Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

Tim Ferris, MD, MPH (Lead Reviewer)
Robert Berenson, MD
Bruce Steinwald, MBA
August 14, 2017

In accordance with the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) ***Processes for Reviewing and Evaluating Proposed Physician-Focused Payment Models and Making Recommendations to the Secretary of the Department of Health and Human Services***, proposals for Physician-Focused Payment Models (PFPMs) that contain the information requested by PTAC's Request for Proposals will be assigned to a Preliminary Review Team (PRT). The PRT will draft a report containing findings regarding the proposal for discussion by the full PTAC. This PRT report is preparatory work for the full PTAC and is not binding on the PTAC. This report is provided by the PRT to the full Committee for the proposal identified below.

A. Proposal Information

1. **Proposal Name:** *Oncology Bundled Payment Program Using CNA-Guided Care*

2. **Submitting Organization or Individual:** *Hackensack Meridian Health and Cota Inc.* (jointly)

Submitter's Abstract: "Among all fields of medicine, oncology is one of the most rapidly evolving and is associated with high variability in clinical outcomes and resource utilization, in part leading to, unsustainable increases in total cost of care. "Adverse variances in care" (too much and too little care) estimated to result in 30% of unnecessary expenditures[1] and sub-optimal clinical outcomes for those affected; which, if adverse variance is identified and prevented, would result in substantial savings in total cost of care and improvement of clinical outcomes for the population being served. Cota, a precision analytics data company, utilizes a patented digital classification system that assigns a numeric code to a patient's manifestation of disease, a code which characterizes all relevant historical, demographic and biologic (including genomics) information about the patient and their disease, as well as the type of therapy intent (i.e. adjuvant vs. neoadjuvant) and progression status. This enables the identification of adverse variance for targeted prevention or intervention. In

[1] Berwick; JAMA 2012

using the CNA classification system, patients with identical CNAs can be grouped and compared for clinical and cost outcomes based on treatment chosen by provider. In multiple clinical settings using real world evidence, Cota has demonstrated that by identifying adverse variance, behavior modification of providers follows, leading to less adverse variance and a corresponding improvement in relevant clinical cancer outcomes, including survival and in total cost of care. Several payers, hospital systems, physician networks and life sciences currently utilize the Cota's CNA system to facilitate outcome improvements and total cost of care reductions.

Hackensack Meridian Health (HMH), a 13-hospital healthcare system in New Jersey with a large cancer population, seeks to leverage Cota's technology to assist in the transformation from fee for service to value based reimbursement with its traditional Medicare population, beginning in oncology. The HMH Oncology Payment Program (also referred to as bundles and lanes program) is an alternative payment model developed by HMH and Cota, in partnership with a major payer, to improve relevant clinical outcomes and reduce the total cost of care of oncology patients starting with the most common cancers (breast, colon, rectal and lung cancer). HMH has designed 27 bundles that encompass the care for patients with all stages and presentations of these cancer types. HMH, Cota and our payer partner have conducted a three year retrospective analysis to determine the historic CNA, and treatment care plan "lane" for all patients to define the clinical and total cost of care baseline for each patient. Without the precision of the CNA diagnosis, in common practice bundle and lane assignment varies considerably, leading to adverse variance. In learning from the CNA coding system, Cota and HMH have compared clinical and total cost of care outcomes retrospectively at a level of precision unfeasible using traditional classification systems (e.g. ICD-10). In the program with the payer, we plan to prospectively assign CNA at diagnosis and use CNA Guided Care™ to optimize bundle and lane selection with the intent of reducing adverse variance to improve clinical outcomes and reduce total cost of care. In this proposal, we seek to expand this program to traditional Medicare patients at HMH."

B. Summary of the PRT Review

Criteria Specified by the Secretary (at 42 CFR§414.1465)	PRT Conclusion	Unanimous or Majority Conclusion
1. Scope of Proposed PFPM (High Priority)	Meets the criterion	Unanimous
2. Quality and Cost (High Priority)	Meets the criterion	Unanimous
3. Payment Methodology (High Priority)	Meets the criterion	Unanimous
4. Value over Volume	Meets the criterion	Unanimous
5. Flexibility	Meets the criterion and deserves priority consideration	Unanimous
6. Ability to be Evaluated	Meets the criterion	Unanimous
7. Integration and Care	Meets the criterion	Unanimous

Coordination		
8. Patient Choice	Does not meet the criterion	Unanimous
9. Patient Safety	Meets the criterion	Unanimous
10. Health Information Technology	Meets the criterion and deserves priority consideration	Unanimous

C. PRT Process

The *Oncology Bundled Payment Program Using CNA-Guided Care* (available on the PTAC website) was received by PTAC on March 23, 2017. The PRT conducted its work between April 20, 2017 and August 11, 2017. During this time, the PRT reviewed the proposal, all public comment letters received on the proposal, and written responses from the submitter (Hackensack Meridian Health and Cota Inc.) to questions from the PRT. After review of the submitter's written responses to the PRT's questions, the PRT held a conference call with Hackensack Meridian Health and Cota Inc. to better understand certain components of the proposal. In addition, the PRT reviewed additional, relevant data and information from other sources on key aspects of the proposed model.

The PRT's summary of the proposal and description of the additional, relevant data and information on key aspects of the proposed model reviewed by the PRT are described below. The PRT's questions to Hackensack Meridian Health and Cota Inc., and their responses, a transcript of the PRT's telephone discussion with Hackensack Meridian Health and Cota Inc. and all letters received from the public are available at the PTAC website.

1. Proposal Summary:

The "*Oncology Bundled Payment Program Using CNA-Guided Care"* submitted by Hackensack Meridian Health (HMH) and Cota Inc. proposes a novel bundled payment method for care of patients with newly diagnosed episodes of breast, colon, rectal, and lung cancer.

The submitters were clear that their proposal is intended as a pilot for Hackensack Meridian Health and not a more general payment model, at least initially. They note that such a complex model has numerous unanswered questions that would need to be worked out in a pilot before a more general payment model could be defined. They nonetheless asserted that other entities could implement the model as a follow-up to the pilot.

The proposed payment model consists of prospective, comprehensive, bundled payments that include cost of care for: 1) the oncology services in the four cancer categories, and 2) "unrelated services." The bundle starts on the day of pathologic diagnosis of cancer and the duration is one year. The model proposes 27 bundles for the four cancer types, and these bundles are themselves composed of aggregations of what Hackensack calls CNAs (Cota nodal addresses). There can be hundreds of CNAs within a bundle, and the assignment of a person to a CNA is determined by numerous demographic, biologic, and treatment decision factors.

The assigned CNA determines all subsequent care. We understand the payment model to operate as follows:

- HMH will work with the Centers for Medicare and Medicaid Services (CMS) using historical claims data pertaining to HMH patients to estimate the Medicare 12-month cost (either total or oncology only) for each CNA represented in the model's patient population.
- The costs of each CNA will be aggregated up to the bundle level using a weighted average approach. For example, if there are 2 CNAs in the bundle costing $10,000 each and one costing $40,000, the average cost would be $20,000.
- These average costs would be used to compute a prospective 12-month price for each of the 27 bundles that cover all the CNAs in the 4 cancer types. HMH would be paid an amount that would be the sum of the bundled price times the number of patients in each bundle.
- This approach adjusts payments for case mix – if a different mix of patients (as identified through CNAs) presents in the performance year compared to the base year, then the payments will adjust to reflect the different mix.
- HMH will receive these prospective payments and use them to compensate providers and pay for care coordination and other uncovered services.
- Because the payment is prospective, HMH will be at risk for the costs of delivering care if their costs exceed what they are paid. HMH estimates they will save 25% on covered services (such as hospitalizations and diagnostic tests), reduced by what they spend on uncovered services.

At the end of a year the bundle payment will no longer apply to an enrolled patient so all medical services will revert to FFS reimbursement. The proposal also requests a stop loss arrangement due to the limited number of patients enrolled and the extended time frame. HMH would like CMS to consider a stop loss threshold at twice bundle payment per patient. "If the expenses for a patient reaches the designated stop loss threshold, such patients will then exit the bundle and be considered outliers."

Once a patient is enrolled in a bundle, all claims billed to CMS from any HMH-related provider will be forwarded to HMH. HMH will then provide compensation for those claims. HMH would distribute payment to physicians in accordance with services rendered, based on the standard FFS Medicare rate. Part of the compensation to physicians would be incentive-based – based upon services provided, achievement of clinical quality and patient satisfaction outcomes, and total cost of care. HMH does not have plans to place physicians at "downside" risk. Physicians will receive a higher compensation through the bundle if performance metrics are achieved. Physicians who do not meet performance and quality standards will be asked to exit the team and will be unable to participate in any future financial models.

The submitters assert that this financial model will support a more efficient, higher quality care model. The care model is described as adherence to a proprietary patient classification

system (Cota Nodal Address [CNA]) that assigns each patient to a care path based on historical, demographic and biologic (including genomics) information about patients and their diseases, as well as types of therapy (e.g., adjuvant vs. neoadjuvant) and progression status. There are hundreds of CNAs and each CNA has multiple treatment pathways, called "lanes." The Cota system is proprietary, though the treatment algorithms are based on nationally accepted guidelines, mostly from NCCN (National Comprehensive Cancer Network) and ASCO (American Society of Clinical Oncology). The submitters noted that other centers could participate by either purchasing Cota, or those not wishing to utilize Cota could use their own care pathways.

This model initially would only apply to physicians participating in the CIN [clinically integrated physician network] at HMH. These physicians are currently participating in a Medicare Shared Savings Program (MSSP). All physicians affiliated with HMH's CIN would be included in the model if expanded later. An estimated 2,500 – 3,000 patients would be eligible for the PFPM in its initial stage.

Only patients with a CNA would be enrolled into the payment model. Once a patient receives his or her CNA, he or she would be assigned to a bundle, and the physician and patient will choose the patient's treatment lane from among the lanes in the bundle. Treatment lanes are pre-determined sets of treatment care protocols developed by the submitter based on a three-year retrospective analysis by the submitter of patient characteristics, treatments, outcomes, and costs of care. Processes for patient care included in the lanes include diagnostics, imaging, surgery, chemotherapy, physician visits – including follow-up care, comorbidity management and routine care management. Through the selection of the treatment lane, everything for the patient is prescribed, from the points in time the patient sees the physician, to the labs that need to be ordered, to monitoring of patients on chemotherapy. All participating physicians in this model will use EPIC as their EHR. HMH and Cota will evaluate clinical quality metrics and financial metrics.

2. Additional Information Reviewed by the PRT.

a) Environmental Scan and Literature Review

ASPE, through its contractor, conducted an abbreviated environmental scan related to this proposal. Documents comprising the environmental scan were primarily identified using Google and PubMed search engines. Key words guiding the environmental scan and literature review were directly identified from the Letter of Intent (LOI). The key word and combination of key words were utilized to identify documents and material regarding the submitting organization, the proposed model in the LOI, features of the proposed model in the LOI or subject matter identified in the LOI. Key terms used included "oncology bundled payment models," "disease specific episode payment," "disease specific episodes," "Cota nodal address cancer," "episode payments electronic health records," "data driven pricing healthcare,"

"cancer patient categorization pricing," "physician focused payment model," "Cota Oncology Care Model," "Oncology Care Model," "episodes of care oncology," and "oncology episode-based payment model." This search produced seven documents from the grey literature and eight peer-reviewed articles. These documents are not intended to be comprehensive and are limited to documents that meet predetermined research parameters including a five-year look back period, a primary focus on U.S. based literature and documents, and relevancy to the LOI. The PRT also requested a comparison of this with CMMI's Oncology Care Model. The abbreviated environmental scan and comparison of the model with CMMI's Oncology Care Model are both available on the PTAC website.

b) Data Analyses

The PRT sought additional information regarding Medicare fee-for-service beneficiaries with a new diagnosis of breast, colon, rectal, and lung cancer individually:

For the 12-months subsequent to diagnosis:

1. The number of Medicare FFS beneficiaries with a new diagnosis for this type of cancer and the percent that this number represents of all Medicare beneficiaries;
2. A frequency distribution of co-morbid conditions experienced by the Medicare beneficiaries in item #1; and
3. Total Medicare costs of care (Parts A, B and D) for these beneficiaries for the 12 months following their diagnoses.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), through its contractor, produced data tables containing this information that are available on the PTAC website.

c) **Additional Information reviewed.** The PRT also talked with the following parties to better understand key aspects of (and potential effects of) the proposed model:

- The CMS Center for Medicare and Medicaid Innovation (CMMI) to better understand the difference between the proposed model and CMMI's Oncology Care Model.
- The CMS Office of the Actuary.

D. Evaluation of Proposal Against Criteria

Criterion 1. Scope of Proposed PFPM (High Priority Criterion). **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 participate in APMs have been limited.**

PRT Qualitative Rating: Meets

As a payment model for oncology, this proposal addresses a clinical area (and a group of specialist physicians) who already have an alternative payment option with CMS' Oncology Care Model (OCM). Nonetheless, we found numerous aspects of this model novel and potential improvements over perceived weaknesses in OCM. In addition, cancer costs have shown the highest rate of growth for any clinical area for several years and predicted to be among the highest cost growth areas for the near future. We did have concerns that if the COTA model requires the use of the proposed proprietary software, this could limit its uptake. For these reasons, we considered this proposed oncology model, if viable, to be a valuable addition to the CMS portfolio, even though CMS' portfolio already includes the OCM. While we think as written this model is not generalizable, we do think there are some very attractive aspects of this proposal that should be incorporated into an oncology payment model.

Criterion 2. Quality and Cost (High Priority Criterion). **Are 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.**

PRT Qualitative Rating: Meets

With regard to quality, the treatment pathways and the monitoring of variance appear both innovative and evidence-based and have a high likelihood of reducing unwarranted variation. We considered this likely to improve quality of care for patients receiving cancer care services. As one commenter noted, "we applaud the use of a digital classification system to accurately pinpoint oncology patient characteristics so they can be grouped and treated appropriately." We did have some concerns about the implications of having an assigned CNA (and thus all subsequent care decisions defined by that CNA) for the role of patient preferences in ongoing care decisions. We also thought some sort of verification of the pathology and stage, possibly through a clinical audit process, would be reassuring given the significant rate of cancer misdiagnosis reported in the literature.

Determining the impact on cost of this proposal was challenging and depends largely on the pricing of the bundles. Using costs from a single site to set prices limits the pricing to the care patterns at that site. Nonetheless, the prospective nature of the payment method should result in more predictable costs for CMS and will certainly reduce variation in costs for CMS. So for a pilot, we thought this proposal presented a plausible method, but we did

not think that, as described, the model could be generalized to other sites without further refinement. Importantly, unlike other bundled payment models including the OCM, the assignment of patients to clinically specific CNAs dramatically reduces the chance of inappropriate assignment of patients to bundles. The greater precision of diagnosis and treatment in this proposal compared to OCM (through the use of CNAs and treatment lanes) operates in at least two different ways. First, patients are less likely to be enrolled in a bundle without having a documented and auditable need (based on pathology report and captured in the CNA). Second, patients are unlikely to be steered into the wrong bundle given the specificity of the assignment and reliance on prescribed criteria and auditable clinical data. Both of these aspects reduce the potential for gaming this payment system.

Criterion 3. Payment Methodology (High Priority Criterion). **Pay 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.**

PRT Qualitative Rating: Meets

Four aspects of this payment model are particularly strong: 1) the inclusion of cancer stage in the grouping, 2) the one year time frame, 3) the case mix adjustment that occurs in bundle pricing, and 4) the payment is prospective. These four factors are all improvements over the existing OCM. We also considered the inclusion of non-cancer related costs a strength, but we were concerned that this could also be a weakness (see below).

Despite these important strengths, the proposed payment method raised numerous concerns. Will low frequency of some of the CNAs affect the accuracy of the prospective prices? Will the historical data accurately represent unit costs in the prospective model? How will the model handle "leakage" of both patients and doctors? How will savings be calculated and will they be valid estimates? If it's an "oncology costs only" model (the proposal was ambiguous on this point), how will oncology costs be isolated? The proposed calculation for pricing the non-cancer services would make sense at a gross population level, but the costs associated with co-morbid conditions in cancer patients may not reflect the costs in a general population. In fact, PRT analysis of data provided by the CMS contractor found the prevalence of cardiovascular conditions much higher for patients with three of the four included cancers than in the general population. The implications are that proper pricing for non-cancer services would need to adjust for the prevalence of co-morbidities found in each of these cancer populations. Further, the small number of cancer patients in any particular participating provider could make variances at the provider level very significant. We were also concerned that if payments depended on assignment to a CNA, what happens when a patient changes CNA due to disease recurrence or even the patient changing their mind about care goals? Finally, we are concerned about the practical

aspects of the mechanism for initiating the bundle which was not well specified in the proposal. The two possibilities, using a pathology claim or a separate communication, need to be examined and tested. The model proposes to exclude outliers. We would consider a winsorization (reducing costs of outliers down to some predetermined threshold) to be a more appropriate method for dealing with outliers than removing outliers from the bundle altogether.

Criterion 4. Value over Volume. **Provide incentives to practitioners to deliver high-quality health care.**

PRT Qualitative Rating: Meets

As a prospective bundled payment model, the *Oncology Bundled Payment Program Using CNA-Guided Care* provides incentives to practitioners to deliver high quality care. Because enrollment is tied to a pathology report, the enrollment criteria make it unlikely that this model could be abused by incentivizing more bundles as can occur with discretionary procedures. There is some risk of patients not being enrolled appropriately, and this could be used to create an advantageous selection if providers know in advance that a patient will be unusually expensive. Nonetheless, we found the risks well balanced. Protection against skimping on care within the bundle is addressed by the centrality of adherence to high quality, evidence-based treatment protocols that differentiate the lanes, with oversight to assure that clinicians are not "free-lancing." (This commitment by HMH raises issues of generalizability of the model.) While the submitters are relying on the precision of their software and the incentives to reduce costs, the proposal does not describe in any detail the mechanism by which costs will be reduced.

Criterion 5. Flexibility. **Provide the flexibility needed for practitioners to deliver high-quality health care.**

PRT Qualitative Rating: Meets with high priority

We considered the criteria of flexibility to be relevant to three different aspects of this proposal: 1) the use of this specific software, 2) the use of this type of software (in general), and 3) the impact of the financial model on practitioner behavior. If the Cota software system is required for this payment model, then the proposed clinical model provides minimal flexibility to practitioners. As noted below under criterion 9 (Patient Safety), this constraint is likely to benefit patients by reducing unwarranted variation. Nonetheless, we were concerned that the lack of transparency associated with proprietary software could overly constrain practitioner behavior and, importantly, affect patients' ability to express their preferences for treatment options. (See criterion 8, Patient Choice.) We did not evaluate the extent to which 1) each and every treatment or service is explicitly tied to publicly available evidence, nor did we seek to determine the extent to which 2) each recommended action is best standard of care. We considered these two characteristics to

be essential aspects of any care pathway system that constrains practitioner flexibility. Nonetheless, the multiple lanes available within each CNA and the explicit linking to NCCN and ASCO guidelines suggests that practitioners will have sufficient flexibility to provide optimal care to their patients. If any system of cancer care paths can be used with this payment model, and the decision support software includes these essential characteristics, then we considered this proposal as providing practitioners with adequate flexibility. As a relatively minor concern, the proposal does not address what happens if a practitioner encounters a situation where his or her best judgment and the decision support are in opposition. Given the hundreds of protocols and treatment recommendations, this scenario seems very likely. Add to this their intent to provide bonus incentives to practitioners for adhering to the care paths, the combination of decision support advice and a financial incentive to adhere to that advice could put the practitioner in conflict with the best interests of the patient. Obvious mitigation strategies would include limiting the size of the incentives and/or providing practitioners with the option to opt out of recommendations in specified circumstances. If this proposal were implemented more as a proof of concept we would have a chance to learn about the balance between prescriptive lanes, clinical judgment to deviate, and the management controls that work best in these types of situations.

Criterion 6. Ability to be Evaluated. **Have evaluable goals for quality of care, cost, and any other goals of the PFPM.**

PRT Qualitative Rating: Meets

Presumably the evaluation will compare historical to actual costs, possibly using a difference in differences approach. Their plan to measure patient experience and quality metrics seems on track. We were concerned about the challenges created in the overlap between the MSSP and this proposed model. The single site, the use of proprietary software, and the relatively small numbers all limit the ability of this proposal to be evaluated. On the other hand, if one considers the evaluation of a pilot to be more about proof-of-concept than generalizability, then this proposal could be evaluated against that more limited standard.

Criterion 7. 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.**

PRT Qualitative Rating: Meets

To the extent that care integration is an inherent characteristic of a clinically integrated network, and all providers involved were using the same EHR, we did not have significant concerns. We viewed the payment model as encouraging care integration and care coordination in a general sense, but there is limited description of the specific nature of the

care coordination efforts or of the incentives internal to the organization that would encourage these goals. Our data analysis confirms that there are high rates of co-morbidities (especially cardiovascular conditions) in the target population, so care integration and coordination will be important.

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

PRT Qualitative Rating: Does not meet

We were concerned that the proposal did not address how patient preferences are to be handled with regard to assignment (or re-assignment) to CNAs, nor is there any description of formal or even informal shared decision-making processes. None of the examples of why clinicians might select one or another treatment lane mentioned patient preferences as a reason. Given the importance of context-specific choices in cancer care, we found this omission troubling, though the submitters made encouraging statements on this topic during our interview with them.

Criterion 9. Patient Safety. Aim to maintain or improve standards of patient safety.

PRT Qualitative Rating: Meets

The use of HIT to define and monitor the delivery of cancer care should enhance patient safety. As noted above, we would like to see some attention to the verification of the pathologic diagnosis given the research indicating that a significant number of patients are overdiagnosed with cancer and then subsequently subjected to the risks of potentially toxic medications.

Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.

PRT Qualitative Rating: Meets with high priority

The use of HIT to incorporate clinical data into highly specified clinical categories that both define appropriate treatments and monitor variance is a laudable aspect of this proposal. This proposal provides a specific example of how HIT can be used to improve care delivery. In addition, the proposal demonstrates how HIT can be used as a vehicle for improving the payment system by incorporating detailed clinical data into the assignment of patients to specific clinically coherent categories. This grouping supports a payment model that (in concept) appears aligned with clinical care and is less prone to either gaming or errors in performance measurement.

E. PRT Comments

As noted earlier, the PRT was impressed by the precision offered by the HMH-Cota model, particularly as compared to the relative imprecision of CMS' Oncology Care Model already in the field. However, for PTAC to recommend the model for implementation, several issues will need to be addressed. These issues touch on more general policy issues that pertain to other proposals.

First is the proprietary nature of the Cota software. The PRT concluded that the model could be fielded only as a pilot study by Hackensack Meridian Healthcare with possible expansion to other centers in the future. Therefore, by definition the model's reach would be limited to one site initially. Expansion would require either licensing the Cota software or devising a substitute that accomplishes the same precision as the Cota software. Because the payment bundles themselves depend on the specific classification system used in the software, if different software systems were used by different sites then CMS would require multiple payment methods. This seems unrealistic.

Second, and related to the first, PTAC should consider whether and how a HMH-Cota pilot study could yield information that would determine if expansion of the model is appropriate. The HMH-Cota pilot's performance measures would be based on comparing its current patients with its historical patients, all of whom will have a Cota Nodal Address designation. CMS would need to determine how this comparison would provide meaningful information about what might be expected if other sites implemented the model, and how their baselines should be calculated.

Third, assuming that other hurdles are crossed, should the model be a total cost of care or oncology-costs-only model? Because the proposer appears to be open to either approach, the PRT decided to not assume one or the other but to save the issue for full PTAC discussion.

END OF DOCUMENT