Preliminary Review Team (PRT) Questions
from review of: *Oncology Bundled Payment Program Using CNA-Guided Care™*
submitted by Hackensack Meridian Health (HMH) and Cota

Questions for Submitter*

A. Scope. The Proposed model does not appear to be a generic payment model for implementation by multiple providers. Rather, it appears designed for unique implementation by Hackensack Meridian Health (HMH) and Cota using care delivery and work design tools unique to HMH. Please clarify whether the model is intended for use only by HMH and its clinically integrated network. If intended for use by others, please describe:

1. **How a party other than HMH and Cota would implement the model, and**

The model is intended to be scalable to multiple healthcare delivery systems; it is not intended for the sole use at HMH.

The concept of bundled payments is well established in multiple disease states and has recently been applied to medical oncology as a generic payment model for varied providers. This proposal refines and improves on existing bundle concepts by incorporating precision medicine upfront using precise risk stratification (the CNA) and then based on real world evidence guiding care to evidence based (NCCN/ASCO/Peer reviewed literature) pathways ("lanes of care") accounting for currently medically accepted varying "lanes" of therapy within each bundle roughly equating to the various treatment regimens commonly utilized. (example: a bundle may be broadly defined as "anthracycline based chemotherapy for breast cancer" whereas the lanes would be various anthracycline regimens such as "AC-T, CAF, dose dense AC, etc).

Cota currently assists healthcare providers in reviewing their current treatment patterns by reviewing historical records contained in the electronic health record (EHR). The treatment strategies are then grouped into bundles. A center not wishing to utilize Cota to assist in this effort could review their own practice patterns using any tools (or by hand). In the pilot, Cota will support the Hackensack Meridian network, but this concept could be generalized. Each hospital system will have differing treatment strategies (ie, different lanes) and may have even

* Please note that these questions are intended to help the PRT better understand the above proposal. No inferences should be made from the questions about what the PRT might ultimately recommend to the full PTAC. These questions are not intended to give advice to the submitter about the proposed model.

differing bundles for each cancer per their own preference if an evidentiary basis exist to support their choices of care.

Once all the lanes within a bundle are established Cota will use its proprietary classification system to discern for each specific CNA, which lane is yielding the best "value", which will include first, clinical outcomes and then second the total cost of care in a lane. For example, a specific CNA may refer to a women older than 65 years with Stage IV triple negative breast cancer. There are 5 lanes deemed clinically acceptable based on general evidence to choose from. Upon analysis, however, lanes 1, 2 and 3 have fewer toxic events than lanes 4 and 5, but otherwise identical survival outcomes. The first step for a system participating in our bundles program would be to close access to lanes 4 and 5 for patients with this CNA. Next, if in this example lane 1 was associated with a lower total cost of care than lane 2 and 3, patients and physicians would be provided this information to guide their choice. If lane 1 is chosen total cost of care would be reduced on average while an optimal clinical outcome is achieved. The ultimate decision on which lane is "best" will be left at the discretion of the hospital system.

For centers that do not wish to develop their own bundles and lanes, Cota and HMH are available to stand up a program, for a fee. However, the entire concept is generic in theory. The model is not specific to a center or even a disease.

A main aim of this pilot is to demonstrate that the data on past treatments, outcomes, and toxicities, when viewed through the lens of Cota's unique classification schema (the CNA) can inform better decision making. If standards are set for managing distinct bundles of care, and the payment model is based on those standards, then the model is flexible and applicable to a variety of providers.

2. **The required care delivery components of the model.**

The model requires the delivery system to have an electronic health record (EHR) system to gather complex and detailed information on diagnostics, treatments, toxicities, and outcomes.

If a full bundle program is desired, a complete healthcare delivery network including medical, radiation, and surgical oncology expertise within the network, is required. More limited bundled programs could include only a portion of providers (for example, only medical oncology) however the limited programs would need to be monitored to confirm that care is not shifted to non-participating specialists. More comprehensive bundled programs, including networks from primary to tertiary care, are possible in the model. For this pilot, HMH plans to

encompass a broad range of services. The broader the program the more likely the program will truly capture "total cost of care."

B. CNA algorithms. With respect to the proposed use of Cota's CNA-Guided Care algorithms:

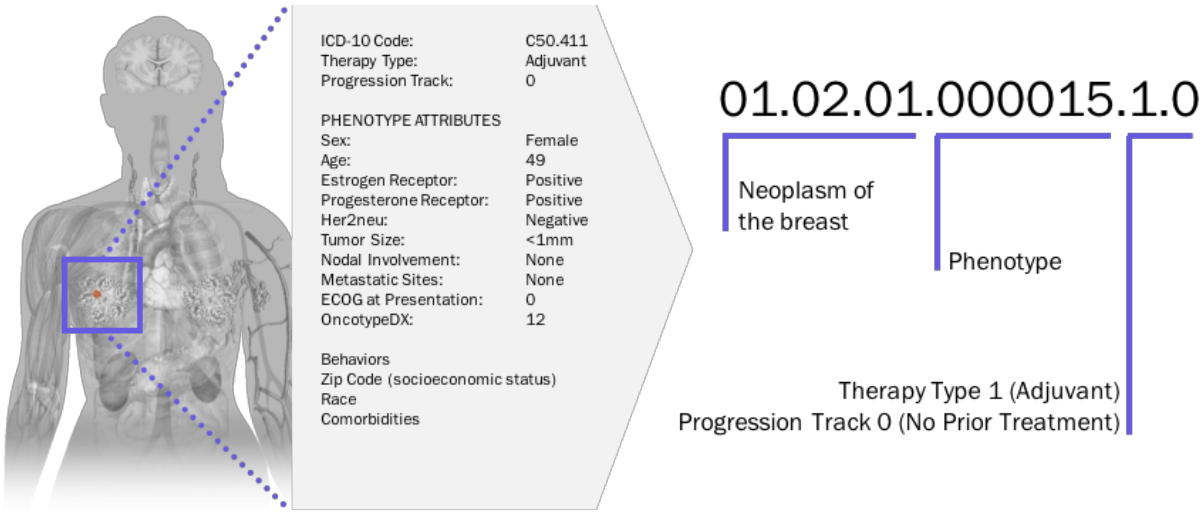
1. **Cota's patented and trademarked CNA-Guided Care software is a key element of the proposal. Is this technology available for use by non-HMH health care providers who would want to implement this model? If so, how would this be accomplished? Would it be provided at no charge to parties who wish to use it?**

The CNA technology is available for use by non-HMH health care providers that are seeking to implement this model. This would typically be accomplished by commencing a retrospective analysis of a given center's population, including mapping CNAs and understanding the distribution of cancer types across the population. Because the retrospective analysis requires labor on the part of Cota as well as assignment of CNA, Cota would expect some form of compensation on the part of parties who wish to utilize this approach to better understand their patient population, draw insights from it, and develop approach to bundled payments and treatment lanes.

2. **How can the public be assured that Cota's CNA-Guided Care algorithms are indeed current "best practice?"**

Cota collects, organizes and enriches real world data from the electronic health records of centers participating in its programs. Cota tracks the treatments patients have been given and the corresponding outcomes and toxicities. Cota uses its proprietary CNA classification schema to group similar patients together. This allows comparisons of therapeutic strategies via the CNA lens. Ultimately, it is the provider that is responsible for drawing insights based on this refined data to drive treatment "algorithm" development. Cota will enable the provider to compare various strategies for best outcomes and costs, something that is not currently commonly practiced in oncology. Current guidelines (such as the NCCN guidelines) are largely consensus opinion as to best practice without "real world" continuous outcome scrutiny. We envision that most centers, including those at HMH, will start care with guideline regimens, but that the CNA based care will gradually narrow choices for specific patient cohorts based on true outcomes.

The CNA itself reflects all the clinically prognostic data elements of a specific patient and their disease that tie together a cohort of clinically similar patients. The CNA elements are routinely updated to reflect new literature, discoveries, or any other features that add precision to a given patient type. Unlike ICD-9 or ICD-10 classifications that are extremely broad, the CNA is built from the ground-up using clinical criteria to be highly specific in separating distinctly prognostic different cohorts of patients. An example of breast cancer CNA construction follows.



3. **The proposal states that the algorithms will be updated "annually." Who determines if an update is correct? How will the algorithms accommodate advances in cancer care that occur more frequently than annually? Shouldn't updates be made as soon as a new standard of care is determined? How can the public (and PTAC) see what the proposal believes is clinically appropriate care, if the Cota algorithms are not fully described and available to the public? Are HMH and Cota willing to share the algorithms and how they were developed with PTAC?**

Cota does not provide or develop treatment algorithms. As noted above, the care decisions are guided by current standards of care as decided by the treating physicians. Cota however does assist physicians in understanding how certain treatments have performed on similar patient cohorts, so that the optimal treatment can be selected. In this demonstration, HMH has developed treatment algorithms and these will reflect the latest advances in cancer care as they are made available to patient care. While updates to the treatment lane can occur as advances are made, for administrative and infrastructure reasons HMH and CMS will need to decide how to reimburse for elements of care that are novel and not figured into the bundle price. We will propose a carve-out for major advances in care, or a pre-determined outlier

threshold, that triggers stop loss payment and otherwise a reversal to a FFS arrangement for such outlier cases.

As for the Cota CNA architecture, this is updated bi-yearly , with more frequent updates triggered by new elements that may impact clinical diagnosis, such as new mutations that are shown to impact care. While the CNA methodology is patented, Cota can demonstrate the hierarchy of certain CNAs to explain the methodology behind incorporating clinically relevant factors into the classification system.

4. **We understand that the treatment algorithms are based on 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." How does the model guard against stinting of care given that many clinical problems can take place in cancer patient that may not have been encompassed in this retrospective review? Please also describe more fully the database (and its limitations) from which this three year review was conducted.**

HMH and Cota consider it very important to guard against underutilization. We guard against this by ensuring that patients are placed in the correct care track, which is designed and requires participating providers to hit minimum standards of care for frequency of visits, quality, and therapy.

To enter a specific treatment bundle and lane in a prospective program, all patients will be required to be assigned a CNA. This assignment will ensure that the "proper" diagnostic evaluation is performed. For example, patients with adenocarcinoma of the lung will be required to undergoing genomic profiling for EGFR and ALK prior to therapy so that correct CNA assignment can be made, and thus appropriate care is delivered.

In the adjuvant care setting, where treatments are given with curative intent but outcomes take years to become apparent, bundle payment methods could encourage decreased dosing to avoid costly toxicities. Thus in a well constructed bundle programs additional safeguards need to be implemented. For example, a requirement that 80% of patients receive an 80% dose-intensity of a published curative adjuvant regimen would ensure adherence to best practices.

Patients are placed in known care paths, not subjectively placed in any financially motivated care path (see example above in scope) . We will also be measuring the group against the standard expectation of quality. Because physicians are compensated on quality and outcomes instead of saving money, we can ensure that there are no incentives for physicians to withhold care. The onus will be on the CIN (Clinically Integrated Network) to manage the patient in the

most efficient method possible. Currently the US healthcare system is operating at the other extreme – there are few mechanisms for preventing the opposite, or overutilization. We seek to bring the focus back to quality and outcomes and HMH will reward providers accordingly.

C. **Payment. Please clarify:**

1. **Why the model limits the episode to one year? What happens to the patient's care and costs after 12 months? Does the model include any provision for patients renewing their enrollment in the model, even for a new, cancer diagnosis?**

The vast majority of cancer care for newly diagnosed early stage patients occurs within the first year of diagnosis, including initial surgery, radiation and adjuvant therapy. Patients with more advanced cancers (ie, metastatic) may undergo prolonged therapy beyond a year, but this is uncommon. The currently Medicare OCM project utilizes a 6-month episode with options to renew that starts with initiation of chemotherapy. We selected a one year episode as a more appropriate time that allows initial diagnostic procedures and surgery, completion of most adjuvant therapies, and for institution of survivorship/monitoring plans. If this time period is successful and we can reasonably forecast treatment patterns beyond one year, then we will consider extending the bundle. However, in this pilot, after one year the bundle program will be over for a given patient and that patient's care will revert to FFS reimbursement. In our commercial program bundles for adjuvant therapy will be for one year and renew annually for three consecutive years. In metastatic disease bundles will renew every 6 months for three consecutive years.

2. **Whether individual bundled payments are made for each CNA "lane," for each diagnosis, or for something else. The proposal states that patients can change treatment "lanes," but how would bundled payment to HMH and HMH payments to providers be determined given the lane changes?**

Each bundled payment will encompass care from a variety of lanes. If a patient is changed from one lane to another but that lane is considered within the bundle category, then no changes in terms of the bundle will be triggered. One bundle will have multiple lanes, as it will not be a 1:1 matching. For example, a patient with breast cancer may switch chemotherapy regimens within a bundle due to toxicities with the same bundle payment.

If however a patient switches to a new bundle it is anticipated that the patient will be excluded from the program. For example, if a patient is started on chemotherapy for early stage disease, and progresses to metastatic disease during the year, the treatment algorithms

would need to be changed to a plan appropriate for metastatic disease. This patient would fall out of the bundle.

3. **The extent to which the CNA lanes are based on SEER cancer categories.**

SEER broadly defines cancer subtypes based largely on race, age, sex and stage. CNAs however classify patients based on multiple prognostically relevant elements. Thus, the CNA classification greatly enhances the specificity of each patient cohort. This allows a comparison of outcomes of "similar" patients. The SEER data is too broad to permit this type of analysis.

4. **For what would HMH be at risk… for total cost of care (cancer care and unrelated care) or only for the costs of cancer care? The proposal suggested both could be used.**

HMH would be at risk for all costs directly or indirectly related to the cancer diagnosis. This means that any costs pertaining to diagnostics, treatments, comorbidity management, or sequelae of the cancer diagnosis would be included in the bundled payment. As it may be difficult to delineate which care is related to the cancer diagnosis, we are willing to discuss a total cost of care agreement. Based on the limited volume of patients to minimize outliers, this would require a stop-loss provision. Our experience in the MSSP program gives us a comfort level regarding average annual cost of care, which would be added to the calculated cost of all cancer related treatment.

The initiation event to enter a bundle is the date of pathologic diagnosis of cancer.

5. **How is "leakage" handled? What proportion of your cancer patients fail to receive all of their cancer care from the HMH physician network? Are the costs of patients who leave the HMH network still included in the patient care costs for which HMH received a bundled payment? If so, how are these cost captured and how are savings shared?**

As HMH did with the ACO model, we will create an expectation and education plan with all providers and patients to orchestrate care and to minimize leakage. We understand that this will help stem leakage but will not prevent it.

We are open to discussing options for managing leakage. At the very basic level we will need for CMS to provide claims on an ongoing basis for patients enrolled in the program so that we can analyze the data for patterns of leakage. Moreover, we are open to discussing a mechanism for reimbursement, such as a claims modifier, when providers submit bills (to HMH or CMS) that signals to CMS that the patient is enrolled in our bundled payment program and

that the claims should be considered an encounter versus paid on a fee for service basis. This assumes that we will be responsible for total cost of care. This is an option that may be able to separate providers that are billing under the bundle, versus for care entirely unrelated to the bundle. The theory would be that providers not engaged with the bundled payment program because their care falls outside of the bundled program, or are unaffiliated with our Network, would not submit claims with the bundled payment modifier.

6. **Page 8 states, "The potential incentive pool will be proportionate to the level of risk borne by the practice." Please clarify what the "level of risk" means as we understand the proposal to not place providers at "down side" risk. This passage of text is under the header, "Feasibility of Program for Small Practices." Does the text only refer to how the model will be implemented in small practices? If so, how are small practices defined, and how will risk be handled in non-small practices?**

To restate, the potential incentive pool will be proportionate to the level of responsibility that individual provider has in the overall care for the patient. Physicians managing the primary oncology diagnosis will have the greatest responsibility, while physicians managing other related symptoms of the disease, such as cardiovascular issues, diabetes, etc., will be considered as having less overall responsibility compared to the principal oncologist. The potential savings will be divided between the Network and the physicians. The Network, assuming the financial risk, will receive a portion of the savings (if available). The physician portion will be distributed based upon attributed responsibility. This will combine attributed lives, adherence to treatment standards (quality), and level of responsibility.

For example, the ACO model was based upon primary care only. HMH used attributed lives and quality metrics to create a percentage of the total save for each physician practice. In that model, the financial share was calculated on a per physician basis, but the distribution went to the practice. Then the practice decided how to distribute the gain share, after a portion was retained by the Network for their financial and ancillary support. We are building a model that supports and provides incentive for all physicians form all disciplines to work as a team. As a team if adverse variance (too much or too little care) is minimized and choosing the lane of care with the best clinical outcome and when able the lowest total cost of care we will achieve our objective of optimizing clinical outcomes for all and reducing the total cost of care for the population served. We realize that for some patients the lane leading to best outcome will be the costliest and this takes precedence over cost. However, our analysis indicates that overall many patients can receive care in a lane that is less costly and result in similar or better clinical outcomes then more expensive lanes.

Participation in bundles requires a practice to be a member of our CIN and can share healthcare information in a timely manner. We will assist small practices by offering access to EPIC at a discount in accordance with all rules and access to Cota. There is no minimum number of patients per doctor and because care is designed at the individual patient level any size practice can participate.

7. **Page 9 of the proposal states, "HMH would distribute payment to physicians in accordance with services rendered, based on <u>fair market value</u>..."**
    i. **Please explain what you mean by fair market value and how you will determine this.**

We are referring to the standard FFS Medicare rate. Because this is a program that can be utilized across the continuum of insurance products, we can use that term to reference reimbursements for other insurance types. However, for Medicare patients, we are referring to rates as determined by CMS.

    ii. **How will revenue and savings be distributed to participating clinicians?**

As previously stated, physicians will be compensated using the current CMS fee schedule. This compensation can either be performed by direct billing to CMS (with modifier), or by billing to HMH (if HMH receives the agreed upon bundle price in advance). Savings will be split between the Network and the physicians. The Network will receive a portion of the realized savings because the Network has assumed the financial risk. The remainder will be distributed to the physicians. The methodology involves identifying all physicians participating in the care of the patient. Each physician will be assigned a percentage based on their responsibility for the individual patient. For example, the oncologist may be responsible for 70% of an individual patients' bundle, a surgeon 15%, and a cardiologist 10%, and the PCP 5%. These numbers become the percentage distribution available when adjusted for quality and attributed lives.

8. **Page 9 of the proposal states, "a bundled payment model creates the conditions that allow care coordination and other case management processes to thrive. . . ." Why can't HMH use fee-for-service payments above cost (payment margins) to pay for care coordination, case management any other patient support services?**

We believe FFS is insufficient for a number of reasons. The current FFS payment model was not set up to pay for comprehensive case management or care coordination across a spectrum of providers. By providing a global payment mechanism for the care of the patient during a specific time period we take the responsibility to manage the care coordination and case management that occurs across providers and care settings. If we are only paid for specific treatment and procedure, those other services do not have any effect on that snapshot of

payment. FFS are snapshot payments, but a series of snapshot, unit-based payments does not promote the comprehensive management of oncology patients, or patients in general.

9. **Please provide an example of how a bundled price would be calculated.**

We calculate the price of a bundle by taking the average cost in a three year look back to provide the best possible care to a Medicare patient, annualized over the region. We take this data and parse it out to the costs for a specific bundle and a lane. These inputs feed into the bundle price for a group or related lanes for certain diagnoses.

10. **Please explain in detail how funds would flow from CMS to providers under both bundled payments and FFS payments, using the following two scenarios:**
    i. A patient is diagnosed with cancer at HMH through the CNA and receives a treatment plan, and returns home to receive treatment from a local oncologist who is not part of HMH.

We are open to working with CMS to establish a mechanism for handling these types of patients. If a patient prefers to receive care outside of HMH, we will not continue their enrollment in the bundled payment program. In this scenario, if a patient continues to receive care outside of HMH, CMS can alert HMH when excess claims related to oncology are received, and a clawback of the initial bundled payment can be reconciled and returned.

ii. A patient receives all oncology care from the HMH but receives primary care and specialty care not related to his or her cancer from providers who are not a part of the HMH CIN.

Again, HMH is open to working closely with CMS to address this scenario. If we choose the claims modifier approach, then disproportionate number of claims without a bundle-designating modifier will trigger a set of logic to remove the patient from the bundle. We would manage the care for all the patients receiving care in our network for all the relevant conditions as previously stated.

11. **Page 15 of the proposal states, "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." How will HMH pay these providers? Will HMH pay the CMS FFS rate or something else?**

HMH will pay such providers the appropriate CMS FFS rate, with a modifier indicating that the claim should be treated as an encounter with zero payment, as the payment for such unit of services would be included within the prospective bundle payment already. We are

open to CMS handling all the FFS compensation but would require real time monitoring of cost per case.

12. **Page 23 states, "There may be a patient financial liability difference between treatments and HMH and Cota will seek to neutralize those through discussions with CMS." Please more fully explain the different types and extent of patient financial liability and what you mean by "neutralize those through discussions with CMS."**

Restated, we will not alter patient financial liability through this program. There may be Medicare patients with Part D coverage that limits the types medications that can be used. While HMH will work to find the appropriate medication or alternatives for such patients, we will not alter patient financial liability.

13. **How will you address high-priced chemotherapy? Will all drugs be included in the bundle, or will very expensive ones be carved out, or "passed through" in some way? How would you prevent stinting in use of high cost, but effective drugs?**

A bundled program does not discourage appropriate use of high cost therapies if they improve clinical outcomes (see example above). In most settings, higher priced therapies would be components of a separate bundle that would have a separate price. For example, one bundle in breast cancer would be "anthracycline based chemotherapy" and a different bundle would be "anthracycline chemotherapy plus Herceptin antibody therapy." The bundles are distinct and do not compete with each other, and can be priced separately. The CNA directed care will evaluate which bundle and what lane(s) in a bundle offers the most value (best clinical outcome lowest total cost of care). The competition for price will be within a bundle between lanes (AC vs CAF) if both treatments yield similar outcomes.

We propose a mechanism to consider a patient an outlier and remove them from the bundle. For example, if total costs for a patient exceeds 100% of expected spend, they become an outlier and are eliminated from the bundle. Effective chemotherapies, even if they are high cost, currently on the market would be included in the bundle and in cost forecasting. These chemotherapies would not be carved out of the bundle. We will create an outlier clause based on total spend.

14. **How will changes in drug pricing that occur after the bundled price has been established be addressed?**

We expect to revisit bundle pricing annually. In the meantime there may be changes in drug pricing but we do not expect changes to change bundle pricing drastically mid-year. Moreover, it may be more appropriate to move a patient from one bundle payment to another if the treatment lane is changed accordingly. However, we will not reprice the bundle mid-stream. For that year, we accept responsibility for the bundle. We accept the standard of care for that drug. It's all based upon a patient's ability to remain within the bundle.

15. **Page 14 states, "In oncology, one of the biggest changes in care delivery will be the introduction of new therapies and corresponding healthcare utilization. We expect to define provisions in the bundle price that reflect the reality of additional reimbursement for drug costs and associated treatment services on a yearly basis for the affected bundles." Please elaborate on this and explain how you will "define provisions in the bundle price that reflect the reality of additional reimbursement for drug costs and associated treatment services on a yearly basis for the affected bundles."**

Scenario 1: An introduction of a therapy that does not trigger a bundle change

If there is a new medication that is available, and we can document its appropriateness within the bundle, this will be re-addressed on an annual basis. A new immunologic agent, or a new diagnostic test, may become standard of care, which will be applied. We may need to create a new bundle to address a sudden, large movement of patients to an alternate set of treatment lanes. We expect based on prior analysis that most new agents will not impact the average cost of all the patients in the bundle.

Scenario 2: An introduction of a therapy that triggers a change in average bundle cost because it becomes standard of care

If a new medication or patient becomes eligible for a change in bundle, we would need to approach this differently, and engage in the model where outlier patients trigger a stop loss threshold that creates an exit of the bundle, or entry into a newly created bundle.

16. **Page 11 states, "Per our forecast, HMH and Cota expect total costs to be reduced by 10-15% for the whole population served." Please provide the rationale for this estimated cost savings and explain how you expect to achieve them.**

Based on our historical treatment of Medicare patients within our ACO, we could generate a minimum of 25% savings for their generalized medical care. Majority of savings was due to care

coordination activities, elimination of waste, and integration of medical care. By extending this to the oncology patients, we feel that unnecessary testing and hospitalization can be decreased by similar amount, however some additional costs will be borne by increased outpatient visits and cost of appropriate testing and therapies, leaving us with 10-15%. Moreover, by providing the standard of care per the pre-set treatment plans, will minimize failure points and patient outcomes.

In one example, we showed that increasing compliance to oncotyping patients tumors in stage II breast cancer led to on average an $11,000.00 reduction in total cost of care (inclusive of the cost of the test $4000.00) for the population because 30% of women had a low scores so did not need to receive adjuvant chemotherapy.

D. Patient enrollment and choice.

1. **Page 9 states, "Only patients with a CNA will be enrolled into the PFPM."**

i. What does this mean? Are their formal or informal inclusion or exclusion criteria? If any formal criteria, what are they?

What we mean by this is that all patients need to have a diagnosis at the level of precision of a CNA for the patient to be enrolled in the bundle program. This will facilitate the tracking of patients throughout their bundle performance, as well as provide Cota the identification of the patient so that the analysis can be done on that patient through Cortex.

CNAs have been established for all known cancer subtypes. The requirement for CNA assignment will ensure that the proper diagnostic procedures are performed (protection for underutilization of testing) and will assist in proper bundle/lane assignment.

ii. How is "cherry picking" avoided? Are all patient auto-enrolled? Is there an "opt-out" provision for patients?

All patients are auto enrolled but these patients are provided with a written form to allow them to opt-out, which will not prevent them from continuing to receive the appropriate treatment. Patient gets a preference to participate, similar to the opt-out processes for the ACO model.

iii. To what extent (and if so, how) would patients be notified of their enrollment in this this program?

We plan to have a combination of patient education sessions with the patient, alerting them of their enrollment, as well as a formal letter mailed to each patient as they are enrolled in the program, similar to MSSP.

2. **Page 9 discusses patient choice. Please describe the extent to which patient preferences are incorporated into CNA's algorithms. What happens (in clinical care and payment), if patients' preferences change after they are assigned to one of the CNA "lanes"?**

To be clear, a CNA is not a lane. A CNA is a type of clinically-based diagnosis categorization. It is the provider's discretion and decision which treatment to give the patient, with their consent, based on their clinically prognostic factors. If a patient chooses to change treatments after commencing on a treatment lane, then that decision will be made jointly with the patient and the oncologist and it will have no bearing on the bundle.

3. **Do you use a formal shared decision-making process, for example, when a patient refuses assignment to a proposed treatment lane?**

The bundled payment arrangement will not change the current process for shared decision making. Patients will continue to need to give consent, nor will they be forced into any particular treatment lane.

E. Quality.

1. **Appendix A sets forth a strong list of quality measures. Please describe how these measures will be scored, and how benchmarks and performance levels will be determined.**

All of the quality metrics are created such that there are only binary responses: yes or no. These measures, because of the binary nature, facilitate easier scoring for each individual item. Please see attached the spreadsheet with the metrics and the scoring system per cancer type.

We will benchmark survival outcomes and incidence and severity of toxicities based on published outcomes accounting for risk adjustments. We will also benchmark against the Cota database for a like CNA. We will track and report patient reported outcomes including quality of life by CNA, bundle and lane and compare providers by CNA to each other.

2. **How can the public be assured that there will be no stinting of care under this model? For example, what happens if a patient experiences a seizure as a result of a brain metastasis? How will subsequent care be assessed from a financial risk perspective?**

As mentioned earlier, if a patient experiences sequelae from cancer treatment, such as a seizure, that will be included in the scope of the bundle. This is because providers will need to manage such sequelae to achieve quality care. If there are catastrophic occurrences that are

not related to the original cancer episode or are of such nature as to become an outlier in terms of costs, HMH will seek to review process for approaching such cases as an outlier clause, in which case patients that meet pre-determined thresholds have their care reverted to FFS to address the outlier high-cost events and prevent the underutilization in catastrophic cases.

Progression of disease is anticipated in the model and with each progression a new CNA is assigned as will be a new bundle and lane appropriate for that CNA.

3. **Please describe more fully the linkage between performance on quality metrics and reimbursement to oncologists and other providers caring for the patient.**

One of the most important quality metrics is adherence to the plan of care and the bundle. Outcomes measurements and complications to care are also part of the quality metrics. Dose intensity, for example, is an integral part of the quality metrics, which facilitates the ability to compare performance across providers.

As noted in the adjuvant setting, the intent of therapy is curative. The best and only reliable surrogate of quality for survival outcomes here is delivered dose intensity of an NCCN or other appropriate standard regimen. Next is toxicity management, including incidence and severity, as well as avoidance of emergency room visits and hospitalizations. Finally, patient reported outcomes including pain management nausea constipation and performance status will be tracked and reported with outlier physician shared savings being at risk. In the metastatic setting where therapy intent is palliative, preservation of quality of life remains the key quality indicator.

4. **Page 11 states, "HMH may also encounter risks in achieving full visibility into measure performance." Please elaborate and explain more fully what this sentence means.**

We will consider the original statement as not applicable because we expect to have reasonably full visibility into the measure performance.

5. **Page 13 states, "HMH is planning on routine reporting and performance sharing with the providers on a quarterly basis using reports generated from both the BI tool and Cota's Cortex platform." Please clarify and explain what the "BI tool" is.**

HMH uses a business intelligence tool to monitor quality and performance across all physicians (not just oncology). The BI tool will continue to be used in the bundled payment program. The oncology program will leverage the Cortex platform from Cota to monitor oncology-specific quality and performance.

F. Relevant data. The proposal states that "HMH also has over 20 years of experience with its prospective bundled payment arrangement for bone marrow transplant patients" and experience with the Medicare Shared Savings Program (ACO). Please provide data on HMH's results in these programs to date.

Results from Medicare Shared Savings Program:

September 1st, 2016

HackensackAlliance ACO at Hackensack University Medical Center: Medicare Shared Savings Program Performance Year 2015 Quality and Financial Results

HACKENSACK, N.J., September 1, 2016– The Centers for Medicare & Medicaid Services (CMS) today announced the 2015 performance year results for the Medicare Shared Savings Program and the Pioneer Accountable Care Organization Model that show physicians, hospitals and health care providers participating in Accountable Care Organizations continue to make significant improvements in the quality of care for Medicare beneficiaries, while achieving cost savings.

In 2015, Medicare Accountable Care Organizations had combined total program savings of $466 million, which includes all Accountable Care Organizations' experiences, for 392 Medicare Shared Savings Program participants and 12 Pioneer Accountable Care Organization Model participants. The results show that more Accountable Care Organizations shared savings in 2015 compared to 2014, and those with more experience tend to perform better over time.

Medicare ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to provide coordinated high quality care to their Medicare patients. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors.When an ACO exceeds quality and financial thresholds – demonstrating achievement of high-quality care and wiser spending of health care dollars – it is able to share in the savings generated for Medicare.

HackensackAlliance ACO at Hackensack University Medical Center is one of the ACOs that shared savings.

"This marks the third year in a row that the HackensackAlliance ACO has generated savings and our best year to date," said Robert C. Garrett, co-CEO of Hackensack Meridian Health. "We are pleased to announce that we saved more than $33 million, placing us seventh in the nation for total savings."

"Year after year, the HackensackAlliance ACO continues to build upon its own success, consistently improving our quality scores," said said Mark D. Sparta, FACHE, executive vice president of Population Health Clinical Operations for Hackensack Meridian Health. "Thanks to the dedication of our physicians and our commitment to population health, our ACO will gladly receive more than $15.6 million for our earned performance payment."

"We are extremely proud of the members of the HackensackAlliance ACO for all of their hard work that has culminated in our best year ever and consistently resulted in savings," said Morey Menacker, D.O., president of HackensackAlliance ACO. "We continue to transform care for our Medicare patients as a result of the members collaborating and making advancements year after year."

Additional Resources
Visit the Medicare Shared Savings Program NEWS AND UPDATES WEBPAGE to access the CMS PRESS RELEASE and FACT SHEET, the link to the PERFORMANCE YEAR 2015 RESULTS FILE, and to learn more about the program.

About Hackensack Meridian Health
Hackensack Meridian Health is a leading not-for-profit health care organization that is the most comprehensive and truly integrated health care network in New Jersey, offering a complete range of medical services, innovative research and life-enhancing care. Hackensack Meridian Health comprises 13 hospitals, including two academic medical centers, two children's hospitals and nine community hospitals, physician practices, more than 120 ambulatory care centers, surgery centers, home health services, long-term care and assisted living communities, ambulance services, lifesaving air medical transportation, fitness and wellness centers, rehabilitation centers, and urgent care and after-hours centers. Hackensack Meridian Health has 28,000 team members, more than 6,000 physicians and is a distinguished leader in health care philanthropy, committed to the health and well-being of the communities it serves.

The Network's notable distinctions include having one of only five major academic medical centers in the nation to receive Healthgrades America's 50 Best Hospitals Award for five or more consecutive years, the number one hospital in New Jersey as ranked by U.S. News and World Report, consistently achieving Magnet® recognition for nursing excellence from the American Nurses Credentialing Center, recipient of the John M. Eisenberg Award for Patient Safety and Quality from The Joint Commission and the National Quality Forum, a six-time recipient of Fortune's "100 Best Companies to Work For," one of the "20 Best Workplaces in Health Care" in the nation, and the number one "Best Place to Work for Women." Hackensack Meridian Health is a member of AllSpire Health Partners, an interstate consortium of leading health systems, to focus on the sharing of best practices in clinical care and achieving efficiencies.

The hospitals of Hackensack Meridian Health include: academic medical centers – HackensackUMC in Hackensack, Jersey Shore University Medical Center in Neptune; children's hospitals – Joseph M. Sanzari Children's Hospital in Hackensack, K. Hovnanian Children's Hospital in Neptune; community hospitals – Ocean Medical Center in Brick, Riverview Medical Center in Red Bank, HackensackUMC Mountainside in Montclair, HackensackUMC Palisades in North Bergen, Raritan Bay Medical Center in Perth Amboy, Southern Ocean Medical Center in Manahawkin, Bayshore Community Hospital in Holmdel, Raritan Bay Medical Center in Old Bridge, and HackensackUMC at Pascack Valley in Westwood.

To learn more, visit WWW.HACKENSACKMERIDIANHEALTH.ORG.

NOTE TO PTAC: HMH and Cota replicated most of the PRT's report in its response to the report. For your ease in locating them, their responses are highlighted below in yellow after each section of the PRT report.

HMH & Cota Response
to Preliminary Review Team (PRT) Review

from review of: *Oncology Bundled Payment Program Using CNA-Guided Care*™
submitted by Hackensack Meridian Health (HMH) and Cota
August 23rd, 2017

A. Summary of the PRT Review by Criterion

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 Coordination	Meets the criterion	Unanimous
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

B. Overall PRT Review Summary

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.

C. 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 1 - HMH & Cota Response:

Bridging precision medicine to population health has become an essential requirement in oncology to deliver true value based care. It will soon become impossible to know what care to provide a patient for their cancer that offers the best possible clinical outcome and the greatest value potential without first accounting for all the characteristics possessed by the patient (i.e. age, sex, family history, behaviors such as smoking, comorbidities, socioeconomic factors, etc.), the specifics of their cancer (i.e. stage, genomics, epigenetics, tumor microenvironment,

etc.) and where they are in the course of their cancer (initial versus first, second, third recurrence, etc.) that will affect clinical and cost outcomes of a proposed therapy.

We have built a numeric framework to account for all potential variables to be assigned prospectively to help providers and patients choose the care plan that offers the greatest value (best clinical outcome for the individual and through avoidance of unnecessary, or adverse variance, reduce total cost of care for the population served). This is comparable to ICD 10 but with much greater precision and clinical relevance. Our approach is compatible with and agnostic to all EHR systems and can be used with paper charts as well. Cota does not provide clinical pathways or guidelines but measures the consequences of real world choices made by providers and patients to guide care prospectively to prior choices of the greatest value for that specific patient based on the provider's local database, compared against a national benchmark for that particular patient.

We believe this approach is broadly generalizable because it is based on real world evidence and is precise at the individual level. About alternatives to Cota; all the elements used by Cota to precisely define all variables know to affect outcome are publically available in peer reviewed literature.

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 2 - HMH & Cota Response:

Patient preference is central to our proposed model. The CNA provides a "lens" through which the provider and patient can view the clinical and total cost of care outcomes of therapy choices made for patients previously who share the same CNA. In the bundles program patients and physicians have full discretion to choose any lane of care they desire and then any sub-lane, as long as there is an evidentiary basis for the choice. This includes the patient choice of no care (observation).

Our program will **not** support the choice of improper care. For example, for patients with BRAF wild type metastatic melanoma, our program would prevent a choice of a BRAF inhibitor because it would not offer any clinical benefit (BRAF must be mutated for inhibitors to work clinically) and is potentially toxic.

Cota does check source documents (pathology reports, lab reports, etc.) for accuracy. Cota does not rely on the progress note solely because of known errors in transcription and dictation common to progress notes.

We believe the model is generalizable because it accommodates local patterns of care, as long as there is an evidentiary basis and it drives value. For example, care in rural areas will have a component that is affected by geography and distance from care sites different from a city setting. Weekly therapy may not be possible if a care site is distant from a patient so the greatest value care in that example may be a monthly regimen. Care patterns are evaluated at the local level through the CNA, accommodating issues unique to a region and its population.

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 3 - HMH & Cota Response:

The CNA does account for comorbidities. For example, two patients with the identical personal characteristics background (age, sex, family history etc.) and cancer specific attributes (stage, genomic, etc) would share the same CNA. If, in another example, this were true but one patient also had severe COPD or CHF, then the CNA would be different for the patient with the co-morbidity. In a bundle program, patients with a CNA that include a co-morbidity would be considered a more complex patient, likely have higher costs, and the risk would be appropriately accounted for through a higher rate to accommodate the comorbidity. Additionally, in regard to the cost of co-morbidities, we are open to using a CNA specific modifier in the bundle program to operationalize a risk adjustment mechanism for patients with comorbid condition.

On a related note, when a patient has disease progression, the CNA changes and that bundle ends. The patient is then eligible to enter a new bundle appropriate for the new CNA.

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 4 - HMH & Cota Response:

Our analysis to date shows significant variation in treatment choices at the CNA level. We have also observed significant utilization differences at the CNA level with the same lane and sub-lane of ancillary services. Our model predicts that greater transparency of these observed results will reduce total cost of care for the population served through reduction of unnecessary (adverse) variance.

Our model realizes that we will spend more on some patients then before to get the best outcome for that individual. However, based our initial retrospective data review, we believe that this will be offset by spending less on the entire population served. Minimizing adverse

variation is our goal in all areas of medicine, and this pilot not only supports standardization in oncology, but we expect it to provide a platform to expand the approach to other disease states.

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 5 - HMH & Cota Response:

We do not believe that practitioners will have limited flexibility in our approach, because the elements comprising a CNA are publically available. We believe the market will find Cota useful and valuable no different than providers now use electronic medical records. Cota has amassed data and information for immediate use. Others can choose to use other potential vendors or build classifications themselves.

The software allows for complete transparency for providers and patients to a level not previously available. There are few resources for providers to share with patients real world outcomes of patients that share all of the known characteristics that may affect outcomes to a proposed treatment regimen/plan.

Our model makes this information available at the point of care, through CNA-Guided Care. All care lanes and sub-lanes in our bundles program are taken from NCCN and other accredited guidelines. Clinical trials are encouraged in our model for patients to participate in and are excluded from bundles.

Of greatest importance, the bundle program first requires achieving an expected clinical outcome based on evidence. Only after achieving that outcome would shared savings be available as determined by the impact on the total cost of care.

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 6 - HMH & Cota Response:

We are planning for this to be the first of several Blue Cross sites across the country to use this approach. We expect this will amplify the data set available for evaluation.

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 7 - HMH & Cota Response:

We will account for comorbidities upfront and analyze outcomes and cost at the CNA level, enabling an enriched data set for CMS.

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 8 - HMH & Cota Response:

As noted above, we believe this model enhances patient choice by providing real world evidence on clinical and cost outcomes prior to therapy decisions at the point of care. In the bundles, physicians and patients are free to choose the approach most appropriate for them as long as an evidentiary basis exists to avoid improper and harmful care. The bundles include all potential choices - from decision to be placed under observation (i.e. no active treatment), to type of surgery (lumpectomy versus mastectomy), to aggressiveness of chemotherapy versus no chemotherapy, etc.

From above Criterion 2, patient preference is central to our proposed model. The CNA provides a “lens” through which the provider and patient can view the clinical and total cost of care outcomes of therapy choices made for patients previously who share the same CNA. In the bundles program, patients and physicians have full discretion to

choose any lane of care they desire and then any sub-lane, as long as there is an evidentiary basis for the choice. This includes the patient choice of no care (observation). This program will not support the choice of improper care. For example, for patients with BRAF wild type metastatic melanoma, our program would prevent a choice of a BRAF inhibitor because it would not offer any clinical benefit – BRAF must be mutated for inhibitors to work clinically – and is potentially toxic.

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 9 - HMH & Cota Response:

Cota reviews source documents (pathology reports, lab reports, etc.) for accuracy. Cota does not rely on the progress notes solely because of known errors in transcription and dictation common to progress notes.

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.

Final 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.

Final Comments HMH & Cota Response:

The payment bundles under consideration were derived by HMH, not Cota. Other providers of oncology care can and will develop bundles of care based on NCCN and other standards. CMS can choose to standardize bundles or outsource bundle development to a third party for national use. HMH bundles are being made available to other centers.

Should the model be expanded, we will gladly support CMS in this effort. Of note, we will be tracking and reporting on all clinical and total cost of care outcomes.

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL

HACKENSACK MERIDIAN HEALTH (HMH) AND COTA,INC.

Friday, July 7, 2017
2:00 p.m.

PRESENT:
TIM FERRIS, MD, PRT Chair, PTAC Committee Member
ROBERT BERENSON, MD, PTAC Committee Member
BRUCE STEINWALD, PTAC Committee Member

MARY ELLEN STAHLMAN, PTAC Staff Director
ANN PAGE, Designated Federal Officer, Office of Assistant Secretary for Planning and Evaluation (ASPE)
JANET PAGAN-SUTTON, PhD, Social & Scientific Systems, Inc.
ERIN DUGAN, Truman Albright Fellow, ASPE

ANDREW K. PECORA, MD, FACP, CPE, Founder and Executive Chairman, Cota, Inc.
ERIC SCHULTZ, Chief Executive Officer, Cota, Inc.
STUART GOLDBERG, MD, Chief Medical Officer, Cota, Inc.
ELENA CASTANEDA, Cota, Inc.
MARINKA NATALE, Cota, Inc.
MOREY MENACKER, MD, HMH

P R O C E E D I N G S

[2:03 p.m.]

DR. FERRIS: So this is Tim Ferris, and we are -- as members of the PRT, we are really pleased to have this chance to talk with you.

I might -- did my -- are my colleagues -- have they been introduced as well?

MS. PAGE: No. Good -- good catch, Tim.

MR. STEINWALD: All right. It's Bruce Steinwald. I am a member of the team, the Preliminary Review Team.

DR. BERENSON: And this is Bob Berenson. I was a former practicing general internist. I'm now a policy wonk, and I'm at the Urban Institute.

DR. FERRIS: And Tim Ferris, a primary care doctor at Mass General and health policy, health researcher, health services researcher.

And I guess in addition to -- thank you for agreeing to this call. On behalf of the PRT, we really appreciate the time and effort you put into creating this proposal. We feel as a group pretty strongly -- and if my colleagues disagree, they won't hesitate to say so -- that the process that we are trying to facilitate here in the PTAC

is what might be called the "grassroots approach to the creation of health policy," which is allow the people who are actually delivering care and understand the subtleties and the difficulties around the intersection between care models and payment models to conceive of and lay out the details of and then potentially even test novel payment models.

And so, in that context, I think the three people on the PRT here, in terms of the members of the PRT, as well as the staff from ASPE, are acutely aware of the extraordinary amount of work it takes to put something like this together, and so -- and we are deeply interested in this. There probably aren't a lot of people in the country who are, who share both your and our passion for this, but -- so all of that is to say appreciate your efforts.

We've spent a lot of time thinking and talking through your proposal and look forward to this chance to clarify some things.

So longwinded introduction. Apologies. Before -- last thing before I get into speaking about the specifics is we are going to in this hour

-- because we only have an hour and there's so much meat here, we're going to focus on the things that we are -- we have questions about and/or concerns about.

I don't want you to come away from this with the impression that we are all negative because that's a potential outcome of this that I think would be incorrect, and in particular, I want to highlight something that we think is really positive about your proposal, which is it has seemed to at least the two clinicians on the PRT from the outset that grouping cancers without -- you know, bundles for cancers, without taking stage into effect in the grouping, which is how it works in other cancer bundle models, the variance between those -- or among the different stages is so high in terms of the utilization of services and the treatment course running that it's really difficult for me as a clinician to conceive of a model, a bundled model for a cancer care services that doesn't take stage or some proxy for stage into account. And it seems to us, unless I'm mischaracterizing it, that that is precisely what your model does, and so that seemed to us to be a

really positive aspect of it.

DR. PECORA: Nope, that's correct.

DR. FERRIS: Okay.

So let's now turn to our questions. And, Ann, I'm looking for it, but I actually can't find my copy of the questions that we sent. So I'm sure they're in front of you, and maybe if you could send them to me while you read the first one?

MS. PAGE: Sure. So the first question -- and our colleagues from Hackensack and Cota have these as well. So the first one is the PRT wanted to talk about the extent to which the model is HMH (Hackensack Meridian Health)/Cota-specific versus a model that could be implemented by other entities, so it's a question about generalizability.

And then, as part of that, the first discussion was clarifying what event triggers the episode, and we note that in the material you sent us before, you said that the initiation event to enter a bundle is the date of the pathological diagnosis of cancer. And so the question is, was there a standard auditable way to be used, or will the trigger require transferring information between the participant and CMS (Centers for

Medicare and Medicaid Services)?

DR. PECORA: So to answer the first question, the model is not just for HMH and Cota. It's a model that is going to be used by many centers across the country. We'll just be first.

The second is the triggering event is -- and this was for payment, and I'll explain this in a second. The triggering event was the time of pathologic diagnosis. So it would be the date of the pathology report to show that you actually have colon, lung, breast, or rectal cancer, and the reason for that -- and this is the key. And I very much appreciate the fact you realize in order to reduce variance, you must account for all the variables that are relevant to affecting outcome.

Our goal is to bridge precision medicine to population health. That's our goal, and for -- so every individual patient gets the ideal oncologic care. But for the population, we reduce total cost of care, and that means for some patients, we'll be spending more money than we did before. But for the entire population, we truly believe we're going to spend less by getting rid of variance, which is -- we call it "adverse

variance," too much or too little care. And it's specific to that specific patient with their specific needs.

And so once you find out you have cancer, then you have to do a workup, and that workup includes the usual stuff, staging, you know, CAT (computed axial tomography) scans, PET (positron emission tomography) scans, but we also have to do molecular studies because we're in the era of molecular medicine. And for lung cancer, you need to know ALK (anaplastic lymphoma kinase) and EGFR (epidermal glomerular filtration rate), and for breast cancer, you need to know HER2 (human epidermal growth factor receptor 2)/neu status and those sorts of things.

So the idea here is -- and when we built this, we built this not just for CMS; we built this because we're going to be doing this with Horizon Blue Cross -- is that it actually becomes the pre-cert and prior auth once you have that tissue diagnosis for all the studies you need to do to get a proper workup, so you can assign the Cota Nodal Address, which is that digital code that tells us and the payer, it's ICD-9 (International

Classification of Diseases), you know, times a hundred. It tells the payer and the provider and the patient exactly who they are, what disease they are, where they are in the history of their disease, and what the intent of therapy is. So that's why we start at the time of pathologic diagnosis.

The way we envision with Horizon that we're going to do it is that we will notify Horizon of the start, and the start will be the date of the pathologic diagnosis. And so we both -- both the payer and we have agreed on that.

If there's something unique to how we would need to communicate to CMS, we're open to discussing it and accommodating the needs of CMS.

REPORTER: I'm sorry. Was that Dr. Pecora?

DR. PECORA: Yes.

REPORTER: Thank you.

DR. BERENSON: So this is Bob Berenson. So if this is a model not just for Hackensack, do you have any ideas about how 10 or 20 different organizations would notify? I mean, is there a claims-based approach to this, or would you

recommend just this kind of separate notification for each organization? Have you thought about that at all?

DR. PECORA: No, no. It -- yeah. No, it could be -- it definitely could be claims-based.

DR. BERENSON: Based --

DR. PECORA: It definitely could be claims-based, and, you know, what --

DR. BERENSON: Based on the pathology claim for interpretation of --

DR. PECORA: Correct.

DR. BERENSON: -- making a diagnosis? Okay.

DR. PECORA: Correct. Exactly right.

And then the other thing, what we're doing with Cota is Cota for us and Horizon is going to be the bridge for once the CNA (Cota Nodal Address) is assigned, the CNA embodied in the CNA itself is all the -- and I'm not suggesting we're going to do this with CMS; I'm just saying this is what we're going to do with Horizon -- is all the pre-certs and prior auths. I mean, we're going to give doctors pre-certs and prior auths for one year's worth of total care as long as it's within what's

accepted as the care for that particular CNA, for the bundle and the length.

DR. FERRIS: So I'm going to -- this is Tim. I'm going to maybe describe a couple scenarios that it would be helpful to hear your thoughts about.

So two different -- I'm not an oncologist, but I'm going to -- I'm going to make this up, and you'll hopefully get the point and forgive whatever clinical misstatements I make.

So one person comes in, and they're -- they have a spot on their lung. They get a -- an external-guided biopsy by the invasive radiologist, and the first thing they get in their workup besides the chest CT (computed tomography) is actually a -- it actually produces the diagnosis.

A second person comes in, and it turns out their lung lesion is peribronchial, difficult to get at, and they get, you know, CT scan, and they actually get their -- because they couldn't schedule the bronchoscopy, they get, you know, their metastatic workup, so they've got a whole bunch of imaging of the rest of their body, including maybe a PET-CT and various things. And

then after all that, they end up getting tissue.

So both lung cancers, one where a lot of the workup occurred before the pathology was -- the final pathology was obtained, the other one where the workup occurred after -- the staging workup occurred after the pathology was obtained. Is that a problem for your model?

DR. PECORA: No, because that doesn't really happen.

So to get that workup, you would have to have a reason for it, and so you don't know until you know what the patient has. So I'm not worried about the workup occurring before you have a tissue diagnosis.

I mean, it could happen the same day, but then it's the same date.

If you had scans before, you may have had scans for other reasons. I mean, there's no way of knowing until you have a tissue diagnosis of cancer what was the purpose of the scans.

The other question you asked, which is a good one, is, well, it costs a lot more to have an open-chest procedure to get tissue to get a diagnosis than it does a thin-needle biopsy, but,

you know, we're focused on once you have a diagnosis of cancer, because sometimes you do a biopsy and it's sarcoid and it's not cancer, it's not lung cancer, or it's a granuloma.

So we're not -- we're not going to start our bundle until we know the patient has cancer. So whatever happens the day before the tissue diagnosis or two days or a year before will not be part of the bundle. We cannot envision a way of adjudicating that after the fact, and that's why we're going with the date of tissue diagnosis.

DR. FERRIS: Okay.

DR. MENACKER: It's almost -- and this is Dr. Menacker. It's almost like saying if you have a bundle for acute MI (myocardial infarction) and a patient undergoes a stress test and gets chest pain and gets taken to the hospital and has an MI, does that stress test count in the bundle for acute MI? Well, technically, it didn't because he didn't have the diagnosis until after the stress test, and it's the same type of a thing.

We're not concerned here right now about the diagnostic evaluation. We're focusing on standardizing the treatment and optimizing the

efficiency of the appropriate treatment for a year or two following the diagnosis of cancer.

DR. FERRIS: Great. That's very helpful.

Other members of the team, questions on the trigger issue?

MR. STEINWALD: This is Bruce Steinwald.

I have a question related to what Dr. Pecora said a moment ago that many centers will use the model, Hackensack first. Are -- and then you mentioned a relationship with Horizon Blue Cross. Are the centers that you're referring to known? Are they within your geographic region, or are they -- what can you tell us about how many others -- centers will be using the model?

DR. PECORA: Other -- other Blue Crosses in other states are in conversations with Cota now with individual centers to do similar things. So they're looking to us as a leader, but there will be other Blue Crosses from other states with other major cancer centers that are going to want to do this.

I don't know that they're going to want to do it immediately with CMS, but they're going to start with Blue Cross. That's not to say they

won't submit grants as well. That, I don't know.

MR. STEINWALD: Okay.

DR. MENACKER: Andrew, maybe you can tell them the size of RCCA (Regional Cancer Care Associates) and the volume of patients that are seen, which will make it a little clearer for them why we're focusing on this and then encouraging other organizations to participate.

DR. PECORA: Yeah. I mean, we have -- this will -- this will involve 11 hospitals in the Hackensack Meridian Health family and over a hundred medical oncologists, then. So this is -- this is big time. This will be -- these will be big numbers.

MR. STEINWALD: Okay. Thank you.

DR. FERRIS: Great. So, actually, picking up on that -- and I'll move, if it's okay with everyone, to 1(b) here -- we are -- we're struggling a bit with the requirement from a payments perspective to make sure that episodes are comparable across different organizations, because if they're -- if they're not comparable, how do you assess performance?

And the statement that is quoted here,

"Each hospital system will have differing treatment strategies . . . and may have even" -- have -- "different bundles for each cancer per their own preference if an evidentiary basis exists to support their choices of care," do I -- I get the idea that choices, you know, within a particular treatment plan, you want an individualized treatment plan, but we -- but elsewhere, we are -- we understand that -- in the proposal, we understand that, you know, if you are assigned to a lane, it's because of a particular combination of pathologic and clinical findings. And is it correct or incorrect to say that those lanes would be defined exactly the same across anyone who participated in this payment?

DR. PECORA: That is correct.

Let me help you there. You know, it's a little tough in words to describe what's actually going on in the real world and what actually CMS is currently paying for.

So there are 27 bundles that all of colon, lung, breast, and rectal cancer fit into -- 27 -- and each one of those bundles have anywhere between seven and nine lanes. And a lane is, as an

example, radiation alone; radiation and surgery; radiation, surgery, and hormone therapy; radiation, surgery, hormone therapy, and aggressive chemotherapy. But once you get to the lane level, there's actually sub-lanes, meaning that if the NCCN Guidelines -- the NCCN, the National Comprehensive Cancer Center Network Guidelines -- which is the evidentiary basis by which oncologists along with ASCO (American Society of Clinical Oncology) use to decide whether or not a care is appropriate for a given patient with cancer at a certain stage. But there's lots of choices. The choices -- there may be -- as an example, hormone-only therapy is one lane, but there are 25 different ways people give hormones. There's five different drugs. They're all FDA (Food and Drug Administration) approved. They're all NCCN Guideline. And, in addition, sometimes they do a variant suppression; sometimes they don't.

So what we're doing out of the box is we're saying as long as the CNA matches to an appropriate bundle and lane and then within that the sub-lane, the specific drug, the specific -- do you give it every week, every three weeks, because

there's all sorts of way people do this -- we will allow that as long as the clinical efficacy and the toxicity is appropriate.

If something is less efficacious or something is more toxic, we will actually shut that sub-lane down. That's step one.

Step two of this process is we are learning as we go, if there's five choices, they're all -- they're all NCCN, ASCO approved. They're all equally efficacious, but choice one and two are 20 percent less expensive because you don't wind up in an ER (emergency room), you don't have unnecessary hospitalization, or the medication is a lot less because it's generic. We're going to incentivize doctors to consider that particular choice.

And part of this project is the ability to know precisely for a given patient, because of the Cota CNA piece, what are the sub-lane choices that are appropriate, and then from that learn, using our retrospective analysis and then prospective, which is the ideal, which gives the best possible outcome at the lowest total cost of care. That's what we meant by the choices.

Well, you're absolutely right. It's not like a lane or sub-lane; it's different from hospital one, from hospital two. They're identical. It's just that we're not in the beginning going to tell every doctor, "You must put that patient with that CNA in that lane and that sub-lane out of the box."

What we're going to do is we're going to show them the consequences of those actions and over time try to drive them to standardizing the -- standardizing their treatment choices.

The last thing I'll say is -- and if you like, we're happy to share the data with you -- is we have the data from the retrospective analysis, and there's vast variation in treatment choices at the bundle lane and sub-lane level for the same CNA. It's vast.

And there's so much opportunity here to change that behavior at scale, to improve outcomes for the individual patient clinically as well as reduce total cost of care for the population. Does that answer the question?

DR. FERRIS: I think so, but I want to check with my colleagues here.

DR. BERENSON: Where I'm just -- I just want to clarify something. You emphasized that -- that really these -- the lane choices shouldn't vary across different cancer centers, and yet I thought there was a fairly strong emphasis. 1(b) says that, "Each hospital system will have differing treatment strategies . . . and may even have differing bundles for each cancer based on their own preference." So I -- I'm sensing some contradictory information. I mean, what you said--

DR. PECORA: No, I think --

DR. BERENSON: -- on the phone just now made perfect sense to me.

DR. PECORA: No, I think it's the way we wrote it, and I just apologize in the drafting.

The lanes -- the definition of lanes and bundles is identical everywhere. We're just saying that one doctor may choose lane one and the next doctor may change, choose lane two --

MS. PAGE: And the bundle --

DR. PECORA: -- for the same patient.

MS. PAGE: I'm sorry. This is ASPE staff, so I'm probably the least clinically knowledgeable person here. But the bundles and lanes will be

standardized by -- by you, by Hackensack and Cota or by NCCN, or where did the 27 bundles and seven to nine lanes each -- where do they -- who articulates them and defines them and standardizes them?

DR. PECORA: We -- Hackensack Meridian Health created them based on what the NCCN and ASCO guidelines say are appropriate choices in the context of how we position bundles and lanes. So the bundles and lane is just an -- if you will, an architectural structure so that we can aggregate data, but the actual treatment choices within the bundles and lanes come out of the NCCN and ASCO and other organizations where there's evidentiary basis for it. It's not like we're coming up with our own way of treating cancer.

MS. PAGE: And the logic on that, are they published so that you would -- all that will be made available as part of the model?

DR. PECORA: Yes, of course. Yes, absolutely.

DR. FERRIS: So I think we just -- this is Tim. We -- or I guess I get lost a little bit in treatments, which absolutely are going to differ,

and if you think of the payment model as separate from the care model, that the payment model is around creating, you might say, guardrails, but it's sort of, you know, what happens after the gun goes off in the foot race. But we got to make sure that the people -- we, you know, thinking about a policy perspective from the national perspective, have to think about who's running in which race and are they comparable across different sites.

So it's -- I get as the race goes on, there's going to be lots of differentiation and an opportunity to decrease variance and all that, but I think we're really focused on when the gun goes off, are we -- is the same cohort of people that should be racing against each other, is that carefully enough defined and standardized sufficiently to be comfortable that, you know, lane one, sub-lane six, blah-blah-blah, at Hackensack is exactly comparable from a, you know, financial total cost-of-care episode basis to someone in, you know, Oakland, California --

DR. PECORA: Yes, yes. And it's not the lane; it's the CNA.

So let me -- let me try this again. So

you have it absolutely correct, but it's the person. So we're going to be able to show you -- and this is why Horizon and this is why the Department of Banking and Insurance in New Jersey is letting us do it. The CNA is the organizer. It says -- you know, say it's breast cancer -- "I am a woman. I have type 1 diabetes. I have congestive heart failure. I'm 72 years old. My mother had breast cancer at 35." Those are all things that are embedded in the actual code in the CNA. I'm making that scenario up. You can make up any scenario you want. I could be 32 and perfectly healthy, and I would just have a different number. And I have stage II breast cancer that's HER2/neu-positive. It was a 3-centimeter tumor, and I'm estrogen receptor-negative, and I have an Oncotype DX test of 26. Right? And then this is my first presentation.

So that code, that number, let's just say the number -- that the first case is a hundred and the -- the number is a hundred, and the second person, who is a different kind of person -- I'm young; I'm healthy. I have no family history of breast cancer. I'm totally fine. I have stage I

cancer that's estrogen-receptor-positive. That's a 200. We're going to aggregate all the 200s. We're going to aggregate all the 100s. And we're going to report on the clinical and cost outcomes of the patient from those groups, and we'll show which bundle, which lane, which sub-lane those patients got pre-intervention, and then we'll show post-intervention, what happens to them. And you absolutely need to do it this way.

So we start off by defining in the most sophisticated way the industry has now in risk adjustment using the CNA of this is precisely the same patient being compared to the same patient. So when you ask the question about Oakland versus New Jersey versus Florida, if you're a No. 100 and as long as where you live doesn't influence your breast cancer outcome -- and in that case, it doesn't -- you know, and that's actually not true because socioeconomic status has a role, and we actually have ZIP (Zone Improvement Plan) Codes embedded in the code, but that's parenthetic.

So we will be able to show CMS on a national level. You know, you use claims data and ICD-10 to aggregate your data to decide whether or

not something is good. This goes one lot deeper in sub-stratification and risk adjustment and allows likes and likes and likes to be compared across big datasets to see what is the best possible path of care.

Does that help?

DR. FERRIS: It's very helpful, yes.

My colleagues?

MR. STEINWALD: Yeah. This is Bruce Steinwald.

I'm going to ask a question related to lumping and splitting. So, as you described those bundles with so much precision, it just started to seem illogic that it could fit into 27. So you're talking about not just the 27 bundles, but something that's one level below that? Is that correct?

DR. PECORA: No. The bundles -- think about the bundles and lanes as what you're doing to the person. They have nothing to do with the person. It's what you choose to do with them. That's the care that CMS and payers pay for.

What I was describing was the person and the disease they have. So if I'm a person, I have

a set of attributes that we already know will affect my outcome, even if I get the identical therapy. So if I have a BRCA (BReast CAncer) mutation in breast cancer and I get a drug, I do differently than if I don't have a BRCA mutation, same drug. Right?

So what the CNA does, it defines the person. That's where all that specificity is. The bundles and lane is exactly what you guys and everybody sees every day. It's just we're using a terminology that you -- someone before said we have to put brackets around things so we can compare treatment one to treatment two. Well, that's what bundles and lanes are. It's just basically --

MS. PAGE: How many --

DR. PECORA: Go ahead.

MS. PAGE: How many CNAs are there?

DR. PECORA: So in breast cancer, there's probably a couple thousand, but they don't evenly distribute. We find that in our first dataset of 10,000 patients, about 80 percent of people were in the top 100, something like that, maybe even top 50. So because of biologic disequilibrium, things don't evenly distribute it, so there's not that

many. So each cell will have plenty of data for comparison.

DR. FERRIS: So this is -- this is very helpful each time we peel back a layer of this onion. It engenders more questions, and so I see where you're saying the CNA is at the level of the individual, but -- and that so much care has been taken about the care model here.

But I want to go back to the payment model. The payment model has to group patients, and is the grouping of the patients in the payment model at the level of the CNA --

DR. PECORA: No. No.

DR. FERRIS: -- the lane or the one --

DR. PECORA: The bundle. You pay at the bundle level. You pay at the bundle level, and -- well, let me -- I don't want to be presumptuous. I don't know what CMS is going to pay out.

But what I'll tell you, the private payers are going to pay at the bundle level, and then for the health care system, our job is to optimize lane and sub-lane assignment. And if we can optimize sub-lane assignment and reduce total cost of care, we benefit in a shared savings with our --

DR. FERRIS: So CNAs -- but effectively within a bundle, within a breast cancer bundle, then, CNA becomes effectively a risk adjustment tool.

DR. PECORA: Yes. Bingo.

DR. FERRIS: Okay.

DR. PECORA: But a risk adjustment tool that's the best, first in class. I mean, and that -- I mean, that we -- what the data we already have, it's striking. We precisely know for a given CNA what care would offer the patient the best outcome and actually reduce care 10, 20 percent. We know that.

DR. FERRIS: Right.

DR. PECORA: Now we're going to -- now we're going to do it at scale.

DR. FERRIS: So one of the things in having unfortunately spent an earlier part of my life creating risk adjustment tools, generally what's required to create an effective risk adjustment tool is very large numbers to do normalization routines across -- get, you know, weights associated with -- with each of the intercepts.

In this case, with -- even with, you know, 10,000 -- with all these CNAs, I can't imagine the models even converging in order to get weights that would allow you to -- and I'm getting quite technical here, but it -- it raises a host --

DR. PECORA: Yes.

DR. FERRIS: -- of technical issues around the use of CNA as a method to risk-adjust within a bundle.

DR. PECORA: Yes. So let me help you there. First off, I said on the first 10,000. We have hundreds of thousands of patients, and within a year, we'll have over a million in the database.

The second is that because the CNAs don't equally distribute -- and with cancer, the only attributes that we are actually accommodating -- and we're not boiling the ocean. These are known attributes that affect outcome. Are you estrogen receptor-positive? Yes or no. Is your tumor HER2/neu-positive? Yes or no. You know, things like that, we know what -- and it's all based on published literature.

So because it is all -- each of those elements are all independently validated as

predictors already from years and years of research, we just figured out a way to combine them in an algorithm, so you get a numeric expression of that. It's like digitization. It's data compression. So that by definition, an individual CNA already has embedded into it a lot of validation, and therefore, you don't need that many to see if one therapy is better than another at the CNA level. And we've been able to show that. We've actually published on it, and we're happy to share our data with you.

So I understand what you said, but I think when you think about it from the perspective of each of the elements that go into the multivariate analysis of assigning a CNA are already validated elements, we're not validating them ourselves.

Now, over time, we will as the data gets more and more mature and we get bigger and bigger datasets, but we already have plenty of data for colon, lung, breast, and rectal cancer -- these are all common cancers -- to know that we're able to represent at the CNA level that, you know, a CNA 110 is different than a CNA 112.

DR. FERRIS: Okay.

Other questions on No. 1 here from the team?

DR. BERENSON: I guess I'd have one. I guess this is the best place to ask it.

My understanding is that there are other centers developing their own comparable approach with software similar to Cota and getting CNA-like association. Is there much variation? Would -- if I went to one of those centers and looked at their software, would they be developing comparable lanes to what is coming out of Cota, or would there be variations? How universal is what you're doing?

DR. PECORA: So, again, the CNA is the definition in a numeric form of the patient and the disease they have.

DR. BERENSON: Mm-hmm.

DR. PECORA: The bundles and lanes is the treatment choices.

DR. BERENSON: Right, right

DR. PECORA: And the bundles and lanes, I think, are pretty standard across the country. I mean, I -- you know, because it comes from the NCCN and ASCO and it's evidentiary-based, so they may group them differently. Like we group -- one of

our bundles is adjuvant therapy HER2/neu-negative versus adjuvant therapy HER2/neu-positive. We chose to do that because the drug Herceptin is very expensive, so it's a nice way to -- so you have less economic variance when you're contracting.

Someone might say, "No. We're just going to put all of the patients together and not separate HER2/neu-negative and -positive." There, you might see some variation, but no, you're going to see pretty similar on the treatment side.

On the CNA side, you know, I think Cota -- I think Cota is a first mover here, and Cota has patented its technology, and, you know, it had the insight to take the biologic narrative and all its complexities and digitize it. And it kind of owns that space, so it is somewhat unique.

That's not to say you can't do this in words, but it's very hard to do this in words and relay that to payers for payment where you can do that with a number. And that was the --

DR. BERENSON: I see. I see.

DR. PECORA: -- I think the genesis of Cota's utility, and the Horizon Blue Cross invested millions of dollars into Cota because of that.

DR. BERENSON: Okay. That's helpful. Thanks.

DR. FERRIS: Okay. Shall we move on to No. 2 here?

MR. STEINWALD: Yeah.

DR. FERRIS: So this one is pretty straightforward to state from our perspective, and I'll just say, you know, so why are you proposing an episode model within an ACO (accountable care organization)? What's underlying that, that question, is an ACO, once you're an ACO, you're free to do anything you want that's consistent with good care in order to standardize your processes and your care paths and all that.

And so what is the reason, then, behind the rationale for a separate payment model? Why wouldn't you just do this -- you know, why wouldn't an ACO just be incented to adopt this because they have an incentive as part of an ACO?

DR. PECORA: We're doing this through our clinically integrated network, our CIN, and our CIN has doctors that are employed by us, but also doctors that are in the private community but members of our CIN. And in order to have a

standard methodology for payment -- this is at least how we understand it -- the bundle arrangement would be between the payer and Hackensack Meridian Health, and then we would then pay the individual physicians, regardless if they're on salary or if they're part of the program under a contractual arrangement with us. And that's how we proposed it.

Morey, am I missing anything?

DR. MENACKER: Let me get into a little bit more detail, Andrew, because I get where the question is coming from.

DR. PECORA: Okay.

DR. MENACKER: The example that I'll give you quickly -- and then I'll expand upon it -- is CJR (Comprehensive Care for Joint Replacement). You know, CJR is a separate program dealing with Medicare patients requiring joint replacement. We participate in that, and it is separate and distinct from our ACO.

The ACO model is a generalized model to really eliminate waste in the system and to optimize management of previously unmanaged patients in the Medicare population. What we're

describing here is a mechanism for, A, Medicare to know in advance what their costs are going to be for each specific diagnosis of cancer. Number two, we're providing a research base where we can standardize the treatment, eliminate the variability, of which currently there is no reason to standardize therapy for an individual doctor. An individual doctor can choose therapies not necessarily based upon, you know, information that would optimize the outcome but maybe optimize his income. Not to say that anyone would do that, but what we're looking at here is taking the next step, which is saying we're looking at total cost of care for patients. We're willing to take a fixed amount for every one of these diagnosed patients for total cost of care for a period of time, be it one year or two years.

ACOs don't do that. ACOs continue. Everything gets paid fee-for-service, and then if you see savings, then you generate revenue. So it's a different model. It overlaps the model, and it's sort of a step-wise progression to going at full risk, which is the direction that we're really moving towards as rapidly as possible.

DR. FERRIS: So that's -- I'm going to follow up, then, and then open it up to my colleagues. That's helpful. And I'm going to just pick up on the word you said in terms of the overlap.

So your description was about interaction locally within your own ACO, but I want to sketch, you know, a different scenario, a scenario that would face anyone on the payer's side from a policy perspective, which is say there's an ACO next door to you that's not your ACO, somebody else's ACO, but they send cancer patients to you.

DR. MENACKER: Mm-hmm.

DR. FERRIS: Now, your participation in your model, your oncology model, would be good for them -- right? -- because you're standardizing oncology care. But the payer -- we'll hypothesize in this setting that it's CMS -- is in a bind because they've made a deal with the ACO that if costs are lower, they'll share those with the ACO.

DR. MENACKER: No. No. I see where you're going with this. Sorry to interrupt, but --

DR. FERRIS: Yeah.

DR. MENACKER: -- as I said, it's very

similar to BPCI (Bundled Payments for Care Improvement) or CJR. Once a patient goes into a specific bundled payment program, they drop out of any of the ACO standard models. That's already standard within the system for MSST (Medicare Shared Savings Program) [sic] and even with Pioneer. That if a patient moves into a bundle for a specific diagnosis, be it BPCI, which has hundreds of bundles, or CJR, which is the, you know, more nationally recognized bundle, all of their cost of care is eliminated from the numerator and the denominator of the ACO, and what we're proposing is we're willing to take a fixed rate for total cost of care, because it's just because of that problem, because of the difficulty of saying this treatment that I'm giving the patient for their heart failure is related to their cancer or is unrelated to their cancer.

So what we're doing is we've got enough confidence in our ability to adjust total cost of care that we'll take the full responsibility once that patient enters the bundle.

DR. FERRIS: Very helpful.

DR. BERENSON: So that's how you all deal

with double counting, which is to follow the precedent that the CMMI (Center for Medicare & Medicaid Innovation) has established with those other episode programs?

DR. MENACKER: Correct.

DR. BERENSON: Okay.

DR. MENACKER: Correct.

DR. FERRIS: Just as a point of clarification, CMS actually is not -- is not consistent on this policy. There are ACO deals under CMS where the ACO trumps any episode, so -- and that was at the insistence of a lot of ACOs who were feeling that episode -- groups that were participating in episodes were taking their savings.

So, as a point of national policy, I think it's fair to say it's unresolved.

DR. MENACKER: Understood. Understood. But as far as we're concerned, we're looking at this organizationally. You know, we're a health care system with 6,000 doctors, eight hospitals, you know, probably over 2 million patients that we manage, and we're trying to move along this road. And we feel that this is the optimal way, and it

has nothing to do with generating revenue. It has to do with proving the philosophy that we can, you know, bend the curve.

DR. FERRIS: That's great.

MR. STEINWALD: This is -- I have a question, Tim, if you don't --

DR. FERRIS: Yep.

MR. STEINWALD: So that was Dr. Menacker?

DR. MENACKER: Yes.

MR. STEINWALD: You said, a couple times, total cost of care. I thought the proposal was proposing only to cover the cost of cancer care, although you did say we'd be willing to discuss the total cost of care agreement.

DR. MENACKER: That's correct.

DR. PECORA: Yeah. We didn't want to presume what model. You know, I've been talking to CMMI about this for a couple of years. I've been working with Patrick Conway and others. You know, we didn't want to presume what model the CMS would be comfortable with. So, you know, we're open to a discussion on that issue.

DR. FERRIS: Okay.

MR. STEINWALD: Thank you.

DR. BERENSON: Let me just jump in there for a second. What would be the tool to actually assign cost to cancer only? The Episode Grouper that CMMI has? And have you looked at that, and do you think it does a decent job of proper allocation to cancer care?

DR. PECORA: So the short answer to that is yes. It does a decent job. There are other ways we're thinking about it, but we haven't really gotten down to that level of detail because we're not sure exactly how CMS would want us to do it, and we want to kind of stay open.

DR. BERENSON: Okay.

DR. FERRIS: All right. Anything else on No. 2?

[No response.]

DR. FERRIS: So No. 3, "We are interested in better understanding the standard of care and quality control components." So here, it is a little bit of a repeat of something that Bob raised earlier, which is -- so I think we've established that treatment inside a lane is sort of up to the doctor and the patient.

Your response to the question that we

asked in the written responses suggested that there would be a process for updating information -- or updating the -- I mean treatment protocols. But we are -- we're still scratching our heads a little bit about how new information -- say the NCCN guidelines change because of a seminal paper that's published. How does -- how does the payer and how does the patient know that you are incorporating these changes in a -- in a -- I hesitate to use the word "real time," but in a near real-time way into your software?

DR. PECORA: Yeah. So couple of things. Number one, the payment is based on achieving hard outcomes, and you have those hard outcomes. So in the -- in the adjuvant setting, it's all about did you give the right drugs in the right doses in the right time intervals, and the Department of Banking and Insurance in New Jersey insisted on that with us because they had -- we had to prove that we would not undertreat patients once we had a fixed payment. And I agree with them on that.

Now, in the palliative setting, it's very different because the goal there is not necessarily to prolong life and that's the only issue. It's

prolong quality of life, so it's much more quality-of-life focus with proper end-of-life care when you cannot cure a patient. So in the metastatic setting for colon, lung, breast, and rectal cancer, unfortunately, we still do not have curative therapies there, so it's much more palliative. And we have all different palliative measures that are all, you know, standard measures.

In regard to new therapies or new technologies, we have an agreement that goes into the bundle arrangement, and we would insist upon this as well. That any new therapy or any new technology, that once it goes through the formal approval process, that, you know, the FDA has to approve the new drug, and CMS has to then agree to pay for it, but once it's available -- and the same thing for the commercial payers -- that it just becomes a passthrough. So instead of going back to the negotiating table and renegotiating everything, the cost of that individual drug or individual technology just gets put in as a passthrough. And it happens in real time, because remember this is being overseen by the quality officers of the hospital, by the oncology quality committees, as

well as by the quality committees of the -- of Horizon. So we have to -- it's not that we have a choice. We have to do this.

In regard to the CNAs, the CNAs are -- the CNAs have a CNA advisory board, and after every ASCO and after every ASH (American Society of Hematology), the CNA advisory board convenes and notifies Cota of whether or not there's a new element that needs to go into the CNAs.

And then when we learn of something new, because of our own ongoing research using CNAs, we actually publish it first, then do a validation study, and then we get to change the CNA. So we have a whole methodology that we're very willing to have you guys do diligence on, if you choose to do this, because Horizon already has done the diligence, so it will be easy to share.

DR. FERRIS: That's very helpful.

Bob and Bruce?

DR. BERENSON: I'm good.

MR. STEINWALD: I'm good, too.

DR. FERRIS: Okay.

And this, I think, was a relatively minor point, 3(b), but we just -- we had trouble

reconciling these two statements, as you can see here. I don't know if I need to read them, "The best and only reliable surrogate of quality for survival outcomes . . . is delivered dose intensity." So you're basically saying delivered dose intensity is the standard, and then "Current guidelines are . . . largely consensus opinion as to best practice without 'real world' continuous outcome scrutiny."

And we -- we struggled with those two statements because it sounded as if NCCN in one sense is definitive and in the second one, it's not.

DR. PECORA: Yeah. I'm going to try to find it. I have to see what you're talking about. Let me just see this.

DR. FERRIS: So you're looking for context. Yeah.

DR. PECORA: Yes.

DR. FERRIS: All right. Well, maybe --

DR. PECORA: Okay. Yeah. Here, I got it.

So I think where this gets -- I think where this gets confusing is in the adjuvant setting, it's delivered dose intensity because the

intent is curative. In the metastatic setting, it's preservation of quality of life, performance status, things like that. And I think somehow that got mixed into here, where it's confusing.

So the NCCN promulgates not just drugs, but actual drug regimens --

DR. FERRIS: Right.

DR. PECORA: -- that doctors then use. So that's not just the drug, but it's the dose.

DR. FERRIS: Right.

DR. PECORA: It's the interval, and we follow that as the gold standard and measure what actually happens at the individual patient level against that. And that's where you get the calculation of delivered dose intensity. You actually see what you're delivering, and you have to deliver a certain -- you have to hit a certain threshold to have done quality care, but that only applies in the adjuvant setting. And I think that's where these things got confused.

In the metastatic setting, where the goal is not give as much chemo as you can for as long as you can to keep the person alive an extra day or two -- and it's much more focused on quality of

life, doing proper end-of-life care -- I think that's where there was -- that that's why that language, and maybe we could have written that better.

DR. FERRIS: Okay. That's very helpful.

And so then turning to (c), the -- though, again, this may have been language in the proposal, but it sounded like, you know, assignment -- I guess if I'm -- if I understood what we've -- the territory we covered so far, you know, it sounds as though the assignment initially is based on the initial characteristics of the patient along the lines that you described.

But we -- it gave us the impression, the writing gave us the impression that once you're in a lane -- and I may be misusing the word "lane" here -- that your treatment is defined. But aren't there tons of situations where reasonable people could have different value discussions about adjuvant therapy, the risk benefit tradeoff from them, and the whole issue of shared decision-making and how shared decision-making is accounted for in this methodology?

DR. PECORA: Absolutely. It's a great

question, and given the fact that, you know, it's always hard to capture everything in words, thank you for the opportunity to explain this.

So in breast cancer, there are seven bundles. One bundle is adjuvant, patient choice. So, basically, that is a person has stage III breast cancer but decides they had surgery, they don't want anything else, because that's what they want. Well, that's a bundle. Now, that bundle is going to cost a heck of a lot less than a treatment bundle, and it is the patient's choice. And they heard the evidence, but they decided, "I'll take my chances. I don't want any chemo or radiation."

When you're in an adjuvant bundle where you have a choice between a lumpectomy or a mastectomy, you get to make that choice. It's just a different lane. A lumpectomy with radiation is a different lane than a mastectomy because a mastectomy, there's no radiation.

The woman and the doctor together decide which they want to have, and, you know, some women have breast mastectomies because they don't want to be exposed to radiation. Others have it because they're afraid that they'll get a second tumor.

Others have it because it's easier cosmetically. We're not going to get in the middle of any of that. That's why there's a little bit of variation.

When you get down to the drug choices, you're absolutely right. That's where the sub-lanes come from. So say someone's in a lane that's hormone therapy only. Well, but there's five different FDA-approved hormones. Now, they cost very different things. We're not going to tell a doctor and a patient, "You must have this hormone," but what we are going to do is we're going to show them that with this CNA, the people who got hormone one, their outcomes were just as good as those that got hormone three, but their total cost of care was 10 to 20 percent less, which means your copay would be less. And so the doctor -- there's an opportunity for shared savings. That's the basic philosophy of what we're going to be doing at scale. I hope that makes it clearer.

DR. FERRIS: It does.

If you'll allow me to try to put it in my own words, the CNAs describe the launching point. The lane that you're assigned to is a product of

shared decision between the oncologist and the patient about their particular treatment choices.

DR. PECORA: That's absolutely correct.

But I'll go -- and you know what? We may -- I'm writing that down. I may steal that from you.

And then -- I'll give you attribution, though. And then the other thing, though, is -- and we've already agreed to this. So, you know, it happens rarely, but it's awful. There's some women that are HER2/neu-negative that get Herceptin.

DR. FERRIS: Yeah.

DR. PECORA: And that's just -- you know, we're not going to allow doctors to choose the wrong thing.

DR. FERRIS: Yeah.

DR. PECORA: So in our program, if you're HER2/neu-negative, your CNA will never go into a bundle where you get Herceptin.

DR. FERRIS: Right.

DR. PECORA: It's not going to happen. We're not going to let it. So that, we are going to restrict, as an example.

DR. FERRIS: Yeah.

And what happens when you are assigned a CNA, as the gun goes off, you agree upon a lane, which is your treatment, and then six months into the -- you're in a lane, you -- the patient decides or a patient decides with the doctor, "You know, I changed my mind. I'm going to stop" whatever the adjuvant is or whatever, whatever change occurs? How does your model, which has these lanes in a bundle and it's the bundle that is the price -- you know, that is priced, how does your model account for the changes in lanes? Or since it's inside the bundle, it doesn't matter?

DR. PECORA: Well, you asked a good question, but let me give you the scenarios.

So let's say that for whatever reason, you're supposed to get six months' worth of chemotherapy and the patient at five months says, "I've had enough," put their hands up. No, we don't give money back. That's just sort of in the sauce at the bundle level, and the reason is it's because we priced the bundle based on the last three years of people with those exact CNAs.

DR. FERRIS: Right.

DR. PECORA: So that is kind of what you

pay for already, so you're not paying more.

DR. FERRIS: Right.

DR. PECORA: Let's say somebody is six months into their treatment and they progress. Well, now they get a new CNA. That bundle stops, and they get put into a new bundle.

Now, what we're able to do with the payer, Horizon, is we can have true-ups. At the end of the year, we can have true-ups. We're willing to do the work with CMS, unless CMS would outsource this, but you're going to have to figure that out if you're going to go to bundles at scale -- not you, but CMS will have to figure that out.

You know, what do you do with someone that needs to change because their disease has progressed, or they -- you know, they need something else?

And then the third is, what happens if somebody moves? Somebody is, you know, four months into their therapy, and they decide "I'm moving to Ohio." Right? So we've worked that out with Horizon about how to true-up. I would -- we would work that out with CMS but under the constraints by which CMS can do such a thing.

DR. FERRIS: Right.

DR. BERENSON: So let me follow up on the point you made, which I certainly am happy about, that you wouldn't allow a woman who had -- was Herceptin -- receptor negative to receive Herceptin. What is the authority that you have over the participants to overrule their treatment choice? I mean, how do you work that out, and how would other centers, as part of a payment model -- what kind of a -- I mean, what is necessary to make sure that happens broadly when this model is put into effect?

DR. PECORA: Yes. That's the beauty of the CNAs.

So the CNAs -- each CNA will have the medically appropriate approved bundles and lanes and sub-lanes from which to pick that the doctors on the provider side and the payer doctors on the payer quality side will pre-agree to.

So if you're a 113 and 113 means you're HER2/neu-negative and your doctor tries to assign you to a HER2/neu-positive bundle, you're going to get a big -- [indicates sound]. You're going to get denied. And the patient as a member will be

notified, and we have this all pre-wired -- we have pre-wired. So it's going to be impossible. You know, we will not allow wrong care. That's one of the big things we're going to do, and the doctors haven't complained at all about it because it's blatantly wrong. It's not a judgment call; it's wrong.

MS. PAGE: How would it work if a center that was participating used some other model other than CNA?

DR. PECORA: They can't in this -- in this -- in our model, they can't. I mean, I don't know how they would do it without using CNA. They'd have to come up with a way where you would have to have a pre-cert function, where you're -- they have to show you, I guess, with words that, and that's why I think, you know, Cota is doing so well across the United States, because, you know, this is -- this is basically ICD-10 for precision medicine. It gets you where you need to be, and it allows you to do pre-certs and prior auths.

So I don't know how to answer -- to be honest, I don't know how to answer that question.

MS. PAGE: Yeah. So it kind of has to be

done with Cota.

DR. PECORA: Yeah, I think so. I mean, or Cota -- something that's similar to Cota that does this, that does risk stratification and assignment adjudication.

DR. FERRIS: So can -- since we've circled back on this issue a couple times, so I want to, you know, press a little further, because you did say -- I think I heard you say that you'd be willing to expose the rules used that -- that create the different CNAs and lanes and so forth, and maybe I misheard that. First of all, did I mishear that? Is it essentially the entire software system that you have would -- are the rules for that transparent, or are they -- are you protecting them as intellectual property?

DR. PECORA: Well, no. Cota -- Cota is a separate company from Hackensack Meridian Health. That's their intellectual property. So someone would have to engage Cota. Hackensack Meridian Health -- and Cota will share, share its rules. Like it's Cota is going to be working with the FDA. It's going to share all of its rules with the FDA. It's working with Horizon. It will share all of

its rules with Horizon. The payer and the provider, it will show what it does.

In regard to Hackensack Meridian Health, we're very happy to show people how we're doing it. You know, we're an academic, not-for-profit institution. We're happy to show people how to do it. We're happy to go help people to set it up. You know, we're happy to -- we're happy to do that.

MS. PAGE: But the proposal is from both Cota and Hackensack. So what's Cota's position on it?

DR. PECORA: Well, Cota is a separate company, and Cota would be amenable to -- we're paying Cota -- Hackensack Meridian Health is paying Cota to do this. It's a software. It's like people pay Epic to use their EHR (electronic health record). You don't get that for free. So Cota is how we're doing this, and if another center wanted to do this exact thing, they have the right to contract with Cota no differently than we did.

MS. PAGE: I'm sorry. Who was speaking? I didn't --

DR. PECORA: This is Dr. Pecora.

MS. PAGE: Okay, got it. So when -- I

know you wear two hats, so that you are Hackensack, but you're also the chairman of Cota. So when you said that, were you speaking as Cota or Hackensack?

DR. PECORA: No, I'm speaking as Hackensack now because I thought that's what this was.

MS. PAGE: Right. But --

DR. PECORA: I'm not representing Cota here. I'm just saying that this is -- Horizon Blue Cross, Cota, and Hackensack Meridian Health have come together to do this program.

MS. PAGE: Is Mr. Hervey, who was the other submitter -- is he -- the CEO of Cota -- is he on the call?

DR. PECORA: He's not on the call, no.

Do you want to speak to him?

MS. PAGE: I would -- I just wanted to hear that answer from the Cota perspective. So if someone else is on the call from Cota who can speak to it, that would be great.

DR. PECORA: Dr. Goldberg is here.

Stuart?

DR. GOLDBERG: Hi. Hi. It's Stu Goldberg. I'm the chief medical officer for Cota.

So could you rephrase your question again?

MS. PAGE: So it gets to the -- how this would play out, what started out with a question of how a party who was not using Cota could do the model, and then it sounded like it would be difficult for that to be the case. And so then the next question is, to what extent is Cota willing to make its -- you know, the software, the decision logic, the whatever, available to participants in the model?

DR. GOLDBERG: Yeah. So, I mean -- so yes. As you said, Cota has developed the Cota Nodal Address, the classification for every disease, refining all the prognostic variables into a digital code.

Theoretically, another -- another company could, you know, say, "Well, these are the important elements." They couldn't use the digital codes the way we've constructed it, but they could do it through words, although that would be much more difficult.

But the theory of the whole idea that once you refine the patient's disease into a -- sort of a similar outcome, you know, similar type of

patient, you could then apply that to the different bundles and lanes program as, you know, would be translatable from one hospital to another hospital. If --

MS. PAGE: But what's the --

DR. GOLDBERG: Yes.

MS. PAGE: -- the pricing construct?

DR. GOLDBERG: The price construct?

MS. PAGE: Yeah. So if I'm a hospital, if I'm a community hospital, or if I'm an oncology practice or whatever and I want to use this, what generally sort of is the ball park? How much does it cost me?

DR. GOLDBERG: So for our program, we're paying a fee for the CNA assignment, and we pay a setup fee. And I think it was a couple hundred dollars -- $300 for the CNA assignment, and we're paying -- so each patient, we pay $300, and we get not just the CNA assignment. We get all -- they do all the reporting, all the interfacing with -- with the insurance company. They do all the logistics work for us, and they generate all the reports. So that we're paying 300 bucks to Cota for it, and there is a nominal setup fee. We have Epic, and so

they connect HL7 (Health Level Seven International) compliantly to Epic. And that was a fee, and it was into the low thousands of dollars.

DR. FERRIS: Can I -- I'm going to ask a question, and I'm going to -- because of the sort of interweaving of these issues, I'm going to actually try to create a scenario that's very different from the one we're looking at here and ask your opinion about federal policy in this context, which is if a company that had a particular scope proposed a payment model and the payment model required that everyone who participate in the payment model use this one scope -- there was no other one that would work with this payment model -- as a taxpayer, how would you feel about that, that federal policy would require the use of a single-source vended product?

DR. PECORA: We all pay for ICD-10. We all have to load it into our systems. We all have to work with -- you know, I'm not saying -- you know, look, I -- so I'm not even sure how I should respond to this.

I am not suggesting that CMS make Cota a necessary requirement; however, Cota is a first-in-

class breakthrough technology. One of the former CMS administrators is on the board of Cota, Don Berwick. You know, this is something that could be really helpful for the system.

I would think that if people want to come to CMS and do a bundles and lanes program and they don't want to use Cota, they have every right not to use Cota, and they have to show CMS how they're going to do it. And if they have a way to do it and it's not using Cota, great. If it's using Cota, good, too. I don't -- we're not -- I'm not suggesting it's required that -- that the government uses Cota. I'm not sure what else to say.

DR. FERRIS: No, that's helpful.

And I just -- for the record, it's not exactly clear what the answer is here. But I wanted to make sure you understood the situation, and you clearly do.

DR. PECORA: Yeah. No, I do, but, you know, it's like -- it's like NCCN guidelines. They're not for free. You know, you got to register. You got to pay a fee. I mean, so, hopefully, Cota could be a ubiquitous source of big

precision, analytic big data, and, you know, the FDA is going to be using Cota. They've already made that publicly aware. I mean, you know, it's going to be ubiquitously used. How far? How wide? Well, that will -- the quality of what it does will determine that.

I mean, I didn't -- and just help me here because the nature of the questions -- we are proposing for our health care system a model to try, and if the model proves to work, that you use a precision analytic methodology to, up front, define the starting point where a patient starts -- you know, your great way of phrasing it -- and then we're able to show that we're able to modify behavior at scale, optimizing clinical outcomes first and reducing total cost of care second, and we're able to do it at the size of what we are, I would think a lot of places are going to want to try it. And, you know, we've figured out how to bridge precision medicine and population health, and this is what I thought CMMI was looking for, was a novel way of attacking a fundamental problem.

DR. FERRIS: So there's -- I think there's no question about your last statement that -- and

we are interested in novel ways of attacking a fundamental problem, and you understand that we function with a set of constraints on us. And the constraints on us are the rules by which CMS has determined we must evaluate payment models.

DR. PECORA: But the thing -- I guess what I don't get is that you can't do this without an electronic health care record. Most academic centers in the United States have Epic. That's one -- that's not 20 companies. That's one. We all pay Epic. I don't think, you know, the payment would be to Hackensack Meridian Health and Hackensack Meridian Health will use some of the money to pay for Epic, some of the money to pay for nurses, some of the money to pay for Cota. How is it different paying Cota versus Epic to do this?

DR. FERRIS: Well, actually, there's -- Epic has quite a few competitors. While they are dominant, they are not a single source, and that's a critical distinction.

DR. PECORA: I see. Well, let me -- let me come back to you, then, because I've got to believe there's other companies that are going to try to do something like this.

Like Remedy Partners, didn't they -- didn't they do something in -- they didn't do it in cancer, but they did it in heart failure. Didn't they have an algorithm they worked with CMS on?

DR. FERRIS: Yeah. I don't -- we're not going to resolve this issue on this phone call. It is a -- it's a longstanding issue with CMS. It didn't start with payment model reform, but it is something that, you know, the CMS lawyers and everybody else, including the taxpayers, wrestle with. And, you know, we don't have a position on it. So we are -- we are looking for your articulation of your view, which was, in fact, very thoughtful and very helpful.

DR. PECORA: No, I appreciate that, and if I'm at all sounding defensive, it's not that at all. I'm just trying to, you know -- I didn't think about it from that perspective, and I understand you have to, so I respect that.

DR. FERRIS: Well, before closing, I want to say from my part, I am so glad we had this phone call. There are a number of things that are much clearer in my head. I hope that we -- I'm sure we've got them in the transcript because I'm sure

when I think about it again, because this is so complicated, that I -- it will become foggier for me over time. But with this moment of clarity that you've provided us, I want to thank you both for the approach you had to our questions, which was really positive and forthright, and probably in the bigger picture, I want to thank you for your obvious passion to take what is largely chaos in the world of oncology care and actually create some order out of it that is clearly better for patients and the people you're serving at Hackensack.

So I've really enjoyed this hour and a half, so thank you very much, and I want to give my colleagues a chance to weigh in as well.

MR. STEINWALD: Yeah. This is Bruce.

I'm a lot more clear with what you're proposing now than I was an hour ago, so thanks for that.

DR. BERENSON: And I will second all of those good words.

DR. FERRIS: Great.

So do you have any -- in closing, do you have any final questions for us?

DR. PECORA: Yeah. Just on process. So

we will have -- we had this call. What are the next steps, and how does this all work?

DR. FERRIS: Oh, gosh. Well, for that, I am going to look directly to Ann Page.

MS. PAGE: Sure. So the PRT then has to look at all the information that's collected. They will produce their conclusions in a report to the full PTAC.

You will get a copy of that, and so we are trying to see if it's going to be possible to have this discussed at the September PTAC meeting, and that would mean that we would send you the PRT's report about three weeks before that meeting, and then that gives you a week to say anything that you'd want to say back to the PRT -- I mean to the full PTAC, so that the full PTAC would have any statement or information from you before that time.

So, you know, roughly, it would be you would get a report from the PRT in August. I'm thinking like August, around the 11th thereabouts. So that would be the next thing you'd see. You would see the written PRT's report.

DR. PECORA: All right. Great.

DR. FERRIS: All right.

DR. PECORA: Well, and then after -- if the PRT report is favorable, does it then go to another agency to make a decision, or is that the decision?

MS. PAGE: Oh, no. So the PRT is the three people that you've spoken with on this call. The PTAC is 11 members. The report of this PRT is not binding at all on the PTAC. It's just a deep dive. It's a way to dig at issues. It's a way to present information. All of the information that the PRT has looked at will go to the full PTAC, and it's that body that makes the recommendation to the Secretary.

DR. PECORA: Oh, okay. Great.

Okay. Thank you. Thank you for the clarification, and by the way, thank all of you for the opportunity. We obviously are passionate about really trying to do something here, and we hope we can do it with you, so thank you so much for your time.

DR. FERRIS: Great. Thank you.

DR. BERENSON: Thanks a lot.

MS. PAGE: Thanks, everyone.

[Whereupon, at 3:27 p.m., the conference

call concluded.]