Physician-Focused Payment Model Technical Advisory Committee

Public Meeting Minutes

September 8, 2017

9:00 a.m. – 1:00 p.m. EDT

Hubert H. Humphrey Building

200 Independence Avenue, SW

Washington, DC 20201

Attendance Physician-Focused Payment Model Technical Advisory Committee (PTAC) Members In-Person

Jeffrey W. Bailet, MD (PTAC Chair; Executive Vice President of Health Care Quality and Affordability, Blue Shield of California)
Robert Berenson, MD (Institute Fellow, Urban Institute)
Paul N. Casale, MD, MPH (Executive Director, New York Quality Care)
Timothy Ferris, MD (Senior Vice President for Population Health Management, Partners HealthCare)

Timothy Ferris, MD (Senior Vice President for Population Health Management, Partners HealthCare) Rhonda M. Medows, MD (Executive Vice President of Population Health, Providence Health & Services) Harold D. Miller (President and CEO, Center for Healthcare Quality and Payment Reform) Elizabeth Mitchell (PTAC Vice Chair; President and CEO, Network for Regional Healthcare Improvement) Len M. Nichols, PhD (Director, Center for Health Policy Research and Ethics, George Mason University) Kavita Patel, MD, MSHS (Nonresident Senior Fellow, Brookings Institution) Bruce Steinwald, MBA (Consultant, Bruce Steinwald Consulting)

PTAC Member Not in Attendance

Grace Terrell, MD, MMM (Founding CEO, Envision Genomics)

Presenter: PTAC Remarks

John Michael O'Brien, PharmD, MPH (Deputy Assistant Secretary [of Health Policy] for Planning and Evaluation)

Submitters' Representatives: Hackensack Meridian Health (HMH) and Cota, Inc.: Oncology Bundled Payment Program Using CNA-Guided Care

Elena Castañeda (Director of Managed Care and Strategic Partnerships, Cota) Stuart Goldberg, MD (Division of Leukemia at HMH; Chief Science Officer, Cota) Andrew Pecora, MD, FACP, CPE (President, Physician Enterprise, and Chief Innovation Officer, HMH; Professor of Medicine and Oncology, Georgetown University; and Founder and Executive

Professor of Medicine and Oncology, Georgetown University; and Founder and Executive Chairman, Cota)

Laura Kudlacik, RN (Vice President of Oncology, HMH)

Morey Menacker, DO (Vice President, Specialty Care and Care Transitions, HMH; President and CEO,

Hackensack Alliance Accountable Care Organization)

Andrew Norden, MD (Chief Medical Officer, Cota)

Public Commenters:

Ann Hubbard (Director, American Society of Radiation Oncology) Mallory O'Connor (Director, Health Policy and Federal Programs, Biotechnology Innovation Organization) Jeff Micklos (Executive Director, Health Care Transformation Task Force)

NOTE: A transcript recording all statements made by PTAC members, the proposal submitters and public commenters at this meeting is available on the PTAC website located at: https://aspe.hhs.gov/meetings-physician-focused-payment-model-technical-advisory-committee.

The website also includes copies of all presentation slides and a video recording of the September 8, 2017 public meeting.

PTAC Opening Remarks

Dr. John Michael O'Brien, Deputy Assistant Secretary for (Health Policy) Planning and Evaluation (the Deputy Assistant Secretary), welcomed the public, thanked the Committee for all of their work, and thanked the proposal submitters for their commitment to proposal development. The Deputy Assistant Secretary announced that the U.S. Department of Health and Human Services Secretary's (the Secretary's) response to PTAC's proposal recommendations from the April 10, 2017 and April 11, 2017 public meetings would be disseminated later in the day.

The Deputy Assistant Secretary also discussed the Secretary's concern with models that rely on proprietary technology or software and models specific to a single submitter. He emphasized the Secretary's interest in proposals that were applicable to many physicians in the United States and in proposals that multiple entities could implement.

Welcome and Deliberations and Voting Procedures

Jeffrey Bailet, PTAC Chair, welcomed attendees to the PTAC meeting. The Chair reminded the public that PTAC deliberates and discusses proposals only in public meetings and informed the participants that the deliberations and voting proceedings would occur in the following order:

- 1. PTAC members will disclose any potential conflicts of interests and threats to impartiality.
- 2. The designated Preliminary Review Team (PRT) will present their report to the full Committee.
- 3. PTAC members will have an opportunity to ask PRT members questions concerning the reviewed proposal.
- 4. Submitters will be permitted to make a statement to PTAC, if desired.
- 5. The meeting will be opened up for public comments.
- 6. PTAC will deliberate and vote on the extent to which the proposal meets each of the Secretary's criteria.
- 7. PTAC will deliberate and vote on a final recommendation to the Secretary.
- 8. PTAC will provide instructions to staff on drafting comments to accompany their recommendation to the Secretary.

Hackensack Meridian Health (HMH) and Cota, Inc.: Oncology Bundled Payment Program Using CNA-Guided Care

Committee Member Disclosures

Harold Miller stated that he previously provided fee-based consulting to the American Society of Clinical Oncology (ASCO) in developing a patient-centered oncology payment model, and that he had no financial ties to the submitters (HMH and Cota) or to any oncology practices.

Kavita Patel stated that she was familiar with Cota and acquainted with Dr. Andrew Pecora, the proposal submitter, but that she had no previous knowledge of the payment model that would be deliberated on during the meeting.

No additional PTAC members had any disclosures related to this proposal, and the Chair announced that PTAC members had determined that all present PTAC members would fully participate in deliberations and voting.

PRT Report to PTAC

The PRT for the *Oncology Bundled Payment Program Using CNA-Guided Care* proposal consisted of Tim Ferris (the PRT Lead), Robert Berenson, and Bruce Steinwald.

The PRT Lead described the PRT's role, summarized the PRT's review, and presented a report to PTAC. He reminded the public that the PRT reports are not binding and that PTAC may reach different conclusions and recommendations than the PRT during the deliberation and voting process. The PRT Lead also noted that the PRT proceeded with their review with the assumption that a single-site proposal would be acceptable and evaluated it against the Secretary's criteria as a single-site pilot.

He stated that HMH and Cota's proposal, *Oncology Bundled Payment Program Using CNA-Guided Care*, was written specifically as a pilot program. The proposed model focused on a bundled payment for newly diagnosed breast, lung, colon, and rectal cancer using Cota Nodal Addresses (CNAs). Each CNA has multiple treatment "lanes," which are pre-determined sets of treatment protocols developed by the submitter based on their three-year retrospective analysis of patient characteristics, treatments, outcomes, and costs of care. This prospective payment proposal aims to make Medicare costs more predictable and less variable by estimating the Medicare 12-month cost for each CNA using historical claims on HMH patients. The bundled payments include cost of oncology care and "unrelated services." HMH will receive the prospective payments and then use these to compensate providers and pay for care coordination and other uncovered services.

The PRT concluded that the proposed model met nine out of 10 of the Secretary's criteria. In addition, two out of the nine criteria ("Flexibility" and "Health Information Technology") met the criteria and deserve priority consideration. The PRT determined, however, that the proposal did not meet the "Patient Choice" criterion. The PRT was unanimous on all decisions.

[The PRT's presentation slides and full report are available on the PTAC's website at: https://aspe.hhs.gov/proposal-submissions-physician-focused-payment-model-technical-advisory-committee.]

Clarifying Questions from PTAC

The Chair opened the floor for PTAC member questions to the PRT. Issues discussed included the following:

- Complexity of the payment methodology.
- Whether the model is proposed as a pilot test versus a generalizable national model.
- The potential need for inclusion of shared decision-making and patient choice to determine correct lane assignment.
- Implementation costs and whether the model examines total cost of care or solely oncology care costs.
- How the CNAs are generated and clinically validated.
- Ability to implement a model similar to the proposed model without using Cota's proprietary classification system.
- How to handle the cost of patient "outliers."
- The potential effects of incentivizing physicians to follow protocol when the best treatment path for a patient may be to deviate from protocol.
- Inclusion or exclusion of patients currently enrolled in NIH research protocols and what that means for this model, specifically the treatment lanes.
- How to handle patients in the program who transition into another health plan group.
- Generalizability of the model.
- Accuracy of using historic HMH patient claims data to estimate future unit cost.
- Financial provider risk and performance and quality standards.

Submitter Statements

The Chair invited the submitters Andrew Pecora, Elena Castañeda, Morey Menacker, Andrew Norden, Laura Kudlacik and Stuart Goldberg.

Following introductions, the submitters stated that the proposal aims to improve clinical outcomes for individual patients in the breast, colorectal, and lung cancer bundles by using precision medicine to reduce total cost of care for the population. The submitters discussed how CNAs would be used to guide the care of patients with breast, colorectal, and lung cancers, and emphasized they believe their model is generalizable and would not require the use of Cota's CNAs. Additionally, they stated that embedded in the CNAs are evidence-based care pathways from the National Comprehensive Cancer Center Network (NCCN) and the American Society of Clinical Oncology (ASCO).

The submitters explained several components of the model, including patient-physician choice and precision medicine, to ensure that patients are not receiving inappropriate medical care. The submitters discussed their strength in the provision of comprehensive coordinated care, citing HMH's experience as a Medicare Shared Savings Program (MSSP) participant. The model currently specifies an oncology patient population. The submitters stated that although their proposal's approach of using precision analytic risk stratification is oncology specific, it could be utilized in other clinical areas. The submitters indicated that they intend to pursue similar approaches with commercial payers in behavioral health, cardiovascular disease, and orthopedics and publish their results in peer-reviewed journals.

PTAC and Submitter Q&A and Discussion

PTAC engaged in Q&A and discussion with the submitter on the following topics:

- The operations, development, and application of the proposed model, including:
 - o Quality of patient care and outcome measures
 - The generalizability of the model and whether it has the ability to use technology other than Cota (i.e., a proprietary technology)
 - o The basis of grouping factors Cota would use to assist in determining treatment
 - Experience with private payers
 - How individual physicians are incentivized for quality
- Elements of the model's design, including:
 - o The public availability of Cota proprietary software
 - The risk adjustment methodology and transparency of each bundle payment
 - The use of historical patient data to determine bundle payment versus prospective pricing given the evolution of cancer care over time
 - The 12-month time period for the bundle enrollment
 - o Measures of patient-physician engagement and patient choice
 - o How it relates to the capabilities that an ACO offers

The meeting recessed at 11:30 a.m. for 10 minutes.

Public Comments

The Committee reconvened at 11:41 a.m. The Chair thanked the submitter and opened the floor for public comments, which were made by:

- 1. Anne Hubbard, American Society for Radiation Oncology
- 2. Mallory O'Connor, Biotechnology Innovation Organization

A transcript of these commenters' remarks is available on the PTAC website at: https://aspe.hhs.gov/meetings-physician-focused-payment-model-technical-advisory-committee

PTAC Deliberation Continued

The Committee members deliberated on a number of issues that emerged during discussion with the submitter, including: the potential opportunities in the proposed model specifically around precision medicine and payment; the generalizability of the model; whether Cota (i.e., proprietary software) had to be utilized for this model; and the benefits of testing a model across multiple providers or implementing a pilot just at HMH (i.e., limited scale). The PTAC unanimously agreed to move forward with voting on the proposed model.

PTAC Criterion Voting

PTAC discussed and voted on the extent to which the *Oncology Bundled Payment Program Using CNA-Guided Care* proposal meets each of the Secretary's criteria. (Individual member comments are located in the meeting transcript located at: <u>http://aspe.hhs.gov/meetings-physician-focused-payment-model-technical-advisory-committee</u>.)

Given that 10 PTAC members were present for the proposal deliberation on September 8, 2017, six PTAC votes constituted a simple majority. The PTAC criterion votes remained anonymous.

	Criteria Specified by the Secretary (42 CFR§414.146)	PTAC Vote Categories	PTAC Vote Distribution
1.	Scope of Proposed PFPM (High Priority)	1 – Does not meet criterion	0 votes
		2 – Does not meet criterion	0 votes
		3 – Meets the criterion	2 votes
		4 – Meets the criterion	5 votes
		5 – Meets the criterion and deserves priority consideration	3 votes
		6 – Meets the criterion and deserves priority consideration	0 votes
PT	AC DECISION: Proposal Meets Criterion 1.	•	•
2.	Quality and Cost (High Priority)	1 – Does not meet criterion	0 votes
		2 – Does not meet criterion	0 votes
		3 – Meets the criterion	4 votes
		4 – Meets the criterion	5 votes
		5 – Meets the criterion and deserves priority consideration	1 vote
		6 – Meets the criterion and deserves priority consideration	0 votes
PT	AC DECISION: Proposal Meets Criterion 2.	•	
3.	Payment Methodology (High Priority)	1 – Does not meet criterion	0 votes
		2 – Does not meet criterion	1 vote
		3 – Meets the criterion	8 votes
		4 – Meets the criterion	0 votes
		5 – Meets the criterion and deserves priority consideration	1 vote
		6 – Meets the criterion and deserves priority consideration	0 votes
PT	AC DECISION: Proposal Meets Criterion 3.		
4.	Value over Volume	1 – Does not meet criterion	0 votes
		2 – Does not meet criterion	2 votes
		3 – Meets the criterion	4 votes
		4 – Meets the criterion	3 votes
		5 – Meets the criterion and deserves priority consideration	1 vote
		6 – Meets the criterion and deserves priority consideration	0 votes

PTAC Member Votes on Oncology Bundled Payment Program Using CNA-Guided Care

Criteria Specified by the Secretary (42 CFR§414.146)	PTAC Vote Categories	PTAC Vote Distribution
PTAC DECISION: Proposal Meets Criterion 4.		
5. Flexibility	1 – Does not meet criterion	0 votes
	2 – Does not meet criterion	3 votes
	3 – Meets the criterion	4 votes
	4 – Meets the criterion	1 vote
	5 – Meets the criterion and deserves priority consideration	2 votes
	6 – Meets the criterion and deserves priority consideration	0 votes
PTAC DECISION: Proposal Meets Criterion 5.		
6. Ability to be Evaluated	1 – Does not meet criterion	0 votes
	2 – Does not meet criterion	2 votes
	3 – Meets the criterion	6 votes
	4 – Meets the criterion	2 votes
	5 – Meets the criterion and deserves priority consideration	0 votes
	6 – Meets the criterion and deserves priority consideration	0 votes
PTAC DECISION: Proposal Meets Criterion 6.	•	
7. Integration and Care Coordination	1 – Does not meet criterion	1 vote
	2 – Does not meet criterion	1 vote
	3 – Meets the criterion	4 votes
	4 – Meets the criterion	4 votes
	5 – Meets the criterion and deserves priority consideration	0 votes
	6 – Meets the criterion and deserves priority consideration	0 votes
PTAC DECISION: Proposal Meets Criterion 7.		
8. Patient Choice	1 – Does not meet criterion	0 votes
	2 – Does not meet criterion	8 votes
	3 – Meets the criterion	2 votes
	4 – Meets the criterion	0 votes
	5 – Meets the criterion and deserves priority consideration	0 votes
	6 – Meets the criterion and deserves priority consideration	0 votes
PTAC DECISION: Proposal Does Not Meet Crit	terion 8.	
9. Patient Safety	1 – Does not meet criterion	0 votes

Criteria Specified by the Secretary (42 CFR§414.146)	PTAC Vote Categories	PTAC Vote Distribution
	2 – Does not meet criterion	1 vote
	3 – Meets the criterion	5 votes
	4 – Meets the criterion	3 votes
	5 – Meets the criterion and deserves priority consideration	1 vote
	6 – Meets the criterion and deserves priority consideration	0 votes
PTAC DECISION: Proposal Meets Criterion 9.		
10. Health Information Technology	1 – Does not meet criterion	0 votes
	2 – Does not meet criterion	0 votes
	3 – Meets the criterion	1 vote
	4 – Meets the criterion	2 votes
	5 – Meets the criterion and deserves priority consideration	7 votes
	6 – Meets the criterion and deserves priority consideration	0 votes
PTAC DECISION: Proposal Meets and Deserve	s Priority Consideration Criterion 10.	

PTAC Vote on Recommendation to the Secretary

PTAC member votes on their recommendation to the Secretary are presented in the table below. PTAC's *"Processes for Reviewing and Evaluating Proposed Physician-Focused Payment Models and Making Recommendations to the Secretary for the Department of Health and Human Services"* state that a two-thirds majority vote will determine PTAC's recommendation to the Secretary.

Given that 10 PTAC members were present for the proposal deliberation and voting on *the Oncology Bundled Payment Program Using CNA-Guided Care* proposal, a total of seven PTAC votes was required for the final PTAC recommendation vote.

PTAC Recommendation Category	PTAC Member Recommendation Vote
Do not recommend proposed payment model to the Secretary	Tim Ferris
Recommend proposed payment model to the Secretary for	Jeffrey Bailet
limited-scale testing of the proposed payment model	Robert Berenson
	Paul Casale
	Len Nichols
	Kavita Patel
	Rhonda Medows
	Harold Miller
	Elizabeth Mitchell
	Bruce Steinwald
Recommend proposed payment model to the Secretary for	No PTAC members voted for this
implementation	recommendation category
Recommend proposed payment model to the Secretary for	No PTAC members voted for this
implementation as a high priority	recommendation category

As a result of the vote, PTAC recommended the *Oncology Bundled Payment Program Using CNA-Guided Care* to the Secretary for limited-scale testing.

Additional PTAC Report Comments to the Secretary

After PTAC voting, PTAC members made the following comments for incorporation into PTAC's report to the Secretary:

- 1) limited-scale testing should only proceed after obtaining input from other oncology groups and other clinicians involved in patients' care;
- 2) testing should be done in more than one site;
- 3) HHS should give special attention to the advantages and disadvantages of the use of proprietary software in this model; PTAC members were divided in their thinking on this issue; some members stated that testing should require testing in at least one site that does not use the Cota Nodal Address (CNA)-Guided Care software; other members stated that they did not perceive uniform use of CNA-Guided Care as an obstacle to testing and that when ultimately tested at other sites, other patient classification and treatment protocol tools could be included;
- 4) there should be formal processes for patient engagement and shared decision-making;
- 5) testing should make explicit the method of awarding quality incentive payments to physicians;
- 6) testing should be coordinated with other models currently being tested by HHS, such as the Oncology Care Model; and
- 7) HHS should consider how this proposed model might integrate with other models that PTAC has already reviewed and recommended to advance, such as the ACS-Brandeis Advanced Alternative Payment Model.

The comments in PTAC's report to the Secretary will reflect the disagreement as appropriate and relevant.

Additional Public Comments

The Chair opened the floor for public comments not specific to a proposal. One comment was made by:

• Jeffrey Micklos, Health Care Transformation Task Force

A transcript of this commenter's remarks is available on the PTAC website at: <u>https://aspe.hhs.gov/meetings-physician-focused-payment-model-technical-advisory-committee</u>

The public meeting adjourned at 1:15 p.m. EDT.

Approved and certified by:

<u>/Ann Page/</u> Ann Page, Designated Federal Officer Physician-Focused Payment Model Technical Advisory Committee 12/19/2017

Date

/Jeffrey W. Bailet/ Jeffrey W. Bailet, MD, Chair Physician-Focused Payment Model Technical Advisory Committee 12/19/2017

Date