Physician-Focused Payment Model Technical Advisory Committee

October 20, 2017

Eric D. Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Hargan:

On behalf of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), I am pleased to submit PTAC's comments and recommendation to you on a Physician-Focused Payment Model (PFPM) submitted by Hackensack Meridian Health and Cota, Inc. entitled *Oncology Bundled Payment Program Using CNA-Guided Care*. These comments and recommendations are required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) which directs PTAC to: 1) review PFPM models submitted to PTAC by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (Secretary, HHS); and 3) submit these comments and recommendations to the Secretary.

With the assistance of HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE), PTAC members carefully reviewed Hackensack Meridian Health and Cota, Inc.'s proposed model (submitted to PTAC on March 23, 2017), additional information on the model submitted by Hackensack Meridian Health and Cota, Inc. in response to questions from a PTAC Preliminary Review Team (PRT) and PTAC as a whole, and public comments on the proposal. At a public meeting of PTAC held on September 8, 2017, PTAC deliberated on the extent to which this proposal meets the criteria established by the Secretary in regulations at 42 CFR § 414.1465 and should be recommended.

PTAC concluded that the *Oncology Bundled Payment Program Using CNA-Guided Care* payment model has merit, especially because of its support for

precision medicine and recommends it for limited-scale testing with six stipulations. These stipulations include: 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) that HHS give special attention to the advantages and disadvantages of the use of proprietary software in this model; 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; and 6) testing should be coordinated with other models currently being tested by HHS such as the Oncology Care Model. PTAC additionally encourages HHS to 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 members of PTAC appreciate your support of our shared goal of improving the Medicare program for both beneficiaries and the physicians who care for them. The Committee looks forward to your detailed response posted on the CMS website and would be happy to assist you or your staff as you develop your response. If you need additional information, please have your staff contact me at Jeff.Bailet@blueshieldca.com.

Sincerely,

Jeffrey Bailet, MD
Chair

Attachments

Physician-Focused Payment Model Technical Advisory Committee

REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

Comments and Recommendation on

Oncology Bundled Payment Program Using CNA-Guided Care

October 20, 2017

About This Report

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to: 1) review physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (Secretary, HHS); and 3) submit these comments and recommendations to the Secretary. (See Appendix 1 for a list of PTAC members and their terms of appointment.) PTAC reviews submitted proposals using criteria established by the Secretary in regulations at 42 CFR § 414.1465. (See Appendix 2 for the Secretary's criteria.) As directed by MACRA, HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) provides operational and technical support to PTAC.

This report includes: 1) a summary of PTAC's review of a PFPM submitted by Hackensack Meridian Health and Cota, Inc. entitled *Oncology Bundled Payment Program Using CNA-Guided Care*; 2) a summary of this model; 3) PTAC's comments on the proposed model and its recommendation to the Secretary; and 4) PTAC's evaluation of the proposed PFPM against each of the Secretary's criteria for PFPMs. The appendices to this report include a record of the voting by the PTAC on this proposal (Appendix 3); the proposal submitted by Hackensack Meridian Health and Cota, Inc. (Appendix 4); and additional information on the proposal submitted by Hackensack Meridian Health and Cota, Inc. subsequent to the initial proposal submission (Appendix 5).

SUMMARY STATEMENT

PTAC recommends the *Oncology Bundled Payment Program Using CNA-Guided Care* for limited-scale testing with six stipulations. PTAC's support for this model is grounded in the model's robust use of precision medicine practices and proposed payment structure that aims to match precision medicine with precision in payment. Although the proposal as submitted is designed as a pilot project for testing at one institution with the use of a proprietary patient classification system to identify most appropriate clinical care, PTAC believes that limited-scale testing (beyond a pilot test by the submitter alone) can generate important information useful to development of a model for more widespread implementation and testing. PTAC's stipulations for testing this model on a limited scale reflect this belief and require: 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) that HHS give special attention to the advantages and disadvantages of the use of proprietary software in this model; 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; and 6) testing should be coordinated with other models currently being tested by HHS such as the Oncology Care Model. PTAC additionally encourages HHS to 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*.

PTAC REVIEW OF PROPOSAL

The *Oncology Bundled Payment Program Using CNA-Guided Care* was submitted to PTAC by Hackensack Meridian Health (HMH) and Cota, Inc. on March 23, 2017. The proposal was first reviewed by a PTAC Preliminary Review Team (PRT) composed of three PTAC members, two of whom are physicians. These members reviewed the proposal and related data and information on Medicare beneficiaries with diagnoses of breast, lung, colon, and rectal cancers; secured additional clarifying information on the proposal from Hackensack Meridian Health and Cota, Inc.; reviewed all comments on the proposal submitted by the public; and received comments from the Office of the Actuary on the model. The PRT also talked with CMS' Center for Medicare and Medicaid Innovation (CMMI) to better understand the difference between the proposed model and CMMI's Oncology Care Model. The PRT's findings and conclusions were documented in a *Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC),* dated August 14, 2017, and sent to the full PTAC on August 30, 2017 along with the proposal and all related information. At a public meeting held on September 8, 2017, PTAC deliberated on the extent to which the proposal meets the criteria

established by the Secretary in regulations at 42 CFR § 414.1465, and should be recommended.[1] Below are a summary of the *Oncology Bundled Payment Program Using CNA-Guided Care*, PTAC's comments and recommendation to the Secretary on this proposal, and PTAC's evaluation of the proposal compared to the Secretary's criteria for PFPMs.

PROPOSAL SUMMARY

The *Oncology Bundled Payment Program Using CNA-Guided Care* submitted by HMH and Cota, Inc. is a bundled payment model for care of patients with newly diagnosed breast, colon, rectal, and lung cancer.

The submitters were clear that their proposal was intended as a pilot for HMH 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. However, they asserted that other entities could implement the model as a follow-up to the pilot.

The payment model consists of comprehensive, bundled payments that include cost of care for: 1) oncology services for 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; these bundles are designed to ensure payments match the care needs of subgroups of similar patients. These groupings are determined by Cota, Inc.'s proprietary patient classification system called Cota Nodal Addresses (CNAs), which assigns each patient a CNA based on specific historical, demographic, biologic (including genomics), and treatment factors as well as type of therapy intent (e.g., adjuvant vs. neoadjuvant) and progression status. There can be hundreds of CNAs within a single bundled payment category. In the model, each patient is assigned a Cota, Inc. CNA; only patients with a CNA would be enrolled in the payment model.

The assigned CNA directs all subsequent care through the use of pre-determined treatment protocols, called treatment "lanes." Each CNA has available to it multiple, alternative treatment lanes. The treatment lanes were developed by the submitter based on a three-year retrospective analysis by the submitter of patient characteristics, treatments, outcomes, and costs of care and based on nationally accepted guidelines, mostly from NCCN (National Comprehensive Cancer Network) and ASCO (American Society of Clinical Oncology). Processes

[1]PTAC member Grace Terrell, MD, MMM was not in attendance and did not participate in deliberations or voting.

for patient care included in the lanes include diagnostics, imaging, surgery, chemotherapy, and physician visits – including follow-up care, comorbidity management, and routine care management. Through the selection of the treatment lane, many key aspects of the patient's care are 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. Once a patient receives a 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 appropriate for the CNA.

The submitters noted that other oncology practices and cancer centers could participate either by purchasing Cota's Nodal Address™ patient classification system or (for those not wishing to utilize Cota's system) by using their own care patient classification systems and treatment protocols.

The proposed payment model would 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 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, and adjusted for case mix. The payment amounts adjust for case mix in the performance year (rather than in the years the costs were determined); i.e., if a different mix of patients (as identified through CNAs) presents in the performance year compared to the year(s) in which the costs were determined, then the payments will adjust to reflect the different mix.
- HMH will receive the payments at the start of the episode period and use them to compensate providers and pay for care coordination and other uncovered services.
- Because the payment is fixed, HMH will be at risk for the costs of delivering care if their costs exceed what they are paid.

At the end of twelve months, the bundled payment will no longer apply to an enrolled patient and all medical services will revert to fee-for-service (FFS) reimbursement. The proposal also requests a stop-loss arrangement at twice the bundled payment per patient due to the limited number of patients enrolled and the extended time frame. "If the expenses for a patient

reaches [*sic*] 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 accord 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 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 the payment model in the future.

This model initially would apply only to physicians in HMH's CIN (clinically integrated physician network). These physicians are currently participating in the Medicare Shared Savings Program (MSSP). All physicians affiliated with HMH's CIN would be included in the model if expanded later. The submitter states that an estimated 2,500-3,000 patients would be eligible for the payment model in its initial stage. All participating physicians in this model will use Epic as their EHR. HMH and Cota will evaluate clinical quality metrics and financial metrics.

RECOMMENDATION AND COMMENTS TO THE SECRETARY

PTAC recommends the *Oncology Bundled Payment Program Using CNA-Guided Care* for limited-scale testing with six stipulations. PTAC's support for this model is grounded in the proposed model's robust use of precision medicine practices and payment structure that aims to match precision medicine with precision in payment. Although the proposal as submitted is designed as a pilot project for testing at one institution with use of a proprietary patient classification system to identify most appropriate clinical care, PTAC believes that limited-scale testing (beyond a pilot test by the submitter alone) can generate important information useful for developing a model for more widespread implementation and testing. PTAC's stipulations for testing this model on a limited scale include requirements for: 1) limited-scale testing proceeding after input from other oncology groups and other clinicians involved in patients' care; 2) testing in more than one site; 3) attention to the advantages and disadvantages of use of proprietary software; 4) formal processes for patient engagement and shared decision-making; 5) testing should include an explicit formal plan for the quality incentive payments for physicians; and 6) addressing overlap with other models currently being tested by HHS such as CMMI's Oncology Care Model. PTAC additionally encourages HHS to 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*.

Model's aim to pair precision in payment with precision medicine.

PTAC recommends this model for limited-scale testing (beyond a pilot test by the submitter alone) with stipulations because of its innovation and the expected value of matching payment bundles to clinically precise patient categorizations and treatment. PTAC notes the health system's increasing focus on precision medicine, and PTAC is attracted to this model because of the notion of defining a precision payment to support precision medicine. Although the model as proposed is for pilot testing by HMH and Cota, Inc. using Cota's proprietary software, PTAC believes that the model (see stipulation about proprietary software below) should be tested at additional sites in order to determine whether and how it could be expanded nationally.

While PTAC notes several significant issues that would need to be addressed if this were to become a generalized model, PTAC sees the model's innovative approach to bundled payment as important, and PTAC believes that a test of the model is one way to begin addressing these issues. Limited-scale testing would yield information that would determine if expansion of the model is appropriate. PTAC also thought that the model has been sufficiently developed such that (with the support of CMS to help sharpen what further needs to be done before limited-scale testing) a limited scale test would be a valuable step in getting the model ready for much broader implementation and testing. PTAC members observed that there is likely to be a period of time in which the parameters of the model will need to be fully developed and that it would be difficult to develop the parameters of the model accurately without actually implementing the model. PTAC believes that many of the most important details will need to be worked out in practice.

For example, the submitter is a participant in the Medicare Shared Savings Program, and PTAC's analyses find that rates of cardiovascular disease in oncology patients are significantly higher than in the average Medicare population. A limited scale test of this payment model would address payment issues such as handling of payment for co-morbid conditions (designing the model as an oncology-care-only payment model or a Total Cost of Care model), overlapping payment, and avoiding double-counting savings.

Ultimately, PTAC perceives the model as a potentially expandable national model that would need to be tested on a limited scale at multiple sites. PTAC identified the following key issues (stipulations) to be resolved prior to initial, limited-scale testing.

PTAC stipulation for limited-scale testing: limited-scale testing should only proceed after obtaining input from other oncology groups and other clinicians involved in patients' care.

PTAC members noted that this model was submitted by just one provider, not by a coalition or broadly representative group of providers. PTAC members thought it advisable that prior to limited-scale testing that HHS seek comments and input on the model, and on the extent to which it can be operationalized beyond HMH from other oncology groups and other clinicians involved in patients' care. This also is reflected in PTAC's stipulation that limited-scale testing not be interpreted to mean testing in just one site. The ability to recruit additional sites should be improved by obtaining and incorporating the input of other sites. This is especially necessary before considering any expansion of the model to other medical conditions.

PTAC stipulation for limited-scale testing: Testing in more than one site.

Limited-scale testing should not be limited to one site; e.g., Hackensack Meridian Health, as the submitter has proposed. Other test sites should be recruited to participate in the testing. This will help address concerns that the model as described (including the proposed use of specific proprietary software) might be so site-specific that the results might not be generalizable to a broader use of the model.

In the hope that the results of initial testing will be promising, the scalability to other sites (for cancer care and perhaps even for other illnesses) needs to be a central factor in the design of the limited-scale testing to help generate data that will facilitate expansion. Testing in more than one site will help distinguish variation in implementation that does not threaten the integrity and success of the basic model from variation that does. Testing in additional sites is related to PTAC's second stipulation that limited-scale testing proceed after input from other providers.

PTAC stipulation for limited-scale testing: special attention to the advantages and disadvantages of the use of proprietary software in this model.

PTAC acknowledges the central role of the proprietary software, Cota Nodal Address (CNA) Guided Care™, in the submitted model, *Oncology Bundled Payment Program Using CNA-Guided Care,* and also acknowledges the Secretary's prior responses to proposed models that involve use of proprietary software or other products. With respect to the *Oncology Bundled Payment Program Using CNA-Guided Care*, PTAC is divided in its thinking about how this should be addressed in the limited-scale testing of this model. A majority of PTAC members believe that the limited-scale testing should require testing in at least one site that does not use the Cota Nodal Address (CNA)-Guided Care software. This thinking reflects a concern about the

generalizability of the results of limited-scale testing if it were to be implemented using only CNA-Guided Care, and that if the payment and pricing mechanism is tied to that system, then it could be an obstacle to creating a generalizable national payment model. These members recommend that the model be tested both in settings which use CNA-Guided Care software and in settings that use other approaches for classifying patients for determining treatment protocols and determining payment bundles.

A few PTAC members do not agree that limited-scale testing of this model must include testing at a site that does not use CNA-Guided Care. While these members felt it would be desirable to test the model at sites using different software, they expressed concern that *requiring* use of alternative systems at some limited-scale testing sites could potentially slow down the testing or make it impossible to move forward with any testing. These PTAC members view CNA-Guided Care as just a mechanism for translating patient characteristics into treatment groups, and that the structure of the payment model is not dependent on one specific type of software that facilitates that process. These PTAC members did not perceive uniform use of CNA-Guided Care as an obstacle to testing all other aspects of the model in the short term. They point out that when it is ultimately tested at other sites, other patient classification and treatment protocol tools could be used at that stage, or that the CNA-Guided Care system could be made widely available and not necessarily as proprietary as it currently is, or that other tools might be developed in response to the availability of a payment system that would use them. Members also offered that CMS, working with HMH and Cota, Inc., might be able to find a way to make the software more widely available either through some modest licensing arrangement or persuading Cota, Inc. to make it available to all.

Some PTAC members also called attention to the additional issues that need to be attended to when including a proprietary product in a model that is undergoing an evaluation. Specifically they noted the need for transparency and visibility of all aspects of the software that is being tested, so that if any part of it causes variation across sites, it can be understood.

As a result, PTAC recommends that HHS give special attention to the advantages and disadvantages of the use of proprietary software in a limited scale test of this model.

PTAC stipulation for limited-scale testing: formal processes for patient engagement and shared decision-making.

PTAC members expressed concern that the written proposal as submitted did not address how patient preferences are to be handled with regard to assignment (or re-assignment) to CNAs or to selection of treatment. No formal or informal shared decision-making processes were described in the written proposal and none of the examples of treatment selection decisions

mentioned patient preferences as a reason. Given the importance of context-specific choices in cancer care, PTAC found this omission troubling, although the submitters made encouraging statements on this topic during their interview with the PRT and in their presentation to the full PTAC. PTAC also wants to underscore that formal processes for patient engagement and shared decision-making should be developed with input both from oncologists and other clinicians involved in patients' care.

For this reason, PTAC found that the proposal "does not meet" the Secretary's criteria on "Patient Choice." PTAC believes that patient choice is a very important component of cancer care, especially because of the high morbidity associated with some treatment choices. PTAC recommends the development of formalized processes for patient engagement and shared decision-making as a structured part of the model prior to limited-scale testing.

PTAC stipulation for limited-scale testing: testing should make explicit the method of awarding quality incentive payments to physicians.

PTAC had a number of questions about how quality incentive payments would be awarded to individual physicians. Material submitted by the submitter states, "Of greatest importance, the bundled program first requires achieving an expected clinical outcome based on evidence. Only after achieving that outcome would shared savings be available, determined by the impact and the total cost of care." In discussions with the PTAC the submitters also referenced creating a percentage of responsibility for individual patients (attribution), matching up the quality metrics, and then globally looking at all physicians and distributing funds should there be excess above the FFS dollars. This raised questions about how individual physician financial incentives would be determined, calculated and awarded subsequent to each entity's receipt of bundled payments and about how the financial incentives would operate to promote and reward high quality, coordinated care. In order to understand how financial incentives would perform in a test of this model, PTAC recommends that testing make explicit the method of awarding quality incentive payments to physicians.

PTAC stipulation for limited-scale testing: Testing should be coordinated with other models currently being tested by HHS such as the Oncology Care Model.

PTAC was impressed by the diagnostic and treatment precision offered by the HMH-Cota model as compared to CMMI's current Oncology Care Model (OCM). PTAC members noted that OCM is collecting data on staging and other clinical variables through a data registry that may include some of the same discrete elements contained in the CNA-Guided Care algorithms. PTAC members recommend that HHS examine how this new model might inform and complement

current and future aspects of the Medicare OCM, and also that HHS ensure that testing of the model be coordinated with OCM and other models.

In addition to the above stipulations, PTAC encourages HHS to 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*.

EVALUATION OF THE PROPOSAL USING THE SECRETARY'S CRITERIA

PTAC Rating of Proposal by Secretarial Criteria

Criteria Specified by the Secretary (at 42 CFR §414.1465)	Rating
1. Scope of Proposed PFPM (High Priority)[1]	Meets Criterion
2. Quality and Cost (High Priority)	Meets Criterion
3. Payment Methodology (High Priority)	Meets Criterion
4. Value over Volume	Meets Criterion
5. Flexibility	Meets Criterion
6. Ability to be Evaluated	Meets Criterion
7. Integration and Care Coordination	Meets Criterion
8. Patient Choice	Does Not Meet Criterion
9. Patient Safety	Meets Criterion
10. Health Information Technology	Meets Criterion and Deserves Priority Consideration.

Criterion 1. Scope (High Priority Criterion)

Aim to broaden or expand the CMS APM portfolio by addressing an issue in payment policy in a new way, or including APM Entities whose opportunities to participate in APMs have been limited.

Rating: Meets Criterion

As a payment model for oncology, this proposal addresses a clinical area already being addressed by CMS' Oncology Care Model (OCM). Nonetheless, PTAC found numerous aspects of this model innovative, potential improvements over aspects of OCM, and worthy of being part of an oncology payment model. Although many oncologists are participating in OCM, the majority of oncologists are not, so another oncology payment model could provide an

[1]Criteria designated as "high priority" are those PTAC believes are of greatest importance in the overall review of the payment model proposal.

opportunity for additional oncologists to participate. In addition, cancer costs have shown the highest rate of growth for any clinical area for several years and are predicted to be among the highest cost growth areas for the near future. PTAC did, however, have concerns about the proposed use of proprietary software on the potential scope of the model, noting that if the model were to require the use of proprietary software, this could limit its uptake. PTAC also noted other concerns (discussed below), especially about the payment approach. Overall, assuming concerns could be overcome, PTAC considered this proposed oncology model, if viable, to be a valuable addition to the CMS portfolio, even though CMS' portfolio already includes the OCM.

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.

Rating: Meets Criterion

With regard to quality, the treatment lanes contained in this system and the specificity with which the Cota Nodal Address is defined by very highly organized and highly specified patient demographics and diagnostic testing, are innovative and evidence-based. Because of the precision of the diagnosis, including relevant genetic testing, and treatment lanes created for the subsequent care of the patient, this model is likely to reduce variation in the treatment of cancer patients. PTAC considered this likely to improve quality of care for patients receiving cancer care services.

PTAC did have some concerns that having an assigned CNA (and thus having all subsequent care decisions determined by that CNA) could limit the ability of physicians to respond to patient preferences in ongoing care decisions. It 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. One member expressed further concern about the lack of an explicit connection between the payments and performance on quality measures, noting that the proposed payment model puts the oncologist at risk for spending. While the treatment lanes can help protect patients from under-treatment, they cannot ensure that patients' pain or quality of life are adequately addressed. PTAC's last concern was that treatment protocols for cancer change rapidly. As a result, PTAC has some concerns about the speed with which the treatment protocols contained in the software are being updated appropriately and timely.

With regard to cost, PTAC found that determining the proposal's impact was challenging and depends largely on the pricing of the bundles. Using costs from a single site (as the submitter proposed) 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 and reduced variation in costs for CMS. Importantly, unlike other bundled payment models (including the OCM), the assignment of patients to clinically specific CNAs 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) has at least two benefits. 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). Often in bundled arrangements there is a concern about overtreatment in order to take advantage of the bundled payment. PTAC finds that the specificity of criteria for entry into this model mitigates potential gaming of a bundled payment around this, because patients either fall into the criteria or they don't, and this is auditable. 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 are viewed as strengths of the model and 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 PFPM cannot be tested under current payment methodologies.

Rating: Meets Criterion

PTAC finds four aspects of this payment model 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 a fixed amount per cancer category. These four factors are all improvements over the existing OCM. PTAC also considered the inclusion of non-cancer related costs a strength, but was 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 pre-determined prices? Will the historical data accurately represent unit costs in the payment model? How will the model handle "leakage" of both patients and doctors? If payments depend on assignment to a CNA, what happens when a patient changes CNA due to disease recurrence or because the patient

changes their mind about care goals? How will savings be calculated and will they be valid estimates?

Further, the proposed calculation for pricing the non-cancer services may be valid 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. For example, PTAC data analyses 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 comorbidities found in each of these cancer populations. However, how does one correctly project total cost of care with an uneven distribution of comorbidities? Variances inside a bundle could be very significant. There also is a need to understand the non-oncology costs and the payment issues associated with those costs that occur outside of the oncology care system.

In addition, the small number of cancer patients in any particular participating provider could make variances at the provider level very significant. The model proposes to exclude outliers. However, PTAC 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.

PTAC also had questions about the practical aspects of payment. For example, what will be the mechanism for initiating the bundle? While the *concept* was clearly described in the proposal, the practical issue of how to operationalize the initiation of a bundle was not clear. Two potential possibilities (using a pathology claim or a separate communication) need to be examined and tested. Further, how will individual providers be paid? PTAC noted some complexity on the practical side of implementing a model that has multiple recipients of payments, with one overall recipient of the episode payment, who is supposed to then pay all practitioners for their portion of the overall care provided.

Finally, PTAC noted that there was ambiguity around whether or not this was a total cost of care model or an oncology cost-only model. PTAC members noted that an oncology cost only model would be difficult, given the number of comorbidities accompanying a cancer diagnosis. Because the proposer appears to be open to either approach, PTAC highlights this issue for HHS attention and discussion with the submitter.

Overall, PTAC felt that the identified concerns and related questions above could not be answered without some testing of this model.

Criterion 4. Value over Volume

Provide incentives to practitioners to deliver high-quality health care.

Rating: Meets Criterion

As a bundled episode 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. Conversely, 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. 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 "freelancing." Although HMH has committed to this, a mechanism would be needed to ensure similar protection in order to generalize the model.) However, while the submitters rely on the precision of their software and the incentives to reduce costs, the proposal does not describe in detail the mechanism by which costs will be reduced. Nonetheless, PTAC found the risks reasonably balanced.

Criterion 5. Flexibility

Provide the flexibility needed for practitioners to deliver high-quality health care.

Rating: Meets Criterion

PTAC considered the criterion of flexibility to be relevant to three different aspects of this proposal: 1) the use of this specific patient classification and treatment protocol 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 Nodal Address (CNA) Guided Care™ patient classification and treatment protocol 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) however, this constraint is likely to benefit patients by reducing unwarranted variation. The high number of CNAs and their specificity is actually a strength of the proposal in that treatment variability is a well-known problem in U.S. health care. The specificity of the software as presented, and its anticipated reduction in inappropriate variability, despite the constraint on flexibility, would be a positive.

Nonetheless, PTAC was 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.) PTAC did not evaluate the extent to which each and every treatment or service in Cota Nodal Address (CNA) Guided Care™ is explicitly tied to publicly available evidence, nor did it seek to determine the extent to which each recommended action is best standard of care. PTAC considered these two characteristics to be essential aspects of any care pathway system that constrains practitioner flexibility. Overall, PTAC concluded that 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. Alternatively, if any system of cancer care paths can be used with this payment model, and the decision support software includes these essential characteristics, then PTAC considers this proposal as providing practitioners with adequate flexibility.

Another concern is that 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. PTAC observed that there are always situations that arise in clinical practice that do not fit a prescribed model, and if a patient-doctor dyad decided that it was actually in the best interest of the patient to disagree with the recommendation of the software, it is unclear what will be the treatment path. Is it or is it not included in the bundle? Further, the model's intent to provide financial incentives to practitioners for adhering to the care paths could put the practitioner in conflict with the best interests of the patient. Since there are generally multiple protocols and treatment options for any individual patient, oncologists would still have some flexibility to adapt to individual patient needs. However, mitigation strategies would include limiting the size of the incentives and/or providing practitioners with the ability to opt out of recommendations in specified circumstances. If this proposal were tested on a limited scale, HHS 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.

Rating: Meets Criterion

PTAC assumes that an evaluation of this proposed model would compare historical to actual costs, possibly using a difference in differences approach. The submitter's plan to measure patient experience and quality metrics seems adequate. However, PTAC had several concerns. The first pertains to the challenges created in the overlap between this proposed model and

CMMI's Medicare Shared Savings Program (MSSP), in which the submitter (Hackensack Meridian Health) is a participant. How is the overlap between multiple models running simultaneously best handled?

Second, implementation in a single site with proprietary software and with relatively small numbers would both limit the ability of this proposal to be evaluated. Alternatively, 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 have to use multiple payment methods. This seems unrealistic. The model's performance measures also would be based on comparing the submitter's 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, should the model be a total cost of care or oncology-costs-only model? Because the submitter appeared to be open to either approach, PTAC decided to not assume one or the other but to call attention to this question for HHS discussion with the submitter.

However, if one considers the evaluation to be more about "proof-of-concept" than generalizability, then this proposal could be evaluated against that more limited standard. PTAC considered these questions and concluded that a test of the HMH-Cota proposed model could yield information that would determine if expansion of the model is appropriate, and how this could best be done.

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.

Rating: Meets Criterion

PTAC data analysis confirms that there are high rates of comorbidities (especially cardiovascular conditions) in the target population. For example, cardiovascular conditions were over-represented in this group of cancer patients in at least three of the four targeted diagnoses, and this has implications for care; i.e., these are not patients with single discipline problems. So by definition, care needs to be coordinated across a multidisciplinary group, and care integration and coordination will be important. To the extent that care integration is an inherent characteristic of a clinically integrated network, and all providers involved were using the same EHR (both components of the proposed model's proposed pilot test), PTAC did not have

significant concerns. PTAC viewed the payment model as encouraging care integration and care coordination in a general sense.

However, while PTAC noted the model's potential to deliver highly coordinated care, it also noted limited description in the submitter's written proposal of the specific nature of the care coordination efforts or of the incentives internal to the organization that would encourage these goals. PTAC noted also that if the model were not to consist of a single organization providing comprehensive care, that there could be potential for significant care coordination issues.

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.

Rating: Does Not Meet Criterion

This was the only one of the Secretary's ten criteria that PTAC found the proposed model "Does Not Meet." Specifically, PTAC was concerned that the proposed model does not address how patient preferences are to be handled with regard to assignment (or re-assignment) to CNAs, nor is there any description in the proposed model 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, PTAC found this omission troubling, though the submitters made encouraging statements on this topic during their presentation to PTAC.

In its deliberations, PTAC underscored that in cancer care, patient choice is a very important aspect of piece of care (as with all care, but perhaps especially in cancer care because of the high morbidity associated with some treatment choices). Because of this, PTAC wants to ensure that shared decision-making processes are developed and constitute a key component of any test of the model.

Criterion 9. Patient Safety

Aim to maintain or improve standards of patient safety.

Rating: Meets Criterion

The proposed model's use of HIT to define and monitor the delivery of cancer care should enhance patient safety. As noted above, PTAC would like to see some attention to the

verification of the pathologic diagnosis, given 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.

Rating: Meets Criterion and Deserves Priority Consideration

This proposal model would use HIT to advance precision medicine and to support clinical decision-making. 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.

APPENDIX 1. COMMITTEE MEMBERS AND TERMS

Jeffrey Bailet, MD, *Chair*

Elizabeth Mitchell, *Vice-Chair*

Term Expires October 2018

Jeffrey Bailet, MD
Blue Shield of California
San Francisco, CA

Elizabeth Mitchell
Network for Regional Healthcare Improvement
Portland, ME

Robert Berenson, MD
Urban Institute
Washington, DC

Kavita Patel, MD
Brookings Institution
Washington, DC

Term Expires October 2019

Paul N. Casale, MD, MPH
NewYork Quality Care
NewYork-Presbyterian
Columbia Weill Cornell
New York, NY

Bruce Steinwald, MBA
Independent Consultant
Washington, DC

Tim Ferris, MD, MPH
Massachusetts General Physicians Organization
Boston, MA

Term Expires October 2020

Rhonda M. Medows, MD
Providence Health & Services
Seattle, WA

Len M. Nichols, PhD
Center for Health Policy Research and Ethics
George Mason University
Fairfax, VA

Harold D. Miller
Center for Healthcare Quality and Payment Reform
Pittsburgh, PA

Grace Terrell, MD, MMM
Envision Genomics
Huntsville, AL

APPENDIX 2. PFPM CRITERIA ESTABLISHED BY THE SECRETARY

PFPM CRITERIA ESTABLISHED BY THE SECRETARY
1. 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 participate in APMs have been limited.
2. Quality and Cost. 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.
3. Payment Methodology. 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.
4. Value over Volume. Provide incentives to practitioners to deliver high-quality health care.
5. Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care.
6. Ability to be Evaluated. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.
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.
8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.
9. Patient Safety. Aim to maintain or improve standards of patient safety.
10. Health Information Technology. Encourage use of health information technology to inform care.

APPENDIX 3. DISTRIBUTION OF MEMBER VOTES ON EXTENT TO WHICH PROPOSAL MEETS CRITERIA AND OVERALL RECOMMENDATION[1]

Criteria Specified by the Secretary (at 42 CFR §414.1465)	Does not meet		Meets		Priority consideration		Rating
	1	2	3	4	5	6	
1. Scope of Proposed PFPM (High Priority)[2]	0	0	2	5	3	0	Meets criterion
2. Quality and Cost (High Priority)	0	0	4	5	1	0	Meets criterion
3. Payment Methodology (High Priority)	0	1	8	0	1	0	Meets criterion
4. Value over Volume	0	2	4	3	1	0	Meets criterion
5. Flexibility	0	3	4	1	2	0	Meets criterion
6. Ability to be Evaluated	0	2	6	2	0	0	Meets criterion
7. Integration and Care Coordination	1	1	4	4	0	0	Meets criterion
8. Patient Choice	0	8	2	0	0	0	Does not meet criterion
9. Patient Safety	0	1	5	3	1	0	Meets criterion
10. Health Information Technology	0	0	1	2	7	0	Meets criterion and deserves priority consideration

Do not recommend	Recommend for limited-scale testing	Recommend for implementation	Recommend for implementation as a high priority	Recommendation
1	9	0	0	Recommend for limited-scale testing

[1]PTAC member Grace Terrell, MD, MMM was not in attendance.
[2]Criteria designated as "high priority" are those PTAC believes are of greatest importance in the overall review of the payment model proposal.