused on improving health outcomes for patients with asthma, not just reducing spending.

A significant flaw in other episode models is that they assume patients are diagnosed correctly, and that the treatments are the right ones. The asthma proposal explicitly supports diagnostic accuracy and the effort involved in finding a treatment plan that actually works.

Instead of treating all patients as if they are the same, and penalizing physicians who have higher risk patients, the proposed model explicitly focuses resources on the highest need patients.

We believe this kind of approach is essential for improving health equity in this country. For these reasons, the AMA urges you to recommend implementation of the patient-centered asthma care payment proposal. Thank you.

VICE CHAIR TERRELL: Thank you, Ms. Marks, and I'm now moving to Dr. Stephen Imbeau, Allergist and Immunologist.

DR. IMBEAU: Thank you, Madame Chair and committee. I am an allergist asthma doctor in a small practice, in a small town, in a small state, South Carolina.

Thirty percent of our patients are Medicare, and that is, there's basically no enhanced Medicare here. They're all just regular Medicare. Thirty percent are Medicaid, and that, on the other hand, the flip of Medicare, is mostly managed care Medicaid.

And 40 percent are private insurance, which happens, in South Carolina, to be Blue Cross. I live in a region of a million people.

There are no large employers, so we have no ACOs, and we have, as I already mentioned, almost all of just straight Medicare. We, of course, are limited by the Atlantic Ocean by our radius.

I must admit I have been surprised this afternoon, listening to this, that it is,

the model is viewed as complex, and that we are not handling environmental issues.

First of all, I am proud, there's only 5,000 allergy asthma doctors in the United States that are certified allergy immunology as internists or pediatricians.

And so I'm really proud to be part of a small specialty that has done this model. For us, it's not complex. It's what we do every day, and we do well at it.

So I certainly don't, as a sort of a normal guy in the trenches, I don't view this as complex. I'm also surprised about the environment, because smoking is a big deal.

It triggers asthma, it can cause other lung diseases, of course, but it's a major trigger for asthma. We're about as anti-smoking as any doctor you're going to find.

It's part of our normal deal, part of our normal instruction, part of our normal treatment and evaluation process, and including diet and environmental issues, particularly with mold and house dust.

It's interesting to me that,

particularly in the last six months, I have seen an increased referral to our practice from the Medicare population in my local community. Several reasons.

One is, in this time of national emergency, older patients who almost immediately have pneumonia ruled out in the emergency room are just sort of left there, and then finally sent home on oral steroids, so their family doctors say, you know, that's not the right way to treat asthma, and they send them to us.

Just last week, I saw a patient with status asthma actually. Before I saw him of course, he sat all day in an emergency room, and then we were able to make the diagnosis and offer substantial help.

We've been seeing that lady now every week until we can get her stabilized. So there's a real need for this kind of model and cooperation with our family doctors and with our emergency rooms.

I am surrounded, we are surrounded here by two major competing hospitals in this

small town. They don't employ allergists because we don't bring revenue to them, but we can certainly work with their physicians and their family doctors in particular are very anxious for the education that they can get from this model, and the understanding of what we do. The value of spirometry, the value of what we call FeNO[37], the value of methacholine, the value of allergy testing and allergy treatment, because even Medicare patients have allergy, despite what you all might think. So I think --

(Simultaneous speaking.)

VICE CHAIR TERRELL: -- stop now, sir.

DR. IMBEAU: -- this model brings an important thing to the small town and the small rural environment. Thank you.

VICE CHAIR TERRELL: Yes. Yes, thank you very much. I apologize, but we need to move on to Dr. J. Allen Meadows, President of the American College of Allergy, Asthma, & Immunology.

37 fractional exhaled nitric oxide

DR. MEADOWS: All right. Thank you so much for the opportunity to make comments. I am president of the American College of Allergy, Asthma, & Immunology, but I'm coming today as a physician in private practice, a solo practice here in Montgomery, Alabama, and like Dr. Imbeau, it's a relatively rural area.

I helped with the development of this, starting five years ago. I haven't been involved with it very much recently, but with the mind that anyone could participate in this, whether you're in a big practice or whether you're in a small practice.

And many of the top-down solutions that have been proposed, I just can't participate in them. I don't have access to [an] ACO, and I am all in favor of payment reform.

Oh my gosh, we need payment reform, and I want to work with my primary care physician, but they're just, some of the solutions that are available now are just something in a small community like mine, I can't access.

The payment issues have been mentioned. I mean, when, what an alternative payment plan like this will open up for me is that I'll be able to afford to buy a nitric oxide machine.

The payments for the nitric oxide in my community are so low that I can't even pretend to break even. The same with telemedicine or using a social worker to ensure adherence.

Those are just things that I don't have access to in a small area where we don't have ACOs. I know there's been comments about how complex this is, but like Dr. Imbeau said, this is what we do every day.

This isn't complex to me. What's complex to me is trying to form an ACO or join an ACO and follow, and follow all those rules. In closing, I'm just reminded of a patient in a nearby community, that's actually Auburn-Opelika, a smaller community than mine, but they do have a large integrated group there, and was referred a patient over there for allergy testing, a lady that had COPD.

Well as it turns out, this lady didn't have COPD. When we made the right diagnosis and got her on the right medicines, she had reversible lung disease, and her quality of life improved dramatically. And the big system failed her.

And so I would ask the committee, and thanks so much for that, and give us a chance on this one. We want to do something different. This is a tremendous opportunity for us, and I appreciate the opportunity to comment. Thank you.

VICE CHAIR TERRELL: Thank you very much to all of our public commenters, and we had no other commenters after him, so before we proceed to the voting, I want to make sure that all of my fellow commissioners, do you have any other comments, questions, or anything before we move on?

Bruce, I apparently failed to ask about you last time. For that, I apologize.

MR. STEINWALD: Apology accepted, but I have no additional comments.

*** Voting**

VICE CHAIR TERRELL: Okay. All right. So let's begin the voting process, and Jeff went over this morning the methodology, and unless there's an objection, I'm not going to go over that again, but essentially we have 10 criteria we are going to vote electronically to do that.

And then after we've gone through the criteria, we will then vote whether to recommend it with a recommended; or not recommended with a recommended with high priority; or whether to refer for further attention on the part of CMS and CMMI.

So let's go ahead and go. I'm going to have to go back down here and sign back into my app, and we will go to the next criteria.

All right. And I have mine opened. I'm going to assume everybody else has theirs open too.

*** Criterion 1**

VICE CHAIR TERRELL: So the first criteria is scope, high priority, aim to either directly address an issue in payment policy that broadens and expands to the CMS APM

portfolio, or include APM entities whose opportunity to participate in APMs has been limited.

Everybody go ahead and vote. All right. They're all in. I'm going to turn it over to Audrey.

MS. McDOWELL: I am going to expedite the reading of the results. Zero members voted 6, meets or deserves priority consideration; zero members voted 5, meets; two members voted, excuse me, one member voted 4, meets; two members voted 3, meets; four members voted 2, does not meet; one member voted 1, does not meet; and zero members voted, excuse me, 0, not applicable.

We need a majority, which is, a simple majority, which is five votes in this case. And so in this case, for the Criterion 1 scope, the majority has determined that the proposal does not meet Criterion 1.

*** Criterion 2**

VICE CHAIR TERRELL: All right. Let's move to Criterion 2, please. This is quality and cost anticipated to improve health

care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

Go ahead and vote, please. Already voted, so Audrey, tell us what we've got going on here.

MS. McDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; zero members voted 4, meets; five members voted 3, meets; two members voted 2, does not meet; one member voted 1, does not meet; and zero members voted 0, not applicable. The majority has determined that the proposal meets Criterion 2.

*** Criterion 3**

VICE CHAIR TERRELL: All right. Let's move to Criterion 3, please. This is the payment methodology, high priority criterion.

So the payment methodology, it would pay the Alternative Payment Model entities with a payment methodology designed to achieve the goals of the PFPM criteria.

It addresses in detail through this

methodology how Medicare and other payers, if applicable, pay the APM entities, how the payment methodology differs from current payment methodologies, and why the physician-focused payment model cannot be tested under current payment methodologies. Please, everybody, go ahead and vote.

MS. McDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; one member each voted 4, meets, and 3, meets; five members voted 2, does not meet; one member voted 1, does not meet; and zero members voted not applicable. The majority has determined that the proposal does not meet Criterion 3.

*** Criterion 4**

VICE CHAIR TERRELL: Let's move to Criterion 4, please. Value over volume, it provides incentives to practitioners to deliver high quality health care.

MS. McDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; one member voted 4, meets; three members voted 3, meets; three members voted 2,

does not meet; and one member voted 1, does not meet; and zero members voted not applicable.

We need a simple majority, which is 5 votes. At this point, we do not have 5 in either the meets or does not meet category, so I don't know if you would like to have more discussion.

VICE CHAIR TERRELL: Let's move through all the rest of them and come back for more discussion if we need to, okay?

MS. McDOWELL: Okay.

VICE CHAIR TERRELL: Let's move to the next one. Can we do that?

MS. McDOWELL: Yes.

*** Criterion 5**

VICE CHAIR TERRELL: All right. The fifth is flexibility. Provides the flexibility needed for practitioners to deliver high quality health care.

MS. McDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; two members voted 4, meets; three members, excuse me, six members voted 3, meets; and zero members voted 2 or 1, does not

meet, or 0, not applicable. The majority has determined that the proposal meets Criterion 5.

*** Criterion 6**

VICE CHAIR TERRELL: Let's go to Criterion 6, please. Ability to be evaluated, have evaluable goals for quality of care costs and other goals of the PFPM.

MS. McDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; zero members voted 4, meets; two members voted 3, meets; five members voted 2, does not meet; one member voted 1, does not meet; and zero members voted not applicable. The majority has determined that the proposal does not meet Criterion 6.

*** Criterion 7**

VICE CHAIR TERRELL: Let's go to Criterion 7. Integration and care coordination, encourage greater integration and care coordination among practitioners across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the payment model.

MS. McDOWELL: Zero members voted 6,

meets and deserves priority consideration; one member voted 5, meets and deserves priority consideration; zero members voted 4, meets; two members voted 3, meets; four members voted 2, does not meet; one member voted 1, does not meet; and zero members voted not applicable. Simple majority is five votes. Therefore, the majority has determined that the proposal does not meet Criterion 7.

*** Criterion 8**

VICE CHAIR TERRELL: Move on to Criterion 8, patient choice. Encourages greater attention to the health of the population by also supporting the unique needs and preferences of individual patients.

MS. McDOWELL: Zero members voted 5 or 6, meets and deserves priority consideration; one member voted 4, meets; seven members voted 3, meets; and zero members voted 2 or 1, does not meet, or 0, not applicable. The majority has determined that the proposal meets Criterion 8.

*** Criterion 9**

VICE CHAIR TERRELL: Okay. Criterion

9. Patient safety, aim to maintain or improve standards of patient safety.

MS. McDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; four members voted 4, meets; four members voted 3, meets; and zero members voted 2 or 1, does not meet, or 0, not applicable. The majority has determined that the proposal meets Criterion 9.

*** Criterion 10**

VICE CHAIR TERRELL: Criterion 10, health information technology. Encourage use of health information technology to inform care.

MS. McDOWELL: Zero members voted 6 or 5, meets and deserves priority consideration; two members voted 4, meets; six members voted 3, meets; and zero members voted 2 or 1 or 0, does not meet or not applicable. The majority has determined that the proposal meets Criterion 10, health information technology.

VICE CHAIR TERRELL: Okay. All right. I thought it might be helpful to do what we just did, which was to go through all of them

before we go to the Criterion, what was it, number 5, if we could go back to that slide that we split on.

CHAIR BAILET: It was 4, Grace.

VICE CHAIR TERRELL: It was 4, okay. And this was a high priority one, and we split such that there was not a majority, as was required between the eight of us, another reason we need more members so that we won't have that happen perhaps in the future.

I don't know that we need to spend a lot of time on this, but I wanted to open it up for any comments. We could certainly do another, you know, round of voting, but I think a larger issue is the, is the overall voting, but I just wanted to open it up to comments, if anybody had anything they wanted to add to this, since we go through this whole process. I'm not hearing any. Is that correct? Okay.

So I, we really don't have, do we, these are the criterion. Do we have to come to a consensus one way or the other on this by the bylaws, or can we just say that it was a draw and go onto the overall vote?

MS. McDOWELL: If we're not able to, let's see here.

MR. STEINWALD: I think it, I think it rolls down.

VICE CHAIR TERRELL: It rolls down. Okay. Well, if it rolls down, then it would be, it does not meet then. Okay. All right. Now, let's go on to the, to the voting on the overall recommendation.

So the next part of our voting, we're going to vote again electronically, and this is a two-part voting process.

So there's three categories that we're going to vote on. The first is not recommend for implementation as a PFPM. The second one is recommended, and lastly, referred for other attention by HHS.

So we need to achieve two-thirds of a majority of votes for one of these categories, and then if the two-thirds, we can then vote on a subset to basically determine the overall recommendation to the Secretary.

A second vote is for the following four categories, which is the proposal

substantially meets its criteria. The second category is that we recommend further developing and implementing the proposal.

The third is that we would recommend testing the proposal as specified in the comments, and lastly, that we would recommend it, implement it as part of an existing model, but that part of the voting would only occur if it was put forward or recommended to go forward with it.

*** Overall Vote**

VICE CHAIR TERRELL: So I'm going to now have everybody vote, and then we'll see which way we go with this. Okay. Audrey, do you want to go through the results there?

MS. McDOWELL: Sure. Three of the members have voted not recommend for implementation as a PFPM. One member has voted recommended, and four members have voted referred for other attention by HHS.

In this case, we need to have a super majority, which would recommend, which would represent six votes. We currently do not have six votes in any of these three buckets.

MR. STEINWALD: This is Bruce. I would like to hear what people had in mind when they voted refer.

VICE CHAIR TERRELL: Yes. Yes, I was going to say the same thing. So let's go around and hear about the voting, and what people were thinking, and then we will potentially have the opportunity to re-vote.

I can tell you that I will start, that I was the one that recommended that we implement it. So I don't know that I agree with the PRT about anything.

I do think that there is a component of the model that's very important in that it brings in more than one specialty. It's working on a collaborative effort.

It's for a component that may not be able to be part of an ACO or other types of Alternative Payment Models, and I do think that it could be something that, within a more narrowed scope, would be appropriate to recommend that CMMI work with.

I was a little concerned when, it may have been Angelo or one of the other PRT

members, said that it didn't meet the current criteria of the Secretary from the point of view of scope, as that it was not a large portion of the Medicare population.

I'm not sure that that particular criteria, since it's not part of the 10. It's one that I am going to be able to think through as it relates to specialists, who, themselves, may actually take care of a large number of people like this.

So having said that, I will, I will change my recommendation to refer. Now, that won't get us to the two-thirds majority, but that does let you know where I was coming across from that.

And now, just to keep things going, I'm going to turn it over to Jeff to talk about his recommendations.

CHAIR BAILET: Yes. Thanks, Grace. And I recommended to refer. I don't think the model, as it stands, is sufficiently worked out for implementation, but I do think there are lots of elements, many of which have been touched on today, that warrant further

exploration by CMMI, because I do agree that, as the population ages, asthma will become more prevalent.

It is a complicated diagnosis, particularly in older patients. I think there is some value on the payment and the savings, and the amount of collaboration between the specialists and primary care that still need to be worked out.

So I do think the model warrants further evaluation, not, I guess one other comment I would make is we need to get specialty models out in the field.

Harold's comments highlight that, and I think there's enough, there's enough of a framework here that, with CMMI's attention, I think they could get a model out to serve this up to the specialists listed here, and potentially other specialists that take care of asthma patients, as Dr. Tracy mentioned.

VICE CHAIR TERRELL: Thank you, Jeff. I'm going to go to Paul now.

DR. CASALE: Yes, thank, Grace. My comments would echo yours, and Jeff, I voted to

refer, and I do think, you know, specialty models are needed.

On the scope end, you know, although I understood the comments about not including COPD, but in the Medicare population, I think this model would actually be strengthened if COPD would be included under the scope, and I do think there is some work to be done, particularly on the payment methodology.

So I certainly think there are pieces of this that, as the PRT and the submitters said, that could also be potentially useful for other chronic conditions. So for all those reasons, I voted to refer.

VICE CHAIR TERRELL: All right. Thank you, Paul. I'm going to move to Charles now.

DR. DeSHAZER: Yes. I also voted to refer for some of the same reasons Paul and Jeff have mentioned, and the thing that's intriguing to me is the fact that I kept hearing the issue of misdiagnosis, particularly for the Medicare population, and I wasn't completely convinced of the payment model, that

addressed that directly, but it does seem like more collaboration and joint management would support addressing that misdiagnosis aspect.

It does sound like this there is built into it the consideration of social determinants, and those factors, which was an earlier concern. I do think that the complexity issue can be worked through.

I don't think it's overly complex. Coming from an informatics background, the maturity of the data and analytics today should be able to allow us to do assessment and for those to be evaluated.

And I think the, you know, I think also when I heard in the comments that this will support smaller and rural practices as well, to kind of get them onboard in terms of disease management, from that standpoint, and allow them to be able to invest in some of the infrastructure, and overall, I just think it's, it may, you know, full evaluation may provide a way to begin to think about other specialty APMs as well. So for those reasons, I thought it was worth referring.

VICE CHAIR TERRELL: Thank you, Charles. Moving to Kavita.

DR. PATEL: Yes. I initially voted to not recommend, but I've been swayed by my colleagues to change to the refer category.

VICE CHAIR TERRELL: Okay. Angelo?

DR. SINOPOLI: Similarly, I've noted not to recommend, based on a lot of different factors. I do agree that the need to have a specialty APM is significant, and I do agree that with some significant work, this could, I believe, be turned into something that would be easily administrable, and the payment model could be worked on.

So whether the submitters worked on that and resubmit it, or whether CMS or HHS works on it, I think I'd be comfortable either way. So if the group feels like referring is the end result, I'm comfortable with that.

VICE CHAIR TERRELL: Okay. Moving to Bruce.

MR. STEINWALD: I voted not to recommend, but I intended to vote for refer. I'm not really changing my mind, I'm changing

my vote. But I also think that this is channeling Bob Berenson a little bit.

He was a previous member, but he often said if we perceive that there is a problem or a need, we ought not to exclude looking at the fee schedule itself, rather than PFPM.

And I think that ought to be part of their referral is to make sure we examine the fee schedule and determine whether some of the issues raised by the presenter could be addressed once a month with patient care.

And unfortunately, CMS is siloed in this respect. The people who develop models, and the people that manage them, and might apply to fee schedule, or in different countries and things, and often, they don't have a chance to sort of debate what's the better approach. And so I think that's something we should note here.

VICE CHAIR TERRELL: Thank you, Bruce. Moving finally to Jennifer.

DR. WILER: I voted for refer for all of the reasons previously stated, and the other

that I will add is there's clearly engagement and interest in the stakeholder community and some valuable comments that were given to us for consideration, and I thought it was valuable to recognize that as an opportunity to include this category of patients in another payment model, or to refine both the care delivery model, meaning expand the scope to other respiratory conditions, or to refine the payment model.

VICE CHAIR TERRELL: All right. Thank you. I think, I'm hearing that refer is going to pass this time, but let's go ahead.

Can we open the polling back up, please, so we can officially do that? It still says, okay, there it is. All right. Well, look there. Audrey, do you want to give the results?

MS. McDOWELL: Eight members voted to refer for other attention at HHS, and so the finding of the committee is that the proposal should be referred for other attention by HHS.

VICE CHAIR TERRELL: All right. So that concludes this part of the PTAC. I believe you got the comments from everybody, if we can

go offline subsequently, if, to make sure that as we're writing the report, that all of the points get made.

There was the opportunity, I believe, if we had 15 minutes, which we do, for a special sort of short presentation from NORC. Is that still going to happen?

MS. McDOWELL: Yes. Grace, can we just confirm that there are no other comments that the committee members want to --

VICE CHAIR TERRELL: Sure.

MS. McDOWELL: -- have included in the report to the Secretary?

VICE CHAIR TERRELL: Okay. Somebody has a comment.

DR. STEARNS: Audrey, do you want me to do any summary, or that would be later?

MS. McDOWELL: I guess the other question would be, Sally, do you have any questions for the Committee members, or do you think it's pretty clear what they want included in the report to the Secretary? Can you give us a quick summary?

*** Instructions on Report to the**

Secretary

DR. STEARNS: Sure, I'll give you a very quick, I think it's very clear. PTAC appreciates and recognizes the development of a specialty-focused model that involved a team-based approach of, could be very beneficial, not only for asthma, but for other conditions.

A couple points about asthma being costly and often misdiagnosed. So in total, there is belief that an APM model that supports smaller and rural practices, as well as larger practices, is needed, possibly very, possibly especially specific.

There's also, in support of the model, there's evidence of engagement and interest in the stakeholder community. There are still a lot of concerns with the payment model, but by referring the model, some of those concerns could be worked out, and I've got some specific statements of those that will be in the report to the Secretary.

VICE CHAIR TERRELL: Thank you. All right. Do we still have time for the brief presentation?

MS. McDOWELL: Yes.

VICE CHAIR TERRELL: Okay.

*** Discussion: Reflecting on Models Deliberated on By PTAC**

DR. SHARTZER: Hello, everyone. I'm Adele Shartzer, and a member of the contractor support team. I'm pleased today to present with my colleague, Laura Skopec, highlights from two analyses we conducted in February for ASPE and PTAC, which were slated for presentation at the March meeting.

We've made a few minor updates to the slides since then. The full reports are available on the resources page of the ASPE PTAC website.

These slides and accompanying appendix materials will be posted there as well. I'll discuss findings from our review of proposals submitted to PTAC as of December 2019. Next slide, please.

Between December 2016 and December 2019, 34 proposed physician-focused payment models, or PFPMs, were submitted to PTAC for review.

This presentation focuses on the 24 proposed models that were deliberated and voted on by PTAC, and for which reports had been submitted to the Secretary as of December 31, 2019.

The remaining 10 proposals submitted as of that date were either under active review or had been withdrawn from consideration. Since that time, two of the --

(Telephonic interference)

VICE CHAIR TERRELL: Lost sound there.

DR. SHARTZER: -- review was subsequently withdrawn, and one of the proposals that had been withdrawn from consideration was subsequently revised and resubmitted. Next slide.

Overall, we find that PTAC has activated the stakeholder community. The submitted proposals targeted different types of providers, clinical conditions, and --

(Telephonic interference)

DR. SHARTZER: -- practices and individual physicians submitted more than half

of the proposals, and their submissions addressed realtime care delivery needs of those practicing on the ground. The --

(Telephonic interference)

CHAIR BAILET: Adele, your sound is breaking up. So --

VICE CHAIR TERRELL: Yes, it's coming in and out.

CHAIR BAILET: Could you see if you could address that? Thank you.

MR. STEINWALD: Well, it's not going in and out anymore.

CHAIR BAILET: Yes.

VICE CHAIR TERRELL: It's just --

DR. SHARTZER: -- CMMI model development, describing --

(Telephonic interference)

DR. SHARTZER: Can you hear me?

VICE CHAIR TERRELL: We can now.

DR. SHARTZER: Okay. The proposals also included innovations and Alternative Payment Models that can inform CMMI model development. I'll describe these more later.

Likewise, the fact that nearly all

proposals included two-sided risk accountability approaches, can inform future model development. As mentioned, the PTAC process enables stakeholders to raise policy issues related to care delivery and payment reform. The review of their proposals by a panel of experts generates an inventory of information on these topics that can be used to influence APM development, research, and awareness. Next slide, please.

Next slide, please.

The findings I'm presenting today are drawn from an analysis we conducted for ASPE and PTAC. This particular report reviews proposed models that were submitted to PTAC to synthesize and describe gaps in care and payment identified by submitters, and identified key features and common elements of proposed models and payment solutions.

We used a software program to review and summarize findings with input from ASPE project staff. Our main analysis focuses on the 24 proposals voted on by PTAC as of December 2019, with some exceptions, where noted. Next

slide, please.

In this slide, we assessed the types of entities that had submitted proposals to PTAC for review. Among the 34 proposals that were submitted by December 2019, we find PTAC proposals span a range of submitter types, most commonly national provider associations or specialty societies, with 10 submissions, and regional or local single specialty physician practices, with seven submitters. Next slide, please.

In reviewing the 24 proposed models that were included in a report to the Secretary as of December, we identified three main focus areas. Ten models focused on specific health conditions, like cancer, asthma, or end stage renal disease.

In addition, two models focused on advanced illness and care for patients near the end of life, but these models could apply to a range of health conditions. Another subset of 11 models focused on a particular clinical setting or type of practice.

These models focused on improving

primary care, delivering more care in patient homes, enhancing access to care in skilled nursing facilities, improving transitions in care between inpatient, emergent, and home settings, and supporting care delivery in rural settings.

In addition, there were two proposals that were broad end scope, and covered a range of conditions or providers. The American College of Surgery proposed PFPM could apply to more than 100 conditions or procedures, and the Dr. Yang proposal represented a fundamental restructuring of Medicare.

We found the proportion of proposals focused on conditions and clinical settings was nearly equal. Next slide, please.

Submitters were sometimes explicit about perceived gaps in care delivery and payment, and proposed submissions, and at times, these issues were implicitly referenced.

These gaps overlapped and were not exclusive, meaning proposed PFPMs could target several of the issues we identified at the same

time.

In our review of the 24 proposals, these are things we identified, and the gaps in care delivery and payment they addressed. ED visits and hospitalizations that could be avoided with improved care delivery or payment, inadequate support for care management, such as time spent coordinating care with other providers, transitions in care across settings and condition phases that resulted in disruptions in care, sub-optimal handoffs between providers, and poor health outcomes.

Limited access to convenient services for beneficiaries, such as services near or in their home.

Payment for services that differed, based on treatment site, such as physician office versus hospital outpatient department, incentives to deliver a high volume of services, rather than value-based care, and restrictions in current fee schedule codes or existing APMs that submitters felt limited providers' ability to use codes or participate in models. Next slide, please.

In this slide, we focused on the proposed approaches to payment for services and care-related activities in the 22 PFPMs to which the Secretary's criteria were applicable.

The first set of five proposed PFPMs included additional or supplemental payments to the fee schedule. Four of these proposals did not include any downside risk for participating providers.

The next set of nine proposed PFPMs featured per beneficiary per month, or PBPM, payments to support care delivery, and four of these proposals capitated PBPM payment replaced certain fee schedule codes, and providers were at risk for care delivery expenditures that exceeded the monthly payment.

In the remaining five PBPM proposals, providers would continue to build a fee schedule as usual, but would receive supplemental monthly payments to support additional activities, such as remote monitoring or coordination of tests.

All of the PBPM models included some element of shared risk for providers. Eight

proposals adopted an episode-based approach in their proposed payment model.

Common across these proposals was a target price for spending on a defined set of services, and shared risk for performance during the episode, based on spending and/or quality objective.

Four proposals would continue fee-for-service payments during the episode, with retrospective reconciliation, and four proposals would give participating providers a fixed episode payment to cover activities during the episode.

Overall, we find that PBPMs and episode-based models were proposed in about equal proportion, with a smaller number of models proposing additional payments. Next slide.

In assessing how the 22 proposed PFPMs addressed performance-based risk for participating providers, we find that only three did not include any direct performance-based provider risk.

One model included upside-only risk

for participating providers, and several others include upside-only risk in initial phases of the model, but would transition to shared risk in subsequent years.

The remaining models all proposed some variant of shared risk. Five proposed models would adjust the APM payments provided in the model, based on performance. For example, overspending relative to the target could mean a slightly lower PBPM in a subsequent year.

Seven proposed models included two-sided risk for base Medicare payments. In these models, providers would receive a portion of total savings, or be at risk for a portion of total losses relative to the spending target.

We identified five models as proposing full risk for providers, meaning that providers would be at risk for the full cost of care beyond the APM payment.

These models included capitated PBPMs and episode-based models with fixed episode payments. Next slide, please.

Here, we arranged the proposed

approaches to payment with the proposed models focus area to identify whether certain types of models, like condition-focused models, were proposing similar types of payment solutions.

And key findings are that the chronic condition-focused models proposed a variety of different payment approaches, including add-on PBPMs and episode-based approaches.

Both advanced illness models were capitated PBPMs, as were the primary care-focused models. The setting-focused models tended to include additional payments with no downside risk, though two proposed add-on PBPMs, and two others used an episode-based framework.

The broadly focused ACS[38] proposal also adopted an episode-based framework. My colleague, Laura, will now share findings from our synthesis of PTAC's expert review across proposals.

VICE CHAIR TERRELL: And we're right at two minutes to 3, so just reminding you that

38 American College of Surgeons

we need to get this, get through this very excellent proposal pretty quickly.

MS. SKOPEC: Great. Okay. So I'm Laura Skopec, also a member of the contractor team. Next slide, please.

I'm discussing a companion analysis of PTAC voting patterns and comments on proposed PFPMs. The purpose of this analysis was to identify themes and patterns in PTAC analysis and review of proposed PFPMs relative to the Secretary's criteria.

We focused on 22 models deliberated and voted on as of December 2019. We excluded two proposed models for which the PTAC determined that the Secretary's criteria were not applicable.

Our analysis had two components. First, we analyzed PTAC final votes recorded for the 22 proposed models and reports to the Secretary, including votes on each criterion, and the overall recommendation.

We also assessed PRT votes as recorded in the 22 PRT reports. Secondly is NVivo12, a qualitative analysis software to

code PTAC comments and the reports to the Secretary.

This analysis doesn't reflect all comments from PTAC but gives an overview of key themes that emerged from PTAC comments. Our codes covered six domains that were related to but not synonymous with the Secretary's criteria, including scope and scalability, quality, payment model, evidence and evaluability, care coordination, care integration, and shared decision making, and health information technology. Next slide.

For a refresher, here are the Secretary's 10 Criteria. The first three, scope, quality, and cost and payment methodology are the high priority criteria. Next slide.

This table shows the number of proposed models that did not meet that, or met and deserved priority criteria consideration for each of the 10 Criteria.

All or nearly all proposed models deliberated and voted on by PTAC met the scope, value over volume, flexibility, patient choice,

and patient safety criteria.

The major differentiating criteria were payment methodology, met by only half of the proposed models; integration and care coordination met by about two-thirds of the proposed models; and quality and cost, met by about three-quarters of the proposed models. Next slide, please.

Overall, payment methodology, integration and care coordination, and quality and cost were frequently the differentiating criteria between recommended and not recommended models.

Key themes from the scope and scalability domain included praise for proposed models that would provide new opportunities for APM participation, that would provide new services for Medicare beneficiaries, or that identified problems in Medicare's current payment structure.

In addition, PTAC recommended that proposals addressed interaction with existing CMMI models. Key themes from the quality domain included praise for proposed models that tied

payment to quality.

PTAC also recommended designing payment and care delivery models with a focus on improving quality, and PTAC recommended that some proposed models add measures of patient experience and create formal quality assurance procedures.

In the payment model domain, PTAC emphasized that submitters should carefully assess the positive and negative incentives created by the payment model, including the appropriateness of features like two-sided risk and shared savings and penalties based on total cost of care.

PTAC also suggested clarifying and assessing the appropriateness of accountability for care quality and for savings. For some proposals, PTAC suggested exploring alternative approaches to encouraging the proposed care model, like a fee schedule change. Next slide.

Under the evidence and availability domain, PTAC suggested that submitters provide any available evaluation results from previously tested models and strengthen

evidence for the model we're testing that had been conducted.

In addition, PTAC recommended real-world testing for several proposed models, particularly those recommended to the Secretary for limited scale testing.

Under care coordination, care integration, and shared decision making, PTAC suggested that submitters describe formal shared decision making approaches.

For models targeting sensitive populations, such as serious illness care models, PTAC recommended describing in detail how patient preferences and individual needs would be considered.

Finally, PTAC recommended explaining how integration and care coordination would be incentivized and ensured and especially care coordination focused on the whole patient, not just the targeted disease.

In the health information technology domain, PTAC praised the use of novel technologies, where appropriate, but suggested both avoiding proprietary technology and

developing approaches that would limit the provider and beneficiary burdening, burden of adopting new technologies.

PTAC also recommended that submitters describe how any data collected by new technologies would be used. This concludes our presentation on proposed models deliberated and voted on by PTAC as of December 2019. The full reports are available on the PTAC website.

VICE CHAIR TERRELL: Thank you for doing that so quickly and well, and I'm going to turn the gavel back over to Jeff Bailet.

*** Chairman's Closing Remarks**

CHAIR BAILET: All right. Thank you, Grace. I want to thank Laura and Adele, and NORC for the, and the Urban Institute, for that presentation.

You've clearly done a lot of work reflecting the work of the committee, which was not an easy feat, but thank you for that. Thanks for all of the folks participating in our first ever virtual meeting.

I know that sitting through a long meeting is challenging, even in person, so I

appreciate all of you members, submitters, and stakeholders hanging on until the end.

I have one more announcement before we adjourn. I'll make this quick. As many of you know, ASPE prepares an environmental scan for every proposal reviewed by PTAC to give members a good understanding of the clinical and economic circumstances surrounding the proposed model.

To even better inform our review, we are seeking to expand the information included in the scans, and do so, we are asking our stakeholders to contribute additional information for these scans.

PTAC seeks to build upon the insights of stakeholders and use what issues they believe are material to our review to enhance our review and our recommendations to the Secretary.

Therefore, we are looking for your input on several questions to inform our environmental scans in general, and we are also encouraging stakeholders to consider these topics when submitting public comments on a

particular proposal.

These questions will be posted on the ASPE PTAC website, on the for public comment page, soon, for the public to submit responses via email.

The questions will also be emailed out through our distribution lists, which you can join on the ASPE PTAC website. We want to hear from you.

We intend to review the input we receive on these questions at an upcoming public meeting if time allows and we plan to post the input online.

*** Adjourn**

CHAIR BAILET: Issuing that call to action is our last order of business for today. I'd like to thank everyone for participating and for bearing with us as we've had our first virtual meeting, and thank you all for taking time out of your busy schedules to be with us. Please stay safe, take care, be well. The meeting is adjourned. Thank you.

(Whereupon, the above-entitled matter went off the record at 3:06 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Advisory Committee Meeting

Before: PTAC

Date: 06-22-20

Place: virtual meeting

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter