

**Responses to: Preliminary Review Team (PRT) Review of the MASON Model –
Making Accountable Sustainable Oncology Networks
Submitted by: Innovative Oncology Business Solutions**

I appreciate the opportunity to answer your very thoughtful questions. In my approach to MASON I attempted to respond to the comments of Secretary Azar on transparency and to the RFI from CMMI on their new direction that emphasizes pilot projects rather than large programs. For clarity, each of my replies below is prefaced by repeating in blue font the question you presented.

- 1. Question about the care episode:** We did not find the episode of care covered by the payment methodology identified in the main body of the proposal; however Appendix A, describing the Oncology Payment Category Methodology (“Page 201”), refers to using the Oncology Care Model (OCM) episode definition. An OCM episode begins on the date of an initial Part B or Part D chemotherapy claim and continues for six months, although beneficiaries who receive chemotherapy after the end of an episode can begin a new six-month episode. Is this the MASON model’s definition of an episode?

In OCM and most payment models episodes are defined as blocks of time. OCM uses an invariable 6 month episode, but this is problematic as most care does not fit into convenient 6 month intervals.

For example, under OCM, patient care for metastatic disease, or HER positive breast cancer, or cancers requiring multi-disciplinary care, often spills over into a second episode that has very different costs.

Chemotherapy regimens are of varying length. Adjuvant chemotherapy is usually completed by 4-6 months, radiation therapy is usually less than 8 weeks, and the majority of surgical oncologic care requires 6-8 weeks for recovery. Patients with leukemia, metastatic disease, and those requiring multi-disciplinary care have ongoing therapy. For other patients, the episode takes less than 6 months. So the arbitrary 6 month determination does not fit well for many tumor types.

In contrast, MASON uses disease specific and patient co-morbidity specific metrics to create the episode. The length of the episode in MASON depends on the care plan selected for the patient. There is no reason why all episodes should be the same length of time when treatment care plans vary.

The Oncology Payment Category (OPC) is the payment for a specific episode as defined in MASON. The optimal duration of therapy can be specifically linked to tumor types, stage, intent of therapy and particular treatment regimens, thus freeing the episode and the OPC from the arbitrary time based model. Therefore episodes and the length of time covered by the OPC will differ from the currently invariable six-month time interval. Time becomes just one of many variables to be considered.

The first MASON episode should start at the time of the first consultation with an oncologist, rather than at the time of initial chemotherapy administration. The major recipient of direct referrals to oncology is the medical oncologist but the episode is just as easily begun with the referral to a radiation or surgical oncologist. The initial consultation with a cancer patient includes the staging of the patient and the education of the patient and family. This is the time when many referrals are made to other oncologic specialists so that a care plan can be established. Many unreimbursed services are performed, as is discussed in the ASCO Patient Centered Oncology Payment (PCOP) model. In addition, there is significant opportunity for wise use of resources. The ASCO Choosing Wisely program addresses appropriate use of advanced imaging in staging. Starting the episode at the time of the first appointment with an oncology specialist allows the model to take advantage of these saving opportunities while reimbursing more accurately for the care given.

In addition, the OCM determination to start the OCM episode of care with the first chemotherapy treatment did not take into account the patients for whom radiation therapy or surgical excision is more appropriate, nor the patients who need significant reassurance but not therapy. For example low risk prostate cancer patients, women with DCIS, patients with chronic lymphocytic leukemia often require no therapy. They do require a lot of unreimbursed time for patient education. It often takes more physician time to not treat a patient than to just prescribe chemotherapy.

Here are a few detailed examples of how the disease specific manner by which the OPC is created can accommodate the variable time frame of therapy:

The care plan for a patient with early stage prostate cancer who elects radiation therapy includes 3 months of androgen deprivation therapy prior to radiation. For those three months, the utilization of resources would be minimal. Then care would be more expensive as radiation therapy is given. All of the costs of radiation would be in the OPC, as would the original staging procedures, biopsies, pathology, and imaging. The androgen deprivation therapy drug payment would not, but the injection codes payments would, be included. The OPC would be defined by the initiation and completion of the pathway driven care plan. The OPC would include a set number of expected office visit charges, medical home management charges, laboratory fees etc, as determined by the pathway driven standard of care. If the treatment takes longer than expected the practice is at risk for the increased expense, as the OPC will not change and no further payments for services are provided. This is analogous to the joint replacement bundle.

At the end of therapy, the patient is assigned to the next OPC for surveillance of the cancer. Surveillance OPCs can be set to an arbitrary time period, but should be prorated to account for patient variation. For example, the prostate cancer patient in the example above requires no therapy, so the surveillance OPC would include minimal labs and office visits. If the patient were to relapse, another OPC would be

initiated to cover metastatic disease. The surveillance OPC would be prorated to the time before relapse and the imaging, biopsy or other procedures needed to determine relapse would be in the metastatic prostate cancer OPC. The pathways based on the NCCN guidelines include the expected evaluation of relapse. The OPC would include the costs of the pathway driven tests, but any tests not on pathway would not be included. Therefore performing tests off pathway would decrease the chances of total cost being less than the OPC for that patient.

For women with HER 2 positive breast cancer, the first OPC would include the diagnostic testing, the original surgery (lumpectomy or mastectomy) and then involve chemotherapy. The drugs would be separately paid but the infusion fee would be part of the OPC, as would the office visits, lab echocardiograms. If the patient's condition merits radiation therapy after chemotherapy, but with ongoing trastuzumab, the OPC for HER positive breast cancer would include both modalities, and the recommended year of trastuzumab. After completion, the patient would be assigned to the surveillance OPC. Because each of these OPCs are in essence a mini-bundle built from the standard of care for that particular patient's disease, the practice is not at risk for having a sicker or inherently more expensive patient, but is at risk for not managing that patient well within the parameters of the OPC.

Cancer patients would be expected over the course of their illness to have a succession of episodes paid by OPCs tailored to the expected pathway driven treatments, leading to a method to follow patients and determine outcomes based on OPCs.

If a patient were to fire the oncologist, die, or go on hospice, the OPC ends. The practice would have billed and collected for the fee for service given before the event, but there would be no shared savings. COME HOME showed that patients as they near death use more office visits, and in some instances more hospital services. The practice would only collect the expected payments for the disease. This will encourage appropriate end of life discussions when it becomes apparent to the physician that the patient is not going to survive. If the patient uses more resources than the OPC, the reinsurance for the practice would have to pay the overage back to CMS.

- 2. Questions about the payment methodology.** We understand the proposed payment model to consist of four parts: 1) payment for medical management of the patient by practicing oncologists; 2) payment for chemotherapy infusion services by facilities; 3) payment for chemotherapy drugs, and 4) financial incentives for oncologists to meet quality performance targets and spending targets specified in to-be-developed Oncology Payment Categories. Please correct or clarify any parts of our understanding of the payment models as described below:

- 1) A one-time, \$750 payment for new patient consultation as described in the American Society of Clinical Oncology (ASCO) Patient-Centered Oncology Payment (PCOP) model for New Patient Treatment Planning;
- 2) A \$350 payment each month for each patient for care management during treatment as described in the ASCO PCOP model;
- 3) A \$50 payment each month for Care Management During Active Monitoring for each patient during treatment holidays and for up to six months following the end of treatment (as described in the ASCO PCOP model);
- 4) Payment for Evaluation and Management (E&M) codes, imaging, other Medicare fee-for-service codes based on the Medicare fee schedule; and
- 5) Financial rewards or penalties based upon the practice's performance in meeting quality targets and spending targets specified in patient-specific *Oncology Payment Categories*.

2a. Are the five components of MASON payments to oncologists identified above correct? If not please correct our understanding.

The components you listed are essentially correct, but are not complete. Here is a more detailed explanation:

COMPONENTS OF THE OPC

E&M visits:

Certain parts of care are best reimbursed by E&M codes. Face to face office visits for chemotherapy toxicity management prior to doses of chemotherapy are a good example of this. Visits for symptoms and complications between chemotherapy visits or during radiation should continue to be paid as an E&M code. However, under the OPC, more of these visits than expected becomes an expense rather than a revenue stream, encouraging aggressive management of side effects as well as the selection, when efficacy is equal, of less toxic regimens.

PCOP payments:

The original consultation E&M is not sufficient to cover the work done before and after the visit. The first PCOP payment covers that process. ASCO estimated the number of hours of physician and staff time to determine the payment level.

PCOP payments during active therapy cover the expense of the patient teaching, and triage calls when the use is higher. The surveillance PCOP payment covers the use of the triage system for patients who are in surveillance for tumor return but are still recovering from the side effects of the cancer and its treatment.

PCOP payments are included in the OPC.

Facility Fees:

The fixed costs of having an infusion center, or a radiation therapy center are currently paid through cost shifting or by technical fees. The cost shifting leads away from transparency. The fixed costs of an infusion center make up the facility fee and should be identical regardless of the site of service since the equipment and physical plant needs are the same.

Radiation therapy center facility fees could be calculated using the same processes, with the addition of a factor for the usual lifespan of the linear accelerator.

Facility fees are included in the OPC.

Subsequent variable Fee for service payments during the OPC Episode:

Different drugs require different tubing, equipment, diluents and different amounts of pharmacist work. They also take a different amount of time for infusion, have different levels of side effects requiring nursing and physician intervention. Therefore the expected infusion codes for each regimen should be part of the target OPC.

Variable radiation costs: Physics consultations, the use of devices and many other variables occur in radiation and are billed separately and included in the OPC.

Hospital charges are included in the OPC, including DRGs for inpatient care, HOPPS APCs, and the physician fees generated during a hospital stay. This is the source of significant savings. At the beginning of the project, we would use the average hospitalization rates and costs, but as MASON continues and the rate of hospitalization declines the OPC target would also decline.

Hospital facility fees would be modified if the infusion facility fee is billed by the hospital.

Other physician's fees would be included in the OPC. Cancer care currently includes bills submitted by a variety of physicians from primary care to other specialties, hospitalist, pathologists, radiologists. Much of this is predictable as there is a standard of care for using genomics, and support labs for diagnosis and treatment of patients. For patients with additional significant medical problems, such as chronic renal failure, the OPC would be adjusted much as DRGs are for increasing complexity.

Imaging costs whether inpatient or outpatient would be included. Clinicians would be able to see the comparative charges of various facilities for imaging.

Laboratory charges would be included in the OPC.

Quality withhold:

By an accounting process, 2% would be withheld from all E&M fee for service payments delivered by the practice. At the end of the episode, if the quality measures were met (patient satisfaction and pathway compliance over 80%) the money would be paid to the practice. If the measures were not met, CMS would retain that money.

Financial Rewards or Penalties: The Virtual Account:

At the time of the decision of a care plan for a patient, the OPC is assigned. A virtual account is created, which at first consists of the total amount paid for that OPC. The services provided from the first oncologic consultation are subtracted from the Virtual Account. Services provided before the first oncologist visit are not. Each time a claim is submitted for any subsequent service related to the cancer diagnosis, the non-adjudicated claim amount is subtracted from the Virtual Account. If the practice disagrees about the relationship of the claim to the cancer diagnosis, the practice can file a report to CMS explaining why that claim is not cancer related and CMS would have to decide.

When the care plan and therefore the episode is completed and all the claims submitted and adjudicated, the total costs of cancer related care are compared to the original OPC. IF the practice spent more than the OPC the practice would pay back the over-spend to CMS — possibly using stop loss insurance for the funds.

If the total costs of care are less than the OPC and the quality measures are met, the practice does share the savings. We can negotiate the sharing, but equal sharing would be fair.

2b. Since the MASON payment model has adopted the specific payment amounts used in the PCOP model, can you explain to us the basis for how these amounts were determined?

The PCOP codes were determined from COME HOME. During therapy, patients are monitored by phone, have multiple educational sessions with their caregiver and assorted staff members. We priced the salary, benefits, and overhead of having oncology nurses calling patients on prescheduled calls, receiving calls, managing patient's concerns over the phone or directing patients to the right site of care. We added the first responders (lower paid, lesser trained individuals similar to Emergency Medical Service 911 workers) to avoid the direction of patients to the ED on the first call to the practice. These people do the initial screen to determine if a call requires immediate attention and transfer to a nurse, or whether the call is less urgent. We then calculated the amount of time needed per patient on active treatment and per patient after treatment is completed. We divided the costs of the personnel plus overhead (phones, computers, desks, etc) by the amount of time

needed per patient per month. This data was submitted to CMMI when OCM was considering its MEOS payment. Our costs were \$350/patient per month for active patients and \$50/patient /month for surveillance patients. Needless to say we were disappointed when MEOS was set at \$160/patient/month as this perpetuates the cost shifting that occurs when practices are treating Medicare patients.

The numbers were then confirmed by ASCO through the following steps:

1. ASCO's practice survey data was used to determine that the FFS revenue that practices were receiving (other than drugs) represented about 2/3 of the costs the practices were incurring (other than drugs).
2. The claims data was used to determine how much practices were receiving in FFS revenue during each phase of care (new patient, treatment months, non-treatment months).
3. ASCO surveyed practices to find out how much time the physicians and staff spent in each phase of care to determine the relative amounts of payments that the practice should be receiving in each phase of care.
4. ASCO then set the amounts of the PCOP payments in each phase of care such that when you added those payments to the current average FFS payments in each phase of care:
 - The total revenues for the practice overall would increase by about 50% (which would make up the 1/3 shortfall); and
 - The revenues in each phase of care would be proportional to what the survey showed was the relative amount of time that physicians and practice staff spent.

2c. Question about monthly care management payments. If the episode is of six months duration, when would the monthly care management payment change from \$350 per month to \$50.00 per month?

As explained in reply to your first question, the episode matches the care plan and is not always six months duration.

Because each OPC is based on a care plan has a time frame that is appropriate to the disease and the treatment, and the treatment can vary in intensity, it would not be appropriate to link the decrease to the surveillance payment to an arbitrary time frame. That decrease should occur in one of two ways. When the entire course of therapy is completed, as in adjuvant chemotherapy for colon cancer, the time for the change is at the end of treatment. When the treatment has more intensive and less intensive months, such as when a breast cancer patient completes intravenous chemotherapy and radiation, and starts hormonal therapy, two different episodes and OPCs are more accurate. So, in this example, a patient receiving lumpectomy, ACx4 followed by radiation, followed by 5 years of an Aromatase Inhibitor, will have two distinct OPCs. The first includes the diagnostic testing, staging, surgery, IV chemotherapy and radiation. This is the time when COME HOME showed that patients had a very intense utilization of the COME HOME services. At the

completion of that OPC, the episode is closed , shared savings are calculated, and the patient starts the second OPC. This OPC would just include surveillance E&M codes and minimal imaging (mammograms and bone density measurements), minimal lab, and the surveillance \$50/month PCOP fee. Five years would be a long episode and a long time to wait for payment, so for the surveillance episodes only a six month episode is more appropriate.

2d. Question about payments for medical home infrastructure. The proposal states that the Oncology Payment Categories would include the costs of “the PCOP payment for COME HOME medical home infrastructure.” Are these payments made prospectively to oncology providers or are they just an included cost item in the spending targets upon which financial incentive payments are made? How much is this payment/cost item?

The Oncology Medical Home certified practice submits a code every month for the appropriate PCOP payment which is paid by CMS and subtracted from the virtual account.

These payments are included in the OPC, so the practice has to save sufficient money in the care of the patient to cover these services in order to achieve savings to share.

The PCOP payments are the medical home or care management payments. These payments are added to the fee for service (FFS) payments. These are the payments that cover the patient and family education services, care coordination services, nurse triage services, financial counseling services and other items not currently paid under the FFS program, but are essential for treating cancer patients. Different patients require different services based on their social support system, economic condition, ability to travel for care and a multitude of other issues.

2e. Question about payment for chemotherapy infusion services by facilities. The proposal states that one of its goals is:

“g. Development and implementation of a facility fee for infusion centers, both independent and hospital based, that covers the fixed costs including costs from the regulatory requirements.”

Please confirm that the proposal would pay exactly the same amount whether or not the facility is independent or hospital based and describe any progress you have made in the development of this new facility payment.

Yes, there is no reason that there should be a difference between hospital based outpatient facility and the physician office facility as both are doing exactly the same services, using the same personnel and equipment.

USP 800 and USP 797 for hospitals require the same infrastructure. Practices purchase the same equipment and hire the same level of personnel as hospital outpatient infusion centers.

Milliman and Avalere have done studies showing that chemotherapy delivered in a Hospital Outpatient Prospective Payments System (HOPPS) facility costs CMS approximately \$6,000 more per course of therapy. Yet the process should be identical. By extracting the infusion facility fee from the general hospital facility fee, increased transparency will be achieved and both PFS and HOPPS will have the fixed costs covered at a reasonable amount that encourages wise use of resources.

Development of the facility fee:

At NMOHC, we did a time and motion study of the delivery of chemotherapy. The episode measured started with the receipt of the drugs from the distributor. The unpacking, storage and the inventory control of the drugs, the process of ordering drugs, the mixing of drugs in a USP 800 compliant pharmacy, the processes involved in administration of the drugs to the patient through the clean up of the administration area, documentation and billing procedures were all measured for time and supplies.

Costs of supplies, and costs of all staff involved were then calculated.

The template we used is included in a separately attached PDF, showing the template format and actual NMOHC data.

NCCA was presented with this data and is willing to do the same study in each practice. The data would be combined to create a more accurate facility fee and to determine if there is a difference in different geographical areas.

NCCA practices, having survived under the current FFS system, are efficient at chemotherapy administration. Hospital departments may have to increase their efficiency. The goal would be for the payment by CMS to cover the infusion center costs and eliminate the need for cost shifting from commercial payments to cover the shortfall for Medicare patients. Removing cost shifting promotes transparency.

2f. Question about drug charges and payment. The proposal states that:

“All expenses related to cancer care except the drugs are included in the OPC.”

“All charges submitted to CMS from any provider are subtracted from the virtual account before adjudication, except for drugs.”

“Drug charges are submitted and paid at invoice +2%. This amount should account for the variability of drug pricing, provide for fluctuations and assist with transparency.

When “drugs” is used in the above and other sections of proposal, which of the following drugs does it refer to: 1) parenteral chemotherapy administered by infusion centers, 2) oral chemotherapy drugs; 3) non-chemotherapy drugs used to treat cancer side effects such as nausea or bone marrow suppression, 4) drugs prescribed by oncologists or non-oncologists to treat co-morbid conditions; or 5) some or all of these?

All drugs, parenteral chemotherapy, oral chemotherapy, non chemotherapy support drugs and all drugs prescribed by any physicians would be excluded from the OPC.

Explanation:

Drug prices are clearly a pain point in controlling the cost of care. We excluded drug pricing from the OPC and therefore the virtual account because physicians have no control over the pricing of drugs in general, changes in drug pricing, and the development of new practice changing drugs.

In the current system under OCM, efforts to remove new drugs and rate practices as early adopters adds confusion to the system and may randomly reward some practices and harm others. The existing OCM process encourages physicians to not use newer therapies in order to meet financial targets. This can harm patients, as the newer therapies are often significantly better, and we do not want a system to encourage under-treatment of patients.

There are instances where a less expensive choice can be made. However if a patient is intolerant of one drug, the physician must use a different one and should not be penalized for that choice.

In the current FFS world, where we must cost shift from the drug margin to cover infusion costs and the other services that are not paid, practices are encouraged to select chemotherapy or support drugs based on the best margin. We do not want a system where financial considerations primarily determine the selection of drugs.

Under OCM, patients with benign conditions currently treated with biologics or immunotherapies are more expensive to treat compared with the OCM target. For example, a patient with a co-morbidity of inflammatory bowel disease or multiple sclerosis receiving expensive drugs would adversely affect the oncologist’s ability to

meet the OCM target. By removing all drugs from the OPC, we remove any concern that practices would refer patients with expensive co-morbidities to other practices.

By billing and being paid separately for the drugs, based on the invoice of all the drug of that type purchased by the practice for that time period (usually a month), the need for a profit based on the drug is eliminated. The incentive to over or under treat is eliminated. Rebates and discounts become irrelevant, thus disrupting the business models of GPOs and distributors who are making a lot of money from the arbitrage of drugs.

All Part B intravenous chemotherapy, including Part B support drugs would be supplied with the 2% margin over invoice. The Part D or pharmacy- acquired drugs would be paid in the usual manner.

A 2% margin is needed to cover the unique inventory costs of chemotherapy. Drugs can require specific levels of refrigeration. USP 800 has increased the expense of having separate storage for certain drugs. Drugs acquired but not used must be returned in specific shipping containers. Breakage, spills, damaged vials or breached pill packages are unavoidable to some extent, no matter how careful the practice is. No business, pharmacy or practice, can afford to sell a product for the exact same amount they paid for it. 2% is not enough to make a profit, but would cover losses that would otherwise have the ability to put a small practice out of business.

2g-p. Questions about the financial incentives

The proposal states that the “Oncology Payment Category” generated for each patient would include a target price for all patients in the category, adjusted for “co-morbidities as well as for the clinical situation of each individual cancer patient,” and that:

- At the end of an episode of care, actual costs would be compared with the payment amount in the relevant OPC. If the practice spends less caring for the patient, and all the quality parameters are met, the practice shares in savings. “Two percent of the Oncology Payment Category is reserved for a quality pool.” If quality measures are not met, that money returns to CMS.
- The participating National Cancer Care Alliance (NCCA) practices will purchase reinsurance out of their general revenue through NCCA “to cover expenses over the target if the patient is an outlier above a designated amount, or if the practice incurs expenses in aggregate for patients over the designated amount.” If payment exceeds the OPC during the risk sharing years, CMS would be repaid from the reinsurance money. NCCA will coordinate the reinsurance to maximize value for the entire group of practices. (emphasis added)

- “At first, data acquisition is required to develop OPCs for approval by CMS. Shared savings should only become available when sufficient volume of data to predict costs accurately has been acquired.”

2g. How would the cost targets for each OPC be developed? Are these targeted costs anticipated to be a national standard or will there be differentiation based upon regional or provider-specific differences in costs?

The OPC will be developed from a combination of claims data and EHR data. First, clusters of claims for the patients with a given tumor type will be identified. For example, some breast cancer stage 2 patients are relatively inexpensive to treat (elderly women with hormone receptor positive tumors and negative nodes who just need surgery, radiation, and an aromatase inhibitor) and some are more expensive (65 year old women with HER positive, hormone receptor negative disease who need lumpectomy, radiation, chemotherapy and a year of targeted therapy). Both are currently reported as the same stage, but clusters of these patients will have similar charges. The EHR and the pathways selected will give the information as to the HER status, the intent of therapy and the predicted extra required testing (e.g., echocardiograms for patients on Trastuzumab). Once the clinical characteristics that define a cluster of claims are determined, the process can be inverted and patients who present with the clinical characteristics can be assigned to the OPC.

At the beginning of the project, the cognitive computing data scientists will identify the cost clusters. Then the NCCA practices will provide the clinical details to determine the causes of the variation in costs. We expect that most of the causes will be inherent to the patient, but we will be vigilant for variation in imaging, testing, use of consultants, hospitalization and ED visits that are under the control of the clinician. The unavoidable costs will be included in the OPC but the optional costs will not. The pathway development for diagnosis and treatment will allow us to first determine which items are standard of care (e.g. echocardiograms for patients on Trastuzumab) and which are not. The pathways will help determine which items should be included in the OPC.

There will be a need to have a number of patients with the same diagnoses and clinical characteristics treated on a specific pathway to make a statistically accurate OPC. Therefore the common clinical situations (breast cancer with hormone receptor positivity receiving lumpectomy, radiation, and aromatase inhibition) will have accurate OPCs developed before less common cancers (thyroid cancer with metastatic disease refractory to radioactive iodine).

Once an OPC is clearly defined, patients with the appropriate clinical situations can be assigned to that OPC.

OPCs will continue to be modified by the cognitive computing processes over time. As the numbers of patients in each OPC increase, it will be possible to determine subsets of patients within each category, and perhaps divide an OPC into 2 different

OPCs. It may be that as we learn more about the genomics of tumors or can codify the social determinants of health, we can create more specific OPCs.

Cognitive computing with Augmented Intelligence will be used to continually improve the accuracy of the ability to predict the expenses of a given patient and assign that patient to the correct OPC.

Because the OPCs will include DRGs, E&M codes and APCs, all of which have Geographic Price Cost Indicators (GPCI's) the regional variations will be included so the OPC will have to be modified for regions. Therefore the OPC will be a list of codes, but the virtual account will apply the GPCIs to the claims and therefore be adjusted for the region. This is not optimal, as it contributes to the variation in cost of care in different areas of the country, but the modification required to eliminate that would add significant complications to the MASON model.

OPCs Technical construction:

The general idea behind the OPC construction methodology is outlined in some detail in Appendix A of the proposal. The fundamental idea of representing episodes as associative arrays of code: frequency pairs allows you to meaningfully use all historical data, side-stepping the problem with "non-stationary" systems that other target methodologies that train predictive models on cost directly necessarily face (and also necessarily fail); Appendix A explains the rationale for this approach for applying the method to the Part B Carrier and Part B Institutional Claims. Similar constructs can be applied to the DRG and APC part of the claims, where the DRG codes are already provided in the Medicare claims and can be included in the exact same way as in Appendix A. Similarly, the APC groupings based on HCPCS codes and the APC Fee Schedule can also be implemented using the same framework described in Appendix A. The pipeline to construct these OPCs consists of the following steps (and repeated to include the DRG and APC components):

Starting with a cluster of patients with similar disease characteristics, one gathers all the available demographic and clinical data, and applies the Density-Based Spatial Clustering of Applications with Noise (DBSCAN) clustering algorithm.

- (1) This algorithm has several advantages over other clustering techniques (in particular it will not force an instance into a cluster, if there are outliers that really do not fit into a natural cluster, they remain singletons and so do not degrade the results of the rest of the downstream methods used to construct the OPCs). The result is a set of different clusters, or groups of highly similar patients as defined by the demographic information and clinical data.
- (2) Then, for each cluster found in (1), perform the following steps: a. From all of the Part A & B files, carrier and institutional Part A & B, with HCPCS codes, collect each code and its frequency for each member of the cluster. Then the code lists will be sampled to determine the frequency of their occurrence so

that the codes of very rare frequencies can be diluted in impact. (A code that appears once in a cluster of several hundred patients is not likely to be related to the clinical situation, for example if a tonsillectomy code appears in a breast cancer patient it is less pertinent than if it appeared in a patient with tonsillar cancer.) This array of codes with their frequencies then serves as the empirical sampling distribution for the OPC.

- (3) As more data is acquired, codes that appear in higher frequencies are more accurately incorporated in the OPC and codes that are less common have less impact. The combination of the clinical characteristics of the patient and the array of codes by frequency determines the OPC. Because of the variation of individual patient's course of care and attributes, there will be some variation so the OPC is a range, rather than a number. The codes multiplied by their frequencies are translated into costs by the physician fee schedule and the other fee schedules as indicated (APCs, DRGs).

For the determination of the Target Price to be put into the Virtual Account, each of the fees from the code set is adjusted by the Geographic Price Cost Indicator for that patient's site of origin.

2h. Do the target prices include all (non-drug) health care costs - including cost of primary care and cost of care for co-morbid conditions by non-oncologists, or do the target costs only represent oncology cost or oncology-related care? If only oncology and oncology-related care, how is "oncology-related care" defined and calculated?

All claims billed to CMS are listed in the virtual account regardless of which providers submits the claim. The claims are submitted to the virtual account as soon as they are received by CMS, before adjudication. This may over-estimate the amount spent on the patient, but that will allow the practices to manage to the "worst case scenario" for patient expense, as adjudication usually lowers the amount actually paid on the claim.

Primary care physicians will submit their E&M claims, as will all physicians involved in the care of the patient.

DRGs from any hospital admission will be submitted and included in the OPC and the virtual account.

APCs from any hospital outpatient facility will be submitted and included in the OPC and the virtual account.

Claims submitted for care related to pre-existing diagnosis codes would not be included in the Virtual Account and the oncologist would not be affected by that expense. For example, if a patient on dialysis develops cancer, the costs of the

dialysis and the nephrologist or any procedures for dialysis vascular access would not be included.

If the participating NCCA practice determines that a set of codes are unrelated to the cancer care, the practice can submit an appeal to CMS stating why the codes are inappropriate for inclusion in the Virtual Account. For example, if the patient is involved in a car accident, the ED visit, the orthopedic treatment and that hospitalization would be the subject of an appeal and CMS would agree and remove those codes.

OCM struggled with this problem and decided to use the entire cost of care. This means that the oncologist would be financially rewarded for referring patients with other medical conditions to other practices. The ability to hit the OCM targets would depend not just on the actuarial case mix for cancer, but the case mix for all medical conditions.

2.1 How would case-mix, including cancer-related costs associated with co-morbidities, be taken into consideration when calculating oncology costs? For example, we assume that patients with serious chronic conditions are more likely to experience oncology medication-related complications and experience cancer treatment-related hospitalizations because of these co-morbidities.

Like APCs and DRGs if a patient has significant co-morbidities as documented by Hierarchical Condition Categories (HCCs) they will require more interventions and therefore be more expensive to treat. Like DRGs and APCs, the category is adjusted for the costs of the co-morbidities. Each OPC will be based on the codes for the cancer related treatment, and then modified by an increase for patients with significant co-morbidities.

This process avoids any temptation to refer patients with complicated other medical problems out of the practice, as the OPC adjustment should account for the additional needed care without eliminating the incentive to manage care wisely.

However, the clinician should have a process to request elimination of codes from the virtual account if they are not part of the cancer treatment. If a patient is hit by a bus, the separation from cancer care is obvious and those claims should not be included in the Virtual Account, and they obviously would not be part of the OPC. If a patient has anthracycline induced heart failure, those codes would have to remain in the virtual account.

The OCM struggled with how to eliminate non-oncologic charges and eventually decided to go with total cost of care. This is a flaw in that system, but the problem of separating oncology care and oncology-related complications is very complex, especially in this era of autoimmune toxicities from immunotherapies. There are simply too many variables.

Augmented intelligence, (cognitive computing), systems have the ability to learn which complications should be attributed to oncologic care, but will require large amounts of data from both the claims systems and the EHRs. NCCA practices and the Viviphi platform will combine claims and clinical data. The artificial intelligence inference engine is designed to ingest and use discrete data from EHRs, genomic sequencing labs, and other sources. Mason using Viviphi can actually codify the CMS Oncology payment rules too.

Any claim reflecting an activity on the pathways is oncology related.

Any claim of a member of the care team, or any claim where the cancer diagnosis is listed, is oncology related.

Any claim relating to a pre-existing condition should not be included. The hypertension, CHF, COPD, or other condition that was listed as an HCC in the time previous to the diagnosis of the cancer would have to be managed with or without the cancer. However, managing the cancer of a patient with a pre-existing condition is more complex and more expensive than managing that cancer in an otherwise healthy person. So an increase over the level of care delivered in previous years would be included in the OPC and the OPC will have to be increased by that amount.

Cognitive computing systems will eventually have enough data to calculate appropriate adjustments, but until that occurs, the same methodology to adjust DRGs will need to be used.

Determining the difference between costs of care with and without co-morbidities is a different facet of the same statistical problem of determining which expenses are cancer related.

2j. How would socio-economic status be taken into consideration in the OPC targets?

Measurement of the social determinants of health is in its infancy. The AMA, through its program of the Integrated Health Model Initiative, has embarked on the process of developing a code set for the social determinants. Once that code set is available, the effect of various factors can be studied and incorporated into adjustments to the OPCs in the same way that other human or tumor variations are incorporated. NCCA will work with its EHR vendor to provide searchable fields for the social determinants as they are identified.

Until we have accurate measurements, zip code is the most accurate data we can easily obtain.

During COME HOME, we noted that approximately 10% of patients that were offered a same day appointment for a complication of their cancer or their underlying disease, would decline that appointment. We therefore did a two week “micro study” to determine the cause. We learned that the lack of a caregiver was the major factor, but lack of easy transportation was a close second. Patients without caregivers were therefore scheduled for more frequent appointments. We have a foundation that could help with transportation, but most practices do not have access to that assistance. Patients without transportation who then clinically deteriorated, called 911 because the ambulance was perceived as free, thus solving their transportation problem. Once in the ED, those who arrived by ambulance were highly likely to be admitted. If the Stark anti-kickback prohibitions against giving patients something of value, ie a ride to the office, were eliminated, this problem could be solved.

Food insecurity is much more difficult. Experiments with referring people to food banks are underway. NMOHC set up a Foundation to help people with the non-medical expenses, and can give patients grocery store pre-paid cards.

NMOHC has a clinic in Gallup NM where health literacy and poverty are major problems. We have learned that translators, extra time with patient educators that involve the extended family are absolutely essential but very expensive. We have also learned that we must pay medical personnel, from physicians to clerical staff, more than in urban areas where jobs for spouses and schools for children are easier to find. The GPCIs exacerbate this problem, as using non-farm labor and apartment rent is inadequate for a medical facility that must conform to the accepted standards for a facility.

Fewer resources are available in many rural or inner city areas. We do not really know yet how this affects the costs of health care.

A solution to adjustment for the social determinants of health is currently beyond the scope of MASON. However, as the AMA completes its coding development and NCCA practices implement those codes, we should be able to collect data for use by the cognitive computing system to quantify the difference in resource use that accompany the variations in patient’s socioeconomic status.

2k. Is the OPC “target” amount different from the “designated amount” in the text above? If yes, please explain.

The designated amount referred to in the discussion of the purchase of reinsurance is the amount that each practice would set as they determined the amount of financial risk that the practice could afford. This is part of the reinsurance process and is not part of the OPC (the target amount), or the virtual account.

Practices have no reserves, as most are Professional Corporations and retaining reserves creates taxable income to the PC. If the money is not used and is then transferred as income to the physician owner, it is taxed again as income. So there is a strong disincentive for practices to retain capital.

This is the major flaw in the OCM, as the practices, unlike insurance companies who are legally required to have reserves, have no ability to manage the actuarial risk of an adversely selected patient population.

If the practice then has to pay back an amount to CMS for going over the OPC target, ie there is a negative balance in the virtual account, the practice then must obtain the cash to make that payment.

Each practice must determine, through its own finances, what level of reserves it can hold throughout its fiscal year, and how fast it can replenish that amount for a new fiscal year. This is the first “designated amount” we were referring to. Then the practice must purchase a reinsurance policy, collectively with the NCCA practices, to cover the second designated amount of aggregated loss. That decision is internal to each practice, which must weigh the costs of the reinsurance policy vs their internal ability to hold and acquire funds and the level of risk of going over the OPCs they carry.

We anticipate that each practice will designate the amount per patient where risk is manageable and also an aggregate amount of loss above which a stop loss policy can save the practice. We would purchase the insurance policy through NCCA for economies of scale, but each practice would bear their own costs based on their own risk tolerance, resources and experience.

At the beginning of this project, the OPCs will not be as accurate as they will become as more data is acquired and used to refine them. Therefore the risks of spending more money than the OPC predicts will be spent is higher and more reinsurance will be needed. As the OPCs are refined, and the practices become more adept at managing patients efficiently, the risks will decrease and less reinsurance will be needed.

21. What are the shared savings and risk sharing years and how long will they last?

Shared savings occur after the OPCs are constructed and validated. As long as the patient is on an OPC, the practice is eligible for shared savings. Over time as the OPCs become more accurate the funds available for shared savings will decrease, which is why it is important that the baseline payments are sufficient to cover the costs of care. Practices would be wise to consider shared savings as a temporary fund to cover the costs of transition to a new system.

For the first year, the OPCs will be under construction. The NCCA practices will be working with the cognitive computing company to create the OPCs and to learn how to use the virtual accounts as well as make the practice transitions necessary for efficient care.

Once an OPC is judged by CMS, NCCA and IOBS to be sufficiently accurate in reflecting the actual costs of well managed patients getting everything that is indicated and avoiding items that are not indicated, the OPC is ready to be used for shared savings.

OPCs for less common cancers will take longer to achieve the accuracy for shared savings than those for more common cancers. This is actually a good thing, because it will give the practices time to adapt to the OPC system.

The process reflects the diagnostic and therapeutic pathways, so that clinicians treating people on pathway can be confident that they will hit the OPC target amount.

Co-morbidities and pre-existing conditions have adjusted the OPC when the patient is enrolled, determined by pre-existing HCC codes for that patient.

The clinician, practice and the patient should all have access to the Virtual Account. The OPC determines the target amount and publishes that on the Virtual Account. Every time a claim is submitted to CMS for the patient, the claim is also listed on the Virtual Account, and subtracted from the total. This is before adjudication so that it may be seen in a timely manner. The total amount spent may be less after adjudication but is unlikely to be more.

If claims appear that reflect preexisting conditions, or items clearly unrelated to the cancer, the clinician or practice can petition CMS to remove that claim from the Virtual Account. The claim is still paid by CMS in the usual manner, it just is not part of the cancer related virtual account.

2% of the E&M claims submitted by the practice are withheld as a quality pool.

Once the episode is completed, and all the claims are adjudicated, the Virtual Account may still contain money. If that is the case, the quality evaluation for that patient occurs. (This is discussed later.) If the quality metric is met, then the practice receives the quality pool. The remained of the money left in the virtual account is shared between CMS and the practice.

If the Virtual Account is entirely depleted and claims above the amount of the Virtual Account have been paid, the practice must pay back to CMS the claims amount that exceeds the Virtual Account.

If the amount is low, the practice simply pays. If the amount is significant, the practice may file a claim with its reinsurance company to pay CMS.

Continual monitoring of how often the NCCA practices makes shared savings payments or receives money will provide a feedback loop on the accuracy of the OPC.

Over time, as more patients are enrolled in the OPC, the number of practices receiving shared savings will decrease. Once the OPC determines a baseline cost for a patient, it will be possible to develop an episode fee or a fully capitated fee for patients enrolled in that OPC.

Because shared savings by its design eventually will not exist, the OPC must fully cover the costs of care exclusive of counting on shared savings in order to be sustainable. It is a well-established business tenet that all businesses require a margin to keep up with cost of living increases, and to expand and innovate. The OPCs ideally should include a margin so that the practices could survive if all of their patients were enrolled in the OPC system. The duration of shared savings will vary by OPC, and will likely be phased out earlier for more common tumor types or those with more standardized therapies.

2m. Which oncology providers would and would not be incentivized under the model; e.g., would medical oncologists, surgeons and radiation oncologists all be incentivized? Equally incentivized?

All oncology providers in the NCCA practices would have incentives to follow evidenced based pathways and manage patients efficiently. The practices of the NCCA range from solo medical oncologists, in which case the surgeons and radiation or gynecologist oncologists would not have an incentive except to continue to receive referrals. Some of the NCCA practices are multidisciplinary with radiation oncologists, urologists, surgeons, gynecology oncologists, palliative care specialists and others. A unified group will all have incentives to work together.

The sharing of incentives outside the group will vary according to the market. If the local hospital market is working toward value based payments, then arrangements to work with the NCCA practice participating in the pilot will be far greater than if the local hospital system is still counting on a fee for service payment or is competing with the practice and wants to economically damage the practice.

For physicians outside of the group, one would expect them to deliver the usual care. Once they realize that all their claims are visible to the patients and to the practice, the Hawthorne effect of knowing one is observed may make them less likely to overcharge.

The practice will realize which outside hospitals, imaging centers, labs and colleagues provide the best service. Physicians will select those referral that deliver the best value. Physicians who work with physicians in other specialties quickly learn who can be relied on to give good care, and the virtual account will give the financial information that is needed to determine value.

However, managing entities outside of the NCCA practices will be beyond the scope of MASON. Ideally the MASON practice would either be allowed to be part of an ACO or affiliated with the ACO so that all members of the professional care team are motivated for value.

2n. Who owns the reinsurance pool?

The insurance pool, also called stop loss insurance, is a product sold by commercial re-insurance companies to the NCCA practices who will pay the premiums. If no claims are made to the reinsurer for costs of care over the target OCM, the money stays with the insurance company.

NCCA will be able to negotiate as a large group of oncologists but each practice will have to pay a different amount, depending on their performance, what level of risk they choose to keep versus the amount they choose to insure. Different practices may have different tolerances of risk.

The goal is to not burden any practice with a level of risk that may threaten their existence, but still create an incentive to work hard to meet the OPC target.

NCCA may decide to create a captive insurance company with each practice owning a cell, so that the lower level risk is not given to a commercial insurer but kept by NCCA. If that occurs, each practice will own part of its reserves, according to what is allowed by law.

2o. Regarding, “Two percent of the Oncology Payment Category is reserved for a quality pool,” we note that this is much less than the amounts involved in MIPS penalties and bonuses. Why is only two percent in reserve, especially as this will be separate from spending risk? What is the source of funding for the two percent reserve? Is it a withhold? If so, from what payment will be it withheld?

The quality pool is a risk withhold on all the E&M claims submitted by the NCCA practices. The current Medicare payment including Medigap coverage is about 80% (depending on the GPCI's) of the cost of care and the shortfall is currently filled by cost shifting from commercial payers. This is becoming increasingly difficult as commercial payers tighten their payment policies, and as more patients are covered under Medicare. Currently NCCA practices have about 50-60% Medicare and 5-10% other governmental payer.

Therefore every 2% that is withheld adds to the burden practices face in staying solvent and independent. OCM suggests that 8% of Medicare payments be at risk. We are not aware of any practices that can afford an 8% decrease in their CMS fees and stay solvent.

The time cost of money is significant, especially for longer episodes. 2% from payments withheld for more than six months is a significant cash flow problem for most practices.

2% is also the amount of the sequester. Several practices sold to hospitals after the sequester as that eliminated any margin. 2% therefore seemed the maximum a practice could withstand if it had a difficult year. 2% is also enough that practices will work hard to monitor their pathways compliance to avoid the loss.

CMS keeps the quality pool until the end of the episode, and would pay it in a lump sum. So after the first few years, the cash flow problem created by the quality pool would diminish.

2p. With respect to, “At first, data acquisition is required to develop OPCs for approval by CMS. Shared savings should only become available when sufficient volume of data to predict costs accurately has been acquired.” What is the estimated time and sufficient volume of data needed data to predict costs accurately?

David Dooling PhD is the data scientist from IOBS who can best explain this process as follows:

The patient data used to construct the OPCs, consisting of demographic and clinical data at the start of an episode, will likely consist of something on the order of 20 - 30 features. The problem at hand is to take these points living in this high dimensional space and cluster them so that any two points that are within a certain maximum distance apart are identified as being in the same cluster. The DBSCAN clustering algorithm is very fast, and so the limiting factor to achieve this goal is the acquisition of sufficient data so as to arrive at meaningful clusters.

One deficiency of the OCM model is that it does not use clinical data in its predictive model. With the NCCA practices, MASON will have access to both clinical and demographic data, and so the clustering will achieve higher fidelity to what OPCs will represent. The DBSCAN clustering algorithm achieves this goal by specifying two hyper parameters: the maximum distance between two points for them to be considered as in the same neighborhood or cluster, and another hyper-parameter that essentially gives a threshold for the minimum number of points there must be in order to define a cluster. Varying the first hyper parameter essentially increases the quality of the clustering: a smaller maximum distance results in closer neighbors,

and more clusters, and allowing for greater maximum distance leads to fewer clusters with more members.

So the clustering algorithm will work with any amount of input data, but because at the beginning, we want only a few resulting OPCs (approximately 30, corresponding to the 7 tumor types and their various subgroups), and to capture enough informative features to capture the meaningful differences but not so many that there are many outliers not assigned to a cluster, we need access to enough data to densely fill this space.

Preliminary work developing the techniques made use of 14 thousand patient records represented in a 13 dimensional space, and after standard z-score normalizing of the features and setting the maximum distance to 2.5 and demanding at least 50 surrounding neighbors for a point to be a "core" point resulted in 17 tight clusters, but with half of the data relegated to the outlier, not fitting into a cluster category. So with these same type of parameters and using the heuristic that half the training data will be atypical and not fit into a cluster, and with the a prior estimate that there ****should**** be about 30 clusters, I think we would need at least an order of magnitude more records than the beta study, something like 200 thousand instances."

We estimate that we would need about 20K - 30K training instances to be fed in to the clustering algorithm in order to find the estimated 30 OPCs (the 7 tumor types and their various subgroups). The DBSCAN algorithm is very fast and scalable, so the time resources are mostly spent on just collecting the data. Fortunately, most of the NCCA practices use a common EHR vendor, so the merging of the data is not a barrier. Once the data is clustered, the target prices corresponding to the found OPCs just involves the creation of these "synthetic episodes" described in Appendix A and the mapping to costs via the Physician Fee Schedule, the APC fee schedule and the DRG payment rates. This code exists and asking for at least 10K synthetic episodes for each OPC (10K being a standard number for resampling purposes), the creation of the cost distribution for each OPC takes about one day. So estimating the data gathering process to take a few months, a conservative estimate for the whole process of creating ~ 30 high fidelity OPCs would be about 4 or 5 months, after time spent up front just collecting and combining the input training data. So the availability of the OPC will correlate with the frequency of the cancer type. Then some work will be required to validate it against historical data. Our conservative estimate is that the first year will be used in creating and validating the OPCs.

OPCs will need to continually be improved as newer genomic categories are discovered that lead to different care plans newer treatments evolve, and as the costs of delivering care changes with the medicare economic index.

3. Questions about the Oncology Payment Categories.

Oncology Payment Categories would include all expenses related to cancer care except the drugs, and would include the costs of:

- expected fee for service (FFS) payments for physician visits,
- imaging,
- lab,
- radiation therapy,
- surgery,
- infusion with a facility fee for infusion overhead,
- hospital outpatient care (using Ambulatory Patient Classifications),
- inpatient care (using Diagnostic related groups), and
- payments for medical home infrastructure.

The proposal states that it aims to develop Oncology Payment Categories, “starting with the 7 tumor types for which pathways exist from COME HOME.”

3a. What are these seven tumor types and what are your estimates of the volume of data needed to develop OCPs for these seven tumor types adjusted for “co-morbidities as well as for the clinical situation of each individual cancer patient.” Please define “clinical situation of each individual cancer patient.” How is this information specifically applied to the development of OCPs?

The tumor types are lung, colon, breast, thyroid, lymphoma, pancreas, and melanoma which were used in COME HOME. This represents about 60-70% of the cancers seen by a practice and we already have pathways for these in process. However, to be an effective payment process we need to expand pathways to include prostate cancer, ovarian cancer, bladder cancer, myeloma and kidney cancer. Tumor types that are very rare may never need to be paid under a MASON system.

Oncology EHRs are not currently equipped to record the HCCs, and many oncology practices have focused more on the cancer than on the co-morbidities. However, patients with diabetes or chronic renal failure are more difficult to manage than patients with the same cancer who do not have these co-morbidities. There is very little data on the variation in cost.

In COME HOME we found that patients with lung cancer were the hardest to keep out of the ED and the hospital as their underlying COPD predisposed them to feeling very short of breath, which is a frightening feeling that prompted them to call 911.

We will need about 10K - 20K instances for each cancer type. About half of these instances may be in a low density region of the high dimensional space, leaving clusters comprised for each cancer type of about 5K - 10K, which are then further subdivided into the clinical subgroups.

The "clinical situation of each individual cancer patient" is just the clinical information describing that patient at the start of an episode, including tumor type, stage, histology, laterality, genomics, intent of therapy, pathway selected, and the HCCs. All of these features then are used as input in the clustering algorithm. We will have both numeric and categorical features. The categorical features, such as stage, will then be encoded in the standard way. The resulting clusters then will all share the same categorical feature values. The point is to use the data and the clustering techniques to then identify what are the common HCPCS codes and their distributions to ultimately arrive at a distribution of costs associated with those demographic and clinical features.

We will go through this process with and without the HCCs included, so that we can determine what add on amount is necessary to adjust to baseline OPC to one that includes the co-morbidities.

3b. This proposed model would be pilot tested in 16 oncology practices who are all members of the National Cancer Care Alliance (NCCA). Can the sixteen NCCA practices generate the volume of data on these seven tumor types given in your response to 3a from their patient population of 250,000? What are the sixteen NCCA practices' approximate patient populations for each of these seven tumor types?

Currently Available Cumulative Patient Volumes for 2017 – NCCA Practices (13/16)

	Commercial	Medicare	TOTAL
Breast	28,110	24,642	57,752
Lung	6,540	6,084	12,624
Colorectal	7,546	6,867	14,413
Lymphoma	5,418	4,783	10,201
Myeloma	827	704	1,531
Pancreas	919	754	1,673
Thyroid	195	103	298
TOTAL	49,555	43,938	93,492

3c. The proposal states that each NCCN practice will add an average of 300 new patients per oncologist per year. Why, and how can you be sure this will happen? How would the pilot be impacted by any of the sixteen practices becoming acquired by a hospital system?

Oncology Circle has data from many years looking at the standard volume of new patients per oncologist. Many of the practices in NCCA were Oncology Circle practices and contributed to that data. We have verified with the practices that those numbers remain accurate.

3d. The proposal states, “Significant software and data science work pulling data from EHRs and from Medicare claims must occur to create and update OPCs.” and “IOBS is proposing to either request a contract to develop the OPCs working with CMS or apply for a CMMI grant.”

- ❖ Would such a contract or grant be a separate undertaking from implementation of the MASON model?
- ❖ Is receipt of such a contract or grant an essential precursor to implementation of the MASON model?
- ❖ If other vendors applied to develop the OPCs could this model accommodate them?
- ❖ How much resources (time, data and funding) are anticipated to be needed to develop the OPCs?
- ❖ When the OPCs are developed, who would own them? Would they be proprietary? Who would maintain them over time and how would they do this? How accessible would they be to HHS and other oncology care providers?

Collecting the data requires significant work from the practices. The data must be entered by either physicians or practice employees, depending on whether or not it is part of the current EHR system. 15/16 NCCA practices use the same EHR, so we will work with that vendor to make sure there are searchable fields for the data elements that are not currently searchable, such as genomic data or the social determinants of health. For example, we know that patients with stage 4 colon cancer who have metastases to the peritoneum are far more expensive than those with only metastases to the liver, yet there is no place to enter that data. (Patients with peritoneal metastases have bowel obstructions that requires hospitalization for surgery.)

As the science of genomics progresses, more data fields will become important. As we develop biomarkers to predict, for example, which patients are at high risk of cardiomyopathy from chemotherapy, we will need to retrospectively enter that data.

NCCA is committed to doing this with the assistance of IOBS, but it has a cost.

In addition, the data scientists and the cognitive computing company will need to have a significant role in assembling the data and developing the OPCs.

The NCCA physicians and IOBS will need to evaluate the OPCs for accuracy, and make sure they include all the standard of care procedures and therapies in the diagnostic and therapeutic pathways.

The NCCA practices, with the help of IOBS, will need to update the diagnostic and therapeutic pathways and implement the IOBS Triage pathways.

IOBS will be managing the processes and coordinating with all the practices, providing data on performance and pathway compliance, and managing the update processes. IOBS data scientists and the cognitive computing partner will construct the OPCs.

Our cognitive computing partner will be acquiring data, and providing the artificial intelligence to help with the development of the OPCs as well as incorporating the genomic and clinical data into patient centered care plans, digital patient monitoring systems and rapid learning processes to monitor the creation and use of APCs.

The development work contained in producing this new model and developing the OPCs cannot be done for free. Therefore there are three options:

The first option is to have a contract with CMS as a pilot to build and test MASON. The OPCs would then belong to CMS and we would be a contractor to develop them. This is the preferred option, as it would allow for rapid progression across oncology practices, assuming MASON performs as expected. OPCs should be the property of CMS, just as APCs and DRGs are the property of CMS. The MASON project partners would hope to continue working with CMS to further evolve and optimize the OPCs.

The second choice is to have a CMMI award as we did with COME HOME. This would allow us to manage the process and report to CMMI. CMS and CMMI would then have the option to pursue the MASON model if the process proved successful.

The third choice is for IOBS, Viviphi and NCCA to pursue independent development money and if the project proves successful to act as a vendor to CMS or any payers who wish to purchase the MASON process which would then be the Intellectual Property of the partnership between NCCA, IOBS and Viviphi.

It is necessary to do some development work as part of the MASON model prior to activation as an alternative payment methodology, including developing a detailed budget.

It might be possible to find a different vendor than IOBS to develop the diagnostic and therapeutic pathways. NCCN could do this but their pathways are too broad to be selective as to best regimens. VIA Oncology pathways or the US Oncology pathways might work. The grant would then have to cover the cost of acquiring

those pathways, but note should be made that the high cost of these proprietary pathways has been a significant barrier for many practices. Pathways developed by insurance companies are focused on saving money rather than providing optimal patient care and are not trusted by physicians.

Another management company besides IOBS could be hired to administer the processes of pathway development and implementation, the implementation of the medical home as defined by COME HOME and NCQA, the PCOP model for financing the medical home processes and the data collection for the development of the OPCs, the Virtual Accounts and the development of the shared savings. However, IOBS has a contract to manage the NCCA administrative functions, and has earned the trust of the NCCA practices. IOBS managed the COME HOME grant to the satisfaction of CMMI, and IOBS owns the intellectual property of the Triage Pathways® and the electronic data extraction for pathway support. The learning curve would be shorter for the IOBS staff and data scientists who have been working on project development.

There are many EHRs and oncology information management systems. These solutions are designed to secure, warehouse, present, and report patient data. There are several different oncology treatment pathway platforms, designed to digitize and electronically present nationally respected clinical evidence from such esteemed professional associations as the NCCN, ASCO and ASTRO. There are new and emerging next generation tumor sequencing systems (NGS) entering the marketplace, designed to present the patient specific data related to an individual's known genomic variants of significance and connect that data to clinical guidance related to novel immunotherapy and targeted drug options. Finally, there are many stand alone mobile patient relationship management systems (PRMS) entering the market. These products are designed to help capture patient perspectives related to symptom burden and relate that data back to the clinic for consideration and management of early warning signs. The COME HOME Triage Pathways have had more validation than any other product. Interfacing all these independent solutions is cumbersome and costly, and presents an overwhelming amount of data to very busy clinicians, a major source of physician burnout.

Viviphi has created a unique cognitive computing platform. Computers learn in a cognitive way as humans do. With proper "training," they can address human-like situations that are characterized by ambiguity and uncertainty, and deal with pieces of data that change frequently and are often conflicting. Cognitive computing is designed to answer questions posed in conversational language with a range of possible "accurate answers" based on the available information that can then be considered by the attending expert. This capability can be critical as a decision support system to help people extend their expertise across any domain of knowledge to make complex decisions. This is the case in cancer medicine. In oncology, there are often no black-and-white answers. The best answers are based on evolving and often ambiguous or even conflicting literature, colored by individual experiences or intuition. Cost of care is considerable, exacerbated by failed lines of

expensive therapy. Aligning physician decision making with Health Plan/payer rules and with the latest evidence (to create optimal decisions for patients) is challenging. Thus, a cognitive computing platform, akin to the one that has been created by Viviphi Ltd, can become a valuable decision support system for oncologists. The Viviphi platform ingests patient data (from relevant EHR systems, next generation tumor sequencing labs, and other sources) and inferences that unique data against codified clinical rules, codified health payer, associated financial rules (e.g. health plan contracts) and recognized standards, to create patient specific, actionable, and comprehensive treatment plans.

The Viviphi platform replaces the need for redundant OIS systems, redundant treatment pathway systems, redundant NGS bolt on platforms, and redundant PRMS systems. Viviphi's VieCure Precision™ platform includes all the above referenced technology and infrastructure in addition to adding the most important feature – which is the clinical inference engine and 4000+ codified clinical rules. The Viviphi platform actually “thinks” like the treating oncology multidisciplinary team (surgical oncologist, medical oncologist, radiation oncologist, palliative care and supportive care clinicians). In a few seconds, the Viviphi platform generates, with the physician, a patient specific, actionable, and comprehensive treatment plan that reflects the best of nationally respected evidence and aligns with the latest precision oncology clinical guidance.

The only similar system available is IBM's Watson, but as MD Anderson Cancer Center published in 2017, it has been less than helpful to oncologists.

Viviphi is uniquely positioned to work with a group of practices and to do the OPC development in conjunction with IOBS and NCCA.

NCCA is a consortium of practices dedicated to working together to advance oncology practice for improved patient care, research and the oncology medical home. These are advanced practices well positioned to lead the way into a new payment model.

The practices are respected in the community oncology community with many members previously or currently on the COA Board, the ASCO Board and the AMA Board. Dr McAneny is the AMA President Elect, and developed the COME HOME processes that were a contributor to OCM. This development team is uniquely qualified to gain the trust of oncology practices, implement a new program and work closely with CMS and CMMI.

Three of the NCCA practices were part of COME HOME and are experienced in working together to produce the clinical data that is essential to the development of the OPC targets.

The combination of these three entities excited to work together for the improvement of oncology care beyond the strong start of COME HOME and the OCM is a valuable opportunity.

4. Questions about the care model.

4a. How are patients recruited into the model, and how and what are they told about being in the model? How do patients dis-enroll from the model?

Patients are referred to oncologists when the diagnosis of cancer is suspected or proven. With COME HOME, we found that patients were excited to be part of the program and thrilled to receive the Oncology Medical Home services. No patients declined participation. Patient satisfaction was in the 90% range.

The NCCA practices are confident from long experience that we are able to offer the highest possible standard of oncology care, that is well coordinated, current, evidence based and adherent to continuously updated pathways and shared best practices. We are equally confident that our care quality and efficiency will benefit further from the care plan processes offered by Viviphi. We are looking forward to proudly educating our patients about the MASON model. We believe it will be a competitive advantage.

At any time that patients object to being part of MASON, they could be removed from the project and their data not submitted to CMS for a shared savings process. CMS, on receiving notification from the practice that the patient did not wish to participate, could simply not transfer claims to a Virtual Account.

4b. We did not find a discussion of shared decision-making between the patient and oncologist. Please describe the extent to which and how the MASON model would incorporate formal, shared decision-making. How would the patient be informed about and involved in the oncologist's use of the virtual account to select other care providers for the patient based on other providers spending and quality performance? Will the patient be able to choose a higher cost provider if they prefer?

Shared decision-making starts with intensive patient and caregiver education. Patient education is a major part of the success of the Oncology Medical Home. Teaching patients about their illness, their treatment and the possible side effects, using both in-office education and the home 'app' designed by Viviphi to augment shared decision making, is an integral part of the medical home process. The Viviphi care plan process makes the patient and their family, friends and caretakers with whom they choose to share, all part of the care team.

We would encourage interested patients to review the Virtual Account and we would explain how the OPC was obtained. We have found that patients are both reassured and relieved to know that they will be guaranteed to receive evidence based care and to not have to undergo unneeded procedures. Informed shared decision making begins when the oncologist and the patient discuss the reason why there is a need for a procedure and what the likely outcomes will be.

There are an insufficient number of formal decision making resources. Patients often use the information they get from the practice, the internet, from the support groups and from friends and family in order to make their decisions. This is a common event with all tumor types, and stresses the importance of education.

As the NCCA members select other providers and resources, that information will be transparent to the patient. Obviously if a patient has a preference for a given physician or hospital those wishes will be respected as much as possible. The consent form for treatment can include a statement that the patient has the final say as to who is on their care team. If the provider to whom a patient is referred is higher cost, then the OPC will be adversely impacted and the practice will have to absorb that cost. This will be a problem particularly in areas where the NCCA practice faces monopolists or strong competitors.

For this reason, ongoing evaluation of the OPCs with adjustments may have to occur. Practices should not be forced out of business simply because a dominant hospital with higher prices controls the market.

OPCs will never be a finished product. Modification for economic reasons as well as changes in therapy must result in changes in the OPC if the system is to work as expected.

4c. The proposal mentions the “care team” in many places, including “external members of the care team” but the proposal is not explicit about the membership of the team. Who are the members of the MASON oncology care team?

The oncologist is the leader of the health care team that manages the patients. Patients and families form a tight bond with their oncologist and the oncologist with the patient. When a consultant or procedure is needed, the oncologist and the patient discuss the reason why, the procedure and what the likely outcomes will be.

All the people who are part of an Oncology Medical Home team provide navigation for each patient in front of them, from the receptionist to the patient care coordinators. The OMH is built on the premise that a patient simply needs to show up. The practice care team should manage everything else from appointments and travel arrangements, to prior authorization, insurance and co-pay management and assistance with any needed social services. Each member of the team operates at

the top of their license and has communication with the rest of the team for support. The outline of the OMH is best seen in the [NCQA certification processes](#).

External members of the team start with the primary care physician. Any other specialist needed in the care of the patient is part of the team, from nephrologists for patients with renal insufficiency or failure, to high risk obstetricians if the patient is pregnant. Physical therapy, ostomy nurses, psychiatrists or other behavior health professionals will be part of the team as needed. Physicians who are managing the patients for any problem should be considered part of the care team, although some will be managing pre-existing conditions. However, all should be part of the communications about the patient.

The team is not static but will vary over the course of the disease, according to the needs and wishes of the patient.

Family members, and friends and support groups can be effective members of the team, when they are kept informed of the patient's care plan, the progress or problems, needs and wants. The HIPAA list is a useful tool to know who is and is not part of the care team.

The patient has the right to accept or reject a suggested consultant or anyone else as part of the care team.

4d. How are nurses involved in the model? In the care teams?

The care team will vary by patient and will always include nurses. The oncologist leads the care team, and with direction from the patient and input from the rest of the team forms the care plan. Nurses do a lot of the patient education, staff the triage phone calls, provide chemotherapy teaching in the infusion center, call the patients after infusions or the prescription of an oral chemotherapy to check on the patient. In the radiation arena, the nurse makes sure the patient understands the processes and monitors the tolerance of the treatment.

Specialty nurses for ostomies, palliative care, home care visits, hospice and many more could be part of the team, depending on the needs of the patients.

The oncology medical home process depends on every participant working at the top of their license.

4e. How does the model incorporate and reflect radiation oncology practices? If treatment for a patient begins with radiation as opposed to chemotherapy, how will this affect the definition of the episode and episode costs?

Many of the NCCA practices have radiation oncologists as partners. When a patient is referred to any oncologist member of the practice, the OPC would be assigned. The components of the care plan will vary, so the OPC will vary. Radiation oncologists are not considered differently than any other oncologist, as it is the existence of the medical home system that applies.

4f. How would oncologists in the MASON model work with primary care and non-oncology specialists caring for patients participating in the MASON model?

As mentioned above the care team includes many people who are not in the practice. Communication of the care plan as designed by the patient and the oncologist, including the patient's goals, is communicated to the members of the team by records and by phone. Often, the oncologists and the others are in contact by phone or text or email so that each person's role in patient care can continue. As a practicing oncologist, I have found that when I am treating a diabetic patient with a steroid containing regimen, a call to the primary care doctor alerting them to the expected hyperglycemia sets up visits as needed and the care is coordinated. We found in COME HOME that most other physicians were delighted to know that the patient's complications from the cancer and its treatment would be managed by the practice.

The ideal way to include physicians and facilities that are not part of MASON would be to imbed MASON into an ACO. ACOs spend significant time and resources trying to predict who the most expensive patients will be and to manage them. Cancer patients are high utilizers year after year. MASON would give the ACO a method to manage those patients, assuming CMS relents on its prohibition that a physician can only participate in one APM at a time.

Members of the team who are not members of the practice would have their reimbursement occur in the usual manner.

4g. NCCA oncologists have volunteered to participate in the pilot project. What about infusion centers? How would infusion centers be recruited and selected to participate in the MASON model? (NOTE: This item was mislabeled as 4e in the question sheet.)

All of the NCCA practices have infusion centers in their offices as part of the practice, so no external recruitment of infusion centers is needed.

It is unusual to find an oncology practice without an infusion center, because having the center as part of the practice allows for coordinated care when doses are changed or the regimen is changed. If a patient is intolerant of a regimen or has progressive disease, regimens need to be changed. Having an infusion center as

part of the practice allows for rapid changes, and eliminates the risk of patients being continued on the regimen that was discontinued.

Referral to an outside infusion center is also difficult when patients simply need hydration or additional nausea or pain control. Oncologists are fortunate to have the infrastructure to just deliver care. If a primary care physician knows that a liter of saline could prevent an admission, they have to figure out who can deliver that liter. Oncologists just put the patient in the infusion chair and deliver the care.

Blood products are required to be given in hospital infusion centers, at great inconvenience and expense. Fortunately, other infusions can be given in the practice where the team knows the patient, their drugs and their diseases. These charges would be subtracted from the Virtual Account and the infusion center would submit claims and be paid in the usual Fee for service way.

Care coordination is much easier when the in office infusion center is used, as the nurses know how the patient tolerated the drug, the team managed the infusion reactions and can modify the process.

Oncology practices have attempted to manage oral chemotherapy the same way, by developing in house pharmacies that supply oral chemotherapy and support drugs. The goal is to know when the patient receives the medication, to insure appropriate patient teaching, and to schedule appropriate follow up calls and visits. Patients on oral chemotherapy use the medical home support systems in a fashion similar to those receiving intravenous chemotherapy.

Unfortunately with oral chemotherapy, pharmacy benefit managers disrupt the care process. The practice physicians and care team doesn't know when or if the patient actually receives the drug, so it is hard to plan calls or other interventions to promote adherence. The additional fees charged by Pharmacy benefit managers would have to be included in the OPC unless the office pharmacy is allowed to fill all the oral chemotherapy prescriptions.

Many patients receiving oral chemotherapy also have infusions in the office infusion center as part of their care. Integrating the oral and intravenous therapies improves the quality of care and patient satisfaction.

5. Questions about quality assurance and metrics.

The proposal states:

“Clinical quality is measured by compliance with evidence-based pathways as extracted from the EHRs electronically, patient satisfaction surveys and eventually by outcomes of chemotherapy regimens rated for effectiveness toxicity and cost. We are working with EHR vendors to provide solutions for monitoring

and recording HCCs and Socioeconomic situations. As the current IOBS software can update nightly for pathway compliance, monitoring will occur by each physician, each practice manager and IOBS through NCCA.”

5a. What specific clinical quality of care measures will MASON use?

MASON proposes to measure quality in a very different way than PQRS or OCM measures quality.

OCM selects very specific measures for specific sites and stages of disease. For example, one OCM measure is whether or not adjuvant chemotherapy is given for stage 3 colon cancer. This measures only one disease and one situation and gives no information on whether or not other diseases are treated with evidence based therapy. No changes in the management of other diseases or the complications of cancer or its treatment occur because of this measure. We felt that this spot-checking type of quality measure was inadequate.

Therefore we divided Quality into two components, the technical quality and the customer service quality.

Technical quality is defined as knowing and selecting the correct options for therapy for a given cancer type, stage, in the patient’s clinical setting, taking into account patient preference and all pertinent factors such as co-morbidities, histology, and genomics.

Customer Service quality is defined as how well the practice meets the needs of the patient. The patient needs include their medical needs as they manage the side effects of cancer and its treatment, the emotional support needs, the need for respect of patient and family time and wishes, their financial needs, psychological needs among others.

Technical quality:

Rather than spot checking a specific tumor type like the colon cancer example, we feel that general technical quality is best done by having physician approved diagnostic and therapeutic pathways, and measuring compliance with all pathways.

Pathways have been developed for all seven tumor types by a committee of physicians, first as part of COME HOME and now as NCCA. These pathways are updated at least quarterly. These pathways began with the NCCN pathways and were narrowed down to eliminate regimens or tests that were not felt to be currently accepted as standard of care. Radiation therapy is included in the pathways. Clinical trials and palliative care options are defined as always being on pathway.

A software process has been developed during COME HOME to extract the data points of all the pathways and report back to the physician, to the practice and to

IOBS pathway compliance. The software allows each monitoring entity (practice, physician, IOBS, and eventually CMS or other payers) to know whether the clinician is on pathway for each tumor type at every stage. It is possible to sort the compliance data by practice, by individual physician, by individual tumor type and to drill down to individual patients.

The Pathways include diagnostic testing in such a way that if the clinician were to omit a needed diagnostic test, the clinician would be scored as off pathway. If the clinician ordered a diagnostic test that was felt not to be appropriate (PET scan in an asymptomatic stage 1 breast cancer patient, for example) the clinician would be scored as off pathway. If a chemotherapy regimen is not listed as an accepted option for a specific tumor type or stage or intent of therapy, selection of that regimen would be scored as off pathway. If genomic testing were done at the wrong stage or if radiation therapy was not offered when indicated, the clinician would be off pathway.

Pathway compliance is therefore both a general and a specific measure of the technical quality of care.

Because a data base is compiled and maintained, if a specific question arises, such as how often are the NCCA physicians ordering adjuvant chemotherapy for stage 3 colon cancer, this data would be easily available. Pathways therefore incorporate the PQRS quality measures.

The pathway system is also helpful in that it can function as decision support for patients and clinicians when the care plan is being developed.

The pathways extraction can be updated electronically nightly, so that if an error is made, such as the physician entering the wrong stage, it can be corrected. The goal was to be accurate not punitive.

This quality system is more than a quality metric. This will provide the data for practice improvement. For example if a practice finds from low pathway compliance numbers, that they are not properly treating a specific type of cancer as well as they could, remedial CME could be provided. Or the proper regimens and diagnostic workup could be highlighted in the electronic ordering system.

One of the major complaints leveled against the PQRS system is that it required manual data entry, and therefore was prone to human error and increased expense. The pathway compliance quality system avoids both problems.

Another measure of technical quality is how well the practice can deliver its services. For radiation oncology ACR certification is a process that encompasses multiple quality metrics. Achievement of ACR certification is an important indicator.

[ASCO's Quality Oncology Practice Improvement \(QOPI\)](#) certification is a well developed process to ensure that chemotherapy delivery in the practice's infusion center meets rigorous quality standards.

Customer Service Quality Measurement:

OCM uses an extremely lengthy survey that is sent to cancer patients to assess whether or not patients have their needs met. We have tried much shorter surveys at NMOHC and have received feedback from patients that they don't have the energy or the desire to answer even our short surveys.

MASON will continue the COA patient satisfaction survey, despite the reluctance of patients to spend their time filling it out. However, we think there is a better way.

Patients want to have access to their physician or a member of the team when they need us. The IOBS COME HOME Triage pathways provide a systematic approach to ensuring patient access. Patient satisfaction with the Triage process was in the 90th percentile throughout COME HOME. We would continue that, because in addition to making patients very pleased with the prompt service, early intervention kept patients healthier and out of the hospital. We learned that patients really want good health, not just good healthcare.

Patients appreciated the prompt response from the nurse triage line. We received many comments that can be summarized by the idea that people who don't feel well, and may have a short amount of time to live, do not want to spend that time obtaining their health care.

Therefore an appropriate and actionable measurement of quality is the measurement of the times patients waited for the different services provided.

Vivphi has a smart phone 'app' that can generate immediate feedback for patient satisfaction not only for the general quality of customer service delivered by the practice, but for the various components of care and members of the care team.

IOBS worked with NCQA and the Commission on Cancer (COC) to develop criteria for the Oncology Medical Home, which embodies customer service quality of care. Several of the NCCA practices are NCQA or COC certified. We consider this such an important quality metric that the PCOP payments would only apply for a certified oncology medical home.

5b-d. The proposal states:

[“All charges submitted to CMS from any provider are subtracted from the virtual account before adjudication, except for drugs. This account is visible to the practice, and to the patient. All charges from providers external to the](#)

practice are visible so that the practice can evaluate the relative charges and value from specific consultants and outside providers. This will allow the practice to select the consultants with the best outcomes and value for future patients, as well as monitoring the costs of the current patient.” (emphasis added) and

“The development of virtual accounts for every patient can use CMS claims prior to adjudication to estimate expenses as they occur. The practice and the treating physician will learn which providers external or internal to the practice are the most expensive or which provide the most value.” (Emphasis added)

5b. What outcome measures have been developed and would be used for the seven selected cancer types?

Pathway compliance as described under 5a has the flexibility to select specific data points for different tumor types.

5c. The proposal states, “With the visibility of the virtual accounts, costs become obvious. If different hospitals charge different rates for admissions or for surgeries of equal outcome, physicians will rapidly become aware of the difference and select the hospital or clinician that provides more value.” (Emphasis added). Please share with us examples of risk-adjusted surgical outcomes by hospital that can inform hospital selection by cancer patients.

Measuring the quality of surgical outcomes is in its infancy, although the American College of Surgeons Commission on Cancer has led the way.

Having a rating system for hospitals has eluded CMS for some time, and the best available is Hospital compare.

Individual physician practices would be ill advised to publicly rank hospitals or surgeons for medical-legal reasons.

However, practicing oncologists see which patients routinely have positive tumor margins, have complications such as wound infections, have ports placed that don't work or have poor cosmetic outcomes. For each health care market, there are a limited number of surgeons to refer patients to, and those processes can be discussed within the practice.

The Triage pathways will also identify consulting physicians with poorer outcomes. For example if patients are routinely activating a triage pathway for fever or bleeding after surgery by one surgeon, but not by others, that data will be made available to the oncologist. If the hospital charges are much longer for one surgeon than another, showing increased length of stay, we will see that through the Virtual

account. We would also see which surgeons have re-admissions for surgical complications. Because the Virtual accounts create a database, we will be able to compare hospitals and doctors to each other and over time.

Similarly, if one primary care doctor's patients have multiple triage pathway activation or admissions for glucoses out of control, that will also be known to the oncologist.

The Virtual Account shows the claims submitted. For example, a breast surgeon who is doing quarterly breast ultrasounds and aspirating benign cysts adds significantly to the cost of care without adding value. Without the Virtual Account the oncology practice would not know if that were occurring.

As we collect the claims data for increasing numbers of patients, we can plot more accurately surgical charges, readmissions and numbers of antibiotic prescriptions etc for surgical outcome measurement and other hospital specific measures, including patient satisfaction.

5d. How will MASON receive comparative outcome measures for providers who are not one of the sixteen oncology practices that would participate in the MASON model?

Mason can be measured against the other OCM practices. This will be the closest control group. Both cost and quality measures will be available from OCM.

CMS also will have the option to compare the MASON practices with the other oncology providers in the markets of the NCCA practices. If CMS is willing to provide IOBS with that data as it did for COME HOME, we can compare each practice claims data with the other providers in each market.

We will not have the same level of clinical data from non-participants. One of the unique values of MASON is that we will have the ability to truly merge clinical and claims data.

5e. The proposal discussed the integration of genomics and social determinants of health into clinical decision-making. How will data regarding this information be obtained? Will companion diagnostic testing be considered part of lab costs or incorporated into the costs of infusion or drug therapy?

Genomic tests are incorporated into the pathway at the appropriate stage, and intent of therapy. For example a patient with stage 4 colon cancer should have RAS mutations tested and would be on pathway when the intent of care is life prolongation but off pathway if the patient elects palliative care only.

Data regarding the use of genomics will be pulled from the EHR by the pathway compliance software. Genomics is essential for being on the appropriate place on the pathway.

In addition the Viviphi system will provide genomic information in an electronic format for both decision support and evaluation.

Social determinants of health are harder to quantify. Zip code is currently the best surrogate. Zip code is routinely collected by practice management systems.

The AMA Integrated Health Model Initiative is developing a code set for the other social determinants. Once that is ready for testing, we will offer to be a beta site.

5f. How will quality measures be impacted by acceleration of new knowledge from genomics and epigenomics with respect to clinical pathway development and adherence to standardized guidelines?

Incorporation of genomics, epigenomics and proteomics into oncology care is hampered by the rate of change of the science, the difficulty of individual oncologists to stay current with the volume of information, delay in payment and the disruption for payers when genomics suggests that a drug not approved for a given tumor type could be efficacious.

Pathways provide a method of decision support and rapid learning technology will become essential for all oncologists as no one will be able to keep up with the medical science and the new drugs. Busy oncologists need a real time tool to help remember which genes are important in which tumor and which stage and imply which drug is indicated. It is not possible to sort through the medical literature in the middle of a busy clinic, so the information needs to be embedded in the EHR workflow. Pathways can provide that tool.

We are partnered with Viviphi to use the artificial intelligence/cognitive computing processes to incorporate genomics into care plan and pathway development. Viviphi has the ability to acquire genomic data and help insert the appropriate testing into the pathways and guide treatment selections appropriately for inclusion in the care plan. Viviphi needs a group of practices like NCCA to develop their capabilities and NCCA needs a method to make sure we are treating our patients with the most current options.

This process is separate from MASON, but the synergy is obvious. Part of the reason that MASON excludes drugs is that we do not want to create a system where oncologists are penalized for incorporating new innovative — often genomically derived — therapies for patients. In addition, the exclusion of drugs

allows the standard of care processes to be incorporated into MASON for a patient on a trial.

The ability to collate data from individual patients clinical responses with genomic tumor data will also accelerate the science and may change how clinical trials will work. MASON is not a clinical trial platform, but NCCA plans to work with Viviphi and another company called Transmed to accelerate genomically driven clinical trials. One of our member practices is based on providing clinical trials and is expanding the capability of the NCCA network to perform trials rapidly and accurately.

Clinical trials are always on pathway for evaluation of quality.

5g. How will un-adjudicated claims data from non-MASON providers be obtained and entered into the patient's virtual account? As MASON participants will be able to view un-adjudicated claims from non-participating providers, will non-participating providers have access to and be able to see non-adjudicated claims from MASON participants?

If the claims are submitted by part of the care team, the un-adjudicated claims can be shared and stored in the platform to calculate total cost of care. The un-adjudicated claims can be passed through MS-DRG Grouper or APC Grouper to determine the prospective payment from CMS to help understand the cost of the episode.

For the ones who are not part of the care team and do not have an existing claims sharing agreement, we will have to wait until CMS sends the claims data. However, most claims are now submitted electronically so when a claim is submitted on a MASON patients, that information can also be transmitted to the Virtual Account.

MASON participants would not be averse to sharing the Virtual Accounts, assuming all the HIPAA Business Associate Agreements were in order and the patient gives permission.

5h. The proposal states, "Commission on Cancer (COC) or NCQA certification for the Oncology Medical Home should also be reflected in the facility payments and the PCOP payments." To what does "the PCOP payments" refer and what does "reflected in" mean?

Practices have voluntarily submitted for evaluation for QOPI certification to ensure that chemotherapy is administered in a safe manner. The Commission on Cancer and NCQA both have developed programs to certify the quality of the oncology medical home processes by practices. This requires significant time and resource commitment by the practices, and should be rewarded by a payment bonus. Only

practices that have certified as oncology medical homes by COC or NCQA should be able to bill the PCOP payments.

PCOP, the Patient Centered Oncology Payment was developed by ASCO as an alternative payment methodology. IOBS and ASCO are collaborating on MASON and PCOP.

The PCOP payments include the following:

1. Payment for New Patient Treatment Planning

The oncology practice would be able to bill payers for a \$750 payment for each new oncology patient who begins treatment or active management with the practice. This would enable the practice to ensure the accuracy of diagnoses, identify appropriate treatment options and help patients choose the most appropriate treatments, and provide the education and support services that patients need when first diagnosed with cancer. This payment would also finance a portion of the ongoing support services patients need during treatment.

2. Payment for Care Management During Treatment

The oncology practice would be able to bill payers for a \$350 payment for each month in which an oncology patient is receiving parenteral or oral anti-cancer treatment prescribed by the practice. This would enable the practice to deliver effective care management services for all patients and to deliver effective management of oral anti-cancer therapy. This payment would also be made for patients who are in hospice if the oncologist is the hospice physician.

3. Payment for Care Management During Active Monitoring

The oncology practice would be able to bill payers for a \$50 per month payment when an oncology patient was not receiving anti-cancer treatment but was being actively monitored by the practice. This would include any months in which treatment was not received *before* a treatment regimen was completed and up to six months *after* the completion of treatment. This would help the practice to provide both effective survivorship care and end-of-life care.

4. Payment for Participation in Clinical Trials

The oncology practice would be able to bill payers for a \$100 payment for each month in which a patient was participating in a clinical trial (for treatment or follow-up) if the trial sponsors do not provide support for practice expenses related to participation in the trial.

5.i. There is a well-developed literature demonstrating significant misdiagnosis of cancer. As incentive payments will be based on diagnosis and associated payment targets, what does the MASON model do to ensure accuracy in diagnosis, related to pathology, stage, and genomics, where relevant?

Misdiagnosis of cancer is of great concern. The ASCO PCOP program recognized that it takes significant effort to verify the accuracy of the diagnosis. All patients must have a signed pathology report that is reviewed by the oncologist. Imaging studies are reviewed. When needed the oncologists request second opinions on pathology.

Genomic testing is providing a method for verifying the diagnosis, particularly when the histology is unclear.

Inaccurate staging of the cancer could also adversely affect patients by the selection of an inappropriate care plan.

Having the pathways include the appropriate tests for staging and exclude the inappropriate tests will give rapid feedback to ensure that the staging is correct.

5j. The proposal states that NCCA physicians have taken ownership of the DTPs and will update them at least quarterly. And that “NCCA physicians will work with academic colleagues to keep the pathways current.” Who are the academic colleagues and what process and standards of care will be used to quarterly update the pathways so that they reflect the current state of clinical knowledge?

NCCA physicians are leaders in the oncology community.

Every quarter by conference call the pathways are reviewed and new literature is discussed. If NCCN includes a new therapy then it is also included in the MASON pathways. If the new therapy is not yet on NCCN it is listed in the comment section for inclusion.

(See table of NCCA Affiliations on following page — the remainder of this page deliberately left blank.)

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NCCA Affiliations (Info from several practices is pending)

Dayton Physicians Network	<i>See attached PDF, "Dayton Physician Affiliations"</i>
Hematology-Oncology Associates of CNY	<ul style="list-style-type: none"> • Roswell Cancer center • Hospice of CNY • Alliance for Clinical trials in Oncology • Upstate NY society of Medical Oncology and Hematology Associates • Excellus Regional Advisory Board • ION CAN Network • MS resources of CNY
Hematology-Oncology Associates of CNY	<ul style="list-style-type: none"> • Research affiliation with Dana Farber • May have a clinical affiliation with Mass. General in the near future
New England Cancer Specialists	<ul style="list-style-type: none"> • Research affiliation with Dana Farber • May have a clinical affiliation with Mass. General in the near future
Hematology, PA	<ul style="list-style-type: none"> • Affiliation with Dana Farber • Affiliation with Elliot Hospital • Affiliation with Concord Hospital
New Mexico Oncology Hematology Consultants, Ltd	New Mexico Cancer Care Alliance (academic partner since they are tied to UNM research and Dr. Giudice sits on the clinical committee)
Oncology Consultants	<p>Luis T Campos, MD</p> <ul style="list-style-type: none"> • Clinical Professor of Medicine, University of Texas Health Science Center at Houston • Board Member, Texas Society Medical Oncology
Pacific Cancer Care	<ul style="list-style-type: none"> • Visiting Nurse Association (VNA) • Association of Northern California Oncologists (ANCO) • Hospice of the Central Coast • Palliative Medicine Services – Community Hospital of the Monterey Peninsula • Research affiliation with Dana-Farber Cancer Center/Harvard Medical School
RCCA	<ul style="list-style-type: none"> • Academic based practice in Hackensack <p><u>Affiliated with:</u></p> <ul style="list-style-type: none"> • Robert Wood Johnson • Barnabas Health • Atlantic Health • Virtua Health • Meridian Health Systems

6. **Question on the Evaluation methodology.** The proposal states, “Evaluation will be performed by IOBS and contractors during the pilot phase by a case control methodology, comparing costs of patients on MASON with clinically similar patients treated by OCM practices and by patients treated by other practices in the same or similar markets.”

6a. Is the submitter open to having another evaluator of the pilot project? Would another evaluator be able to evaluate (have access to data on) the performance of the Oncology Payment Categories?

MASON is open to having an external evaluation and would share the data.

6b. What is the rationale for using oncology practices participating in the Oncology Care Model as the comparison group rather than other, matched practices as the logical control group?

OCM is the logical comparison group as it consists of similar practices trying to transform their care and save money. Comparison with OCM would help validate the OPC as we would be able to see what the effect of removing actuarial risk is on practice sustainability for continued participation in the model. We see MASON as the next step from OCM in the evolution of value based oncology care, but comparison with OCM ensures that each evolutionary step adds value.

The goal of developing an OPC is to accurately predict costs of optimally managed oncology care. With accurate cost predictions for patients of similar stages and pertinent clinical characteristics, the risk of adverse selection of patients is eliminated and the practice makes shared savings only by efficient delivery of care and by keeping patients healthier.

An important evaluation of MASON would be to use the actual costs of patients treated under OCM and compare with the MASON OPC targets. If we are accurately constructing the OPCs, fewer OCM patients would miss the target and fewer OCM practices would be penalized.

As we continually improve the accuracy of the OPC to determine the baseline cost of care, shared savings becomes harder to achieve. Evaluation of MASON practices vs other practices in the same market will allow CMS and other payers to determine the most efficient practices in the area, for both pathway compliance, patient satisfaction and cost.

Comparison with other matched oncology practices would be ideal, however without the clinical information available from the MASON processes it will be difficult to know if the patients are truly comparable.

7. Other.

7a. Page 8 of the proposal states, “In the recent RFI, CMS requested pilot projects.” Please direct us to this RFI and the request for pilot projects.

The CMS RFI is found here:

<https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>

Item 6 of a list, on page 2 of the document, states that:

"Small Scale Testing – Test smaller scale models that may be scaled if they meet the requirements for expansion under 1115 A(c) of the Affordable Care Act (the Act). Focus on key payment interventions rather than on specific devices or equipment."

Also on page 2 of this document, it is stated:

"The Innovation Center is interested in testing models in the following eight focus areas:

- (1) Increased participation in Advanced Alternative Payment Models (APMs);
- (2) Consumer-Directed Care & Market-Based Innovation Models;
- (3) Physician Specialty Models;
- (4) Prescription Drug Models;
- (5) Medicare Advantage (MA) Innovation Models;
- (6) State-Based and Local Innovation, including Medicaid-focused Models; (7) Mental and Behavioral Health Models; and (8) Program Integrity. However, the Innovation Center may also test models in other areas"

Our submission to the RFI is included as a separate PDF entitled, "McAneny CMMI RFI Response & Pilot".

7b. Provider-specific pilot project versus a generic model. The proposal states that the submission is for a "pilot" program in which all participants are preselected and have existing business relationships; e.g., the Chairman of the Board of IOBS is also the Chairman of the Board of the National Cancer Care Alliance (NCCA). NCCA also will coordinate the reinsurance for the entire group of practices, and IOBS has identified a partner to apply its cognitive computing platform to generate patient-specific treatment plans. The proposal further states, "We are in discussions between NCCA and the major NCCA EHR vendor to allow us to pull all the practice data through the COME HOME system."

- ❖ Must the pilot be limited only to NCCN oncologists?

- ❖ Are the to-be-developed patient classification algorithms the only ones that can be used in the pilot test, or could other oncology groups use other algorithms?
- ❖ How much of the provider-specific tools and resources (e.g. the EHR vendor, cognitive computing platform, and to-be developed payment categories) can be replaced with similar tools selected by other oncologists?

MASON is an attempt to create a new payment system that adds transparency and accurate financial targets to oncology care. It is a care transformation process as well, because practices will need to evolve into very patient centric, efficient systems designed to maintain health and mitigate complications of cancer care in order to succeed. MASON hopes to develop a methodology that can be expanded to other specialties managing acute exacerbations of chronic disease by creating payment targets analogous to DRGs or APCs for use by CMS and other payers.

NCCA was formed by several of the practices that participated in COME HOME, or were in the Oncology Circle. Both of these organizations consist of practices that are motivated to use data to transform health care, deliver better care and work together to remain independent of hospital acquisition attempts. Having practices willing to do the work to create a new payment mechanism is a significant advantage. The practices have worked together before and have gained trust in their working relationship.

IOBS is a familiar entity to both COME HOME practices and OC practices. IOBS is trusted by the practices as having been a fair and honorable partner during COME HOME.

At present limiting MASON to this group of practices will make the project manageable. We need sufficient numbers of patients to generate the OPCs but there is some risk to the practices. Having a collaborative group of practices help point out unintended consequences or develop better ideas for patient care, to work with a common EHR vendor to share ideas for data collection is a major advantage.

By patient algorithms we assume you mean the OPCs. We are not aware of any other statistical attempt to accurately predict oncology costs based on patient characteristics, but if another option is presented it would certainly be considered. Any method that improves the accuracy of the payment target adds value to the project.

MASON should be independent of EHR vendor, but oncology practices have discovered, (as have other specialties) that current EHRs may be adequate for accessing patient data one patient at a time, but are not well designed for extracting population management data or quality measures. Therefore either practices must create EHR specific user groups to demand modifications in the EHRs to allow the transformation to value based care, or must develop separate software to extract

the needed data. Many companies are trying to solve these problems, with varying success, No company will be able to develop a successful product without a group of practices acting as a beta test site.

Other companies working with other oncologists could develop a similar product. Competition to create a more accurate OPC can only improve the process.

Respectfully submitted,



Barbara L. McAneny MD, MACP, FASCO
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ONCOLOGY INFUSION COST TEMPLATE

Assumptions:

Model is designed for an establish Patient with normal vitals and lab work
 **Hourly rate is average hourly rate excluding benefits
 *Time is in minutes

Designed by Laura M. Marez - New Mexico Oncology Hematology Consultants Ltd.

Legend:

Calculated Field
 Input field

Cost to Prep Patient and Administer Premedication Drugs

	Time *	**Hourly rate	Cost
Front Desk Time			
<i>Front Desk greets and checks in the Patient in the OncoEMR System and notifies Medical Assistant</i>	15	13.00	\$3.25
Medical Assistant Time			
<i>Obtain the Patient chart and reviews reason for visit</i>	5	13.11	\$1.09
Medical Assistant Time			
<i>Greet the Patient and bring them back to the MA station</i>	5	13.11	\$1.09
Medical Assistant Time			
<i>Take vitals & key into the OncoEMR System and note in Patient chart</i>	15	13.11	\$3.28
Medical Assistant Time			
<i>Take the Patient back to the Chemo Chair (if Infusion Nurse is going to draw Patient blood from their port)</i>	5	13.11	\$1.09
Medical Assistant Time			
<i>To document Patient is waiting in the Chemo Chair in OncoEMR System</i>	5	13.11	\$1.09
Medical Assistant Time			
<i>Take Patient to lab station (if Infusion nurse is not going to draw Patient blood)</i>	5	13.11	\$1.09
<i>To document patient is in lab station in OncoEMR System</i>	5	13.11	\$1.09
Medical Assistant Time			
<i>After Patient blood is drawn from lab station Medical Assistant takes Patient to the Chemo Chair</i>	5	13.11	\$1.09
<i>To document Patient is waiting in the Chemo Chair in OncoEMR System</i>	5	13.11	\$1.09
Medical Assistant Time			
<i>Place the Patient chart in the rack for the Infusion Nurse</i>	5	13.11	\$1.09
Infusion Nurse Time			
<i>Checks the OncoEMR system to see if Patient has arrived</i>	3	43.52	\$2.18
<i>Obtains the Patient chart from the rack</i>	2	43.52	\$1.45
Infusion Nurse Time			
<i>Reviews patient vital signs, history and lab orders</i>	3	43.52	\$2.18
<i>Reviews patient labs if drawn at the lab station</i>	3	43.52	\$2.18

ONCOLOGY INFUSION COST TEMPLATE

Cost to Prep Patient and Administer Premedication Drugs - Continued

Select if Patient port is going to be used to draw blood for lab orders

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Document that labs will be drawn by Infusion Nurse using Patient port</i>	5	43.52	\$3.63

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Prepare Patient port to draw blood for lab orders</i>	15	43.52	\$10.88

Prep the Patient Port Supplies	Amount	Price	Cost
<i>Purple Gloves</i>	1	0.08	\$0.08
<i>White Gloves</i>	1	0.09	\$0.09
<i>Alcohol Prep</i>	2	0.01	\$0.02
<i>Huber needle set</i>	1	4.78	\$4.78
<i>Luer-lok access device</i>	1	0.83	\$0.83
<i>Central line dressing change kit</i>	1	5.20	\$5.20
<i>Ethyl Chloride Spray</i>	1	0.54	\$0.54
<i>Monject .9% Sodium Chloride - Flush Syringe</i>	1	0.54	\$0.54
<i>Clave Connector</i>	1	1.28	\$1.28
<i>Print Patient lab labels</i>	1	1.20	\$1.20

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Infusion Nurse draws blood from Patient port</i>	10	43.52	\$7.25
	Amount	Price	Cost
<i>Printed Patient label placed on Patient blood tubes drawn from Patient port</i>	1	0.05	\$0.05
<i>Patient tubes placed in bio-hazard bag for lab station</i>	2	0.41	\$0.82
<i>Excess blood drawn is discarded in red bio-hazard container</i>	1	0.46	\$0.46

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Transport Patient tubes to lab station</i>	2	43.52	\$1.45

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>If vital signs are within normal limits and lab work is acceptable then treatment plan is generated for review</i>	5	43.52	\$3.63

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Infusion Nurse reviews all drug dosages on treatment plan</i>	5	43.52	\$3.63
<i>Second Infusion Nurse reviews and approves or denies all drug dosages on the treatment plan</i>	3	43.52	\$2.18

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Once all drug dosages are approved then request is sent to Infusion Pharmacy to prepare Chemo Drugs and Non Chemo Drugs for Patient - Request is done in OncoEMR System</i>	5	43.52	\$3.63

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Take the treatment plan to the Nucleus System to pull Premedication Drugs</i>	10	43.52	\$7.25

Premedication Drug Supplies	Amount	Price	Cost
<i>Purple Gloves</i>	1	0.08	\$0.08
<i>Tempo Tape</i>	1	0.73	\$0.73
<i>Non-DEPH Y Type Catheter Extension Set</i>	1	3.20	\$3.20
<i>Tegaderm Film</i>	1	0.36	\$0.36
<i>Alcohol Prep</i>	2	0.01	\$0.02
<i>Smallbore Extension Set</i>	1	1.37	\$1.37
<i>.9% Sodium Chloride Injection USP 100ml</i>	1	1.91	\$1.91
<i>Clave Connector</i>	1	1.28	\$1.28
<i>Tourniquet</i>	2	0.19	\$0.38
<i>IV Tubing</i>	1	4.73	\$4.73
<i>3M Transpore - Tape or Paper Tape</i>	1	0.48	\$0.48

ONCOLOGY INFUSION COST TEMPLATE

Cost to Prep Patient and Administer Premedication Drugs - Continued

Infusion Pump cost	Yearly Fee	Cost per hour
<i>Cost maintain the Infusion Pump</i>	10,500	\$5.05

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Start the Premedication Drugs w Patient</i>	8	43.52	\$5.80
<i>Take Patient vitals after Premedication Drugs are started and document them in Patient record in the OncoEMR System</i>	3	43.52	\$2.18

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Time to Clean up from starting the Premedication Drugs</i>		43.52	\$0.00

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Update Patient record in OncoEMR System</i>	15	43.52	\$10.88

Total Cost to Prep Patient for Premedication Drugs w/o drawing blood from Patient port	\$83.09
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Total Cost to Prep Patient for Premedication Drugs including drawing blood from Patient port	\$122.19
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ONCOLOGY INFUSION COST TEMPLATE

Cost to Prep Patient for Chemo Treatment and Administer Chemo Drugs

See Infusion Pharmacy Cost Template to prepare Chemo Drug and Non Chemo Drug

Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Receive notification from Infusion Pharmacy that Chemo Drugs are ready for Patient in OncoEMR System</i>	5	43.52	\$3.63
Cost to handle Chemo Drugs and Non Chemo Drugs	Amount	Price	Cost
<i>Purple Gloves</i>	1	0.08	\$0.08
<i>Blue Gown</i>	1	2.71	\$2.71
Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Infusion Nurse picks up Chemo Drugs/Non Chemo Drugs from Infusion Pharmacy bin in special clear bags</i>	5	43.52	\$3.63
<i>Additional Infusion Nurse reviews and approves dosages on Chemo Drugs/Non Chemo Drugs</i>	5	43.52	\$3.63
Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Infusion Nurse updates Patient record that Chemo Drugs/Non Chemo Drugs were received from Infusion Pharmacy in OncoEMR system</i>	4	43.52	\$2.90
Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Infusion Nurse pulls Chemo Drug/Non Chemo Drug supplies to prep Patient</i>	5	43.52	\$3.63
Chemo Drug/Non Chemo Drug Supplies to Prep Patient	Amount	Price	Cost
<i>Purple Gloves</i>	1	0.08	\$0.08
<i>Monject .9% Sodium Chloride - Flush Syringe</i>	1	0.54	\$0.54
<i>Alcohol Prep</i>	2	0.01	\$0.02
Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Infusion Nurse asks Patient their name and DOB and reviews it on Chemo Drug bags</i>	3	43.52	\$2.18
<i>Infusion Nurse sets up Chemo Drug/Non Chemo Drug bag on Infusion Pump</i>	6	43.52	\$4.35
<i>Infusion Nurse takes vitals after Chemo Drug are started and records in the OncoEMR System</i>	3	43.52	\$2.18
Infusion Pump cost for second pump for Chemo Drug	Yearly Fee		Cost per hour
<i>Cost to maintain the Infusion Pump</i>	10,500		\$5.05
Clean up from starting the Chemo Drug	Amount	Price	Cost
<i>Disposing of products in yellow bio-hazard container</i>	1	5.52	\$5.52
Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Update Patient record in OncoEMR system</i>	3	43.52	\$2.18
Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Patient needs another Chemo Drug with Dextrose - (Infusion Nurse review Patient record in OncoEMR System)</i>	5	43.52	\$3.63
Infusion Nurse Time	Time *	**Hourly rate	Cost
<i>Infusion Nurse pulls Chemo Drug supplies for the new Chemo Drug</i>	5	43.52	\$3.63
Chemo Drug Supplies to Prep Patient for second Chemo drug using Dextrose	Amount	Price	Cost
<i>Purple Gloves</i>	1	0.08	\$0.08
<i>Dextrose 5% 50mL</i>	1	1.77	\$1.77
<i>Dextrose 5% 250mL</i>	1	5.75	\$5.75
<i>Dextrose 5% 500mL</i>	1	5.75	\$5.75
<i>Monject .9% Sodium Chloride - Flush Syringe</i>	1	0.54	\$0.54
<i>Alcohol Prep</i>	2	0.01	\$0.02
<i>Tubing</i>	1	4.73	\$4.73

ONCOLOGY INFUSION COST TEMPLATE

Infusion Nurse Time	Time *	**Hourly rate	Cost
Infusion Nurse asks patient their name and DOB and reviews it on Chemo Drug bags	1	43.52	\$0.73
Infusion Nurse sets up Chemo Drug	6	43.52	\$4.35
Infusion Nurse takes vitals after chemo drugs are started	3	43.52	\$2.18

Cost to Prep Patient for Chemo Treatment and Administer Chemo Drugs - Continued

Clean up from starting the Chemo Drug	Amount	Price	Cost
Disposing of products in yellow bio-hazard container	1	5.52	\$5.52

Infusion Nurse Time	Time *	**Hourly rate	Cost
Update Patient record in OncoEMR system	5	43.52	\$3.63

Infusion Nurse Time	Time *	**Hourly rate	Cost
Record how long Patient is in the Chemo Chair	60.00		
Infusion Nurse time to check on patient while in the Chemo Chair ~ 15 minutes	3.00	43.52	\$2.18

Infusion Nurse Time	Time *	**Hourly rate	Cost
Record how long Patient is in the Chemo Chair	60.00	**Hourly rate	
Infusion Nurse taking vitals of Patient ~ 30 minutes	2.00	43.52	\$1.45

Infusion Nurse Time	Time *	**Hourly rate	Cost
Schedule next Chemo visit in OncoEMR System	8	43.52	\$5.80
Document current visit about the Patient in OncoEMR System	15	43.52	\$10.88

Infusion Nurse Time	Time *	**Hourly rate	Cost
Take Patient vitals after all Chemo Drug/Non Chemo Drug are finished	5	43.52	\$3.63
Record Patient vitals in OncoEMR system	3	43.52	\$2.18
Pull supplies to prepare Patient to go home	4	43.52	\$2.90

Supplies to prepare Patient to go home	Amount	Price	Cost
Purple Gloves	1	0.08	\$0.08
Alcohol Prep	2	0.01	\$0.02
Heparin IV Flush syringe 12mL	1	0.39	\$0.39
GuardiVa - Patients that are going home with Walk-Med pump			\$0.00

Disposing of Chemo Drug/Non Chemo Drug bags	Amount	Price	Cost
Special bag used to place the chemo drug bags	1	0.15	\$0.15
Disposing of products in yellow bio-hazard container	1	1.38	\$1.38

Infusion Nurse Time	Time *	**Hourly rate	Cost
Review with Patient their next Chemo visit	6	43.52	\$4.35
Provide Patient with information on what to expect after receiving Chemo Drug/Non Chemo Drug and who to contact with questions or concerns	10	43.52	\$7.25

Infusion Nurse Time	Time *	**Hourly rate	Cost
Infusion Nurse updates Patient record when the Patient leaves the center in OncoEMR System	5	43.52	\$3.63

Infusion Nurse Time	Time *	**Hourly rate	Cost
Clean up site for the next Patient	7	43.52	\$5.08

Supplies to clean up site	Amount	Price	Cost
Purple Gloves	1	0.08	\$0.08
Sani-Cloths or Sani-Wipes	4	0.04	\$0.18

Janitorial Service & Hazardous Waste Service	Amount	Price	Cost
Cost of janitorial services	1	5.00	\$5.00
Cost of Hazardous Waste Pick-up Service	1	6.91	\$6.91

ONCOLOGY INFUSION COST TEMPLATE

Total cost to Prep Patient for Chemo Treatment	\$148.09
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Summary of Total Infusion Overhead Cost
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1. Scenario - Lab Orders drawn at lab station and Non Chemo Drugs	
Total cost for Chemo Treatment for a Patient who's lab orders were drawn at lab station	\$231.18
Total Cost to prepare Non Chemo Drugs for a Patient	\$115.76
Grand Total	\$346.94

2. Scenario - Lab Orders drawn at lab station and Chemo Drugs	
Total cost for Chemo Treatment for a Patient who's lab orders were drawn at lab station	\$231.18
Total Cost to prepare Chemo Drugs for a Patient	\$140.83
Grand Total	\$372.01

3. Scenario - Lab Orders drawn with the Patient port and Non Chemo Drugs	
Total cost for Chemo Treatment for a Patient who's lab orders were drawn with the Patient port	\$270.28
Total Cost to prepare Non Chemo Drugs for a Patient	\$115.76
Grand Total	\$386.04

4. Scenario - Lab Orders drawn with the Patient port and Chemo Drugs	
Total cost for Chemo Treatment for a Patient who's lab orders were drawn with the Patient port	\$270.28
Total Cost to prepare Chemo Drugs for a Patient	\$140.83
Grand Total	\$411.11

5. Scenario - Lab Orders drawn at lab station and Chemo Drugs & Non Chemo Drugs are used for Patient	
Total cost for Chemo Treatment for a Patient who's lab orders were drawn at lab station	\$231.18
Total Cost to prepare Non Chemo Drugs for a Patient	\$256.59
Grand Total	\$487.77

6. Scenario - Lab Orders drawn with the Patient port and Chemo Drugs and Non Chemo Drugs used for Patient	
Total cost for Chemo Treatment for a Patient who's lab orders were drawn with the Patient port	\$270.28
Total Cost to prepare Chemo Drugs for a Patient	\$256.59
Grand Total	\$526.87

Payment for First Hour of Infusion and Subsequent Infusion from Medicare	\$345.00
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1. Scenario - Change from Payment for First Hour of Infusion and Subsequent Infusion from Medicare	-\$1.94
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2. Scenario - Change from Payment for First Hour of Infusion and Subsequent Infusion from Medicare	-\$27.01
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3. Scenario - Change from Payment for First Hour of Infusion and Subsequent Infusion from Medicare	-\$41.04
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4. Scenario - Change from Payment for First Hour of Infusion and Subsequent Infusion from Medicare	-\$66.11
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5. Scenario - Change from Payment for First Hour of Infusion and Subsequent Infusion from Medicare	-\$142.77
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6. Scenario - Change from Payment for First Hour of Infusion and Subsequent Infusion from Medicare	-\$181.87
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❖ **Physician Leaders in Local Healthcare Market - (April 25, 2018)**

- Dr. Ahmad Abouhossein, MD, FACS
 - Board Certified American Board of Urology
 - Fellow of the American College of Surgeons (FACS) Member
 - American Medical Association Member
 - Montgomery County Medical Association Member
 - Ohio State Medical Association Member
 - Wright State University Clinical Associate Professor

- Dr. Howard B. Abromowitz, MD, FACS
 - Board of Managers – Dayton Physicians Network
 - Urology Finance Committee – Dayton Physicians Network
 - Board Certified American Board of Urology
 - Fellow of the American College of Surgeons (FACS) Member
 - American Urological Association Member
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Wright State University Clinical Assistant Professor
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Charles L. Bane, MD
 - President, Board of Managers - Dayton Physicians Network
 - Secretary, Board of Managers - Radiation Oncology Services, LLC
 - Chair, Hematology & Oncology Finance Committee – Dayton Physicians Network
 - Chair, Medical Oncology - Clinical Leadership Committee – Dayton Physicians Network
 - Chair, Pharmacy & Therapeutics Committee – Dayton Physicians Network
 - Principal Investigator, Dayton Physicians Network Clinical Research
 - Board Certified American Board of Internal Medicine, Hematology, Medical Oncology, Hospice and Palliative Medicine
 - Medical Director, Oncology Services – Good Samaritan Hospital / Good Samaritan North
 - American Medical Association Member
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Ohio's Hospice Board Member
 - Chair, Premier Health Oncology Institute
 - Ohio Hematology Oncology Society (OHOS) Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Praveena Cheruvu, MD
 - Radiation Oncology Finance Committee – Dayton Physicians Network
 - Member of the American Society for Radiation Oncology
 - Board Certified American Board of Radiology, Radiation Oncology
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Wright State University Clinical Assistant Professor
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Douglas W. Ditzel, DO
 - Radiation Oncology Finance Committee – Dayton Physicians Network
 - Medical Director, Radiation Oncology – Miami Valley Hospital
 - Board Certified American Board of Radiology, Radiation Oncology
 - American Osteopathic Board of Radiology
 - American Medical Association Member
 - Dayton Clinical Oncology Program
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Wright State University Clinical Assistant Professor
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Douglas B. Einstein, MD, PhD
 - Board Certified American Board of Radiology, Radiation Oncology
 - American Medical Association Member
 - Dayton Clinical Oncology Program
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Wright State University Association Professor
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Howard M. Gross, MD
 - Hematology & Oncology Finance Committee - Dayton Physicians Network
 - Director of Oncology Clinic - Good Samaritan Hospital
 - Co-Director of the Lung Cancer Program – Good Samaritan Hospital
 - Principal Investigator, Dayton Clinical Oncology Program – Miami Valley Ohio Region
 - Chair, Oncology Quality Improvement Committee – Good Samaritan Hospital
 - Associate Director of the Hematology & Oncology Fellowship Program – Wright State University
 - Wright State University Clinical Professor
 - Board Certified American Board of Internal Medicine, Medical Oncology
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Shamim Z. Jilani, MD
 - Pharmacy & Therapeutics Committee – Dayton Physicians Network
 - Assistant Clinical Professor, Department of Medicine at Wright State University
 - Board Certified in Medical Oncology, Internal Medicine, Palliative and Hospice Care
 - Board Certified American Board of Internal Medicine, Medical Oncology
 - American Medical Association Member
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Satheesh K. Kathula, MD, FACP
 - Pharmacy & Therapeutics Committee – Dayton Physicians Network
 - IT Committee – Dayton Physicians Network
 - Pharmacy & Therapeutics Committee – Miami Valley Hospital
 - Board Certified with American Board of Internal Medicine, Hematology, Medical Oncology
 - American Medical Association Member
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Wright State University Clinical Professor
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. David W. Key, MD
 - Vice President, Board of Managers – Dayton Physicians Network
 - Member, ROSLLC Board of Managers
 - Urology Finance Committee – Dayton Physicians Network
 - Associate Clinical Professor of Surgery at Wright State University
 - President - Ohio Urological Society
 - Board of Trustees – Miami Valley Hospital
 - Board Certified American Board of Urology
 - American Urological Association Member
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Reed Nesbit Society
 - North Central Section And Urodynamics Society
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Jhansi L. Koduri, MD
 - Medical Oncology - Clinical Leadership Committee – Dayton Physicians Network
 - Board Certified American Board of Internal Medicine, Hematology, Medical Oncology
 - American Medical Association Member
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Rajeev Kulkarni, MD
 - Hematology & Oncology Finance Committee – Dayton Physicians Network
 - Certified with American Board of Internal Medicine, Hematology
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Lawrence J. Litscher, MD
 - Urology Finance Committee – Dayton Physicians Network
 - Chairman, Editorial & Awards Committee – American Urologic Association’s North Central Section
 - Nominating Committee – North Central Section
 - Board Certified American Board of Urology
 - American College of Surgeons Member
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Wright State University Clinical Professor

- Dr. Mark A. Marinella, FACP, CNSP
 - Medical Oncology – Clinical Leadership Committee – Dayton Physicians Network
 - Pharmacy & Therapeutics Committee – Dayton Physicians Network
 - Chair, Oncology Committee – Miami Valley Hospital
 - Medical Director of Oncology Clinic, Five Rivers Health Center, Dayton
 - Transplant Committee – Miami Valley Hospital
 - Living Donor Committee – Miami Valley Hospital
 - Board Certified in Internal Medicine and Medical Oncology
 - American Medical Association Member
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Daniel B. Miller, MD, FACS
 - Urology Quality/Utilization Committee – Dayton Physicians Network
 - Assistant Clinical Professor at Wright State University
 - Board Certified American Board of Urology
 - Fellow of the American College of Surgeons (FACS) Member
 - American Urological Association Member
 - American Association of Clinical Urologists
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Kelly L. Robbins Miller, MD, PhD
 - Board Certified in Internal Medicine
 - Montgomery County Medical Society Member
 - Wright State University Clinical Instructor

- Dr. Mark A. Monsour, MD, FACS
 - Chair, Urology Finance Committee – Dayton Physicians Network
 - Chair, Urology Quality/Utilization Committee – Dayton Physicians Network
 - IT Committee – Dayton Physicians Network
 - Assistant Clinical Professor at Wright State University
 - Board Certified American Board of Urology
 - Fellow of the American College of Surgeons (FACS) Member
 - American Medical Association Member
 - American Urological Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Mohan R. Nuthakki, MD
 - Medical Oncology – Clinical Leadership Committee – Dayton Physicians Network
 - Board Certified American Board of Internal Medicine, Medical Oncology
 - American Medical Association Member
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Nkeiruka E. Okoye, MD
 - Medical Oncology – Clinical Leadership Committee – Dayton Physicians Network
 - Board Certified American Board of Internal Medicine
 - American Medical Association Member
 - American College of Physicians
 - American Society of Clinical Oncology
 - American Society of Hematology
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member

- Dr. Rebecca J. Paessun, MD
 - Board Certified in Radiology, Radiation Oncology
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member

- Dr. Radhika Rajsheker, MD
 - Board Certified American Board of Internal Medicine
 - American Medical Association Member
 - American Clinical Oncology Program Member
 - American Society of Clinical Oncology
 - American Society of Hematology
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Participating in MD Anderson Cancer Network®, a program of MD Anderson Cancer Center, at Premier Health

- Dr. Gregory M. Rasp, MD
 - President, Board of Managers - Radiation Oncology Services, LLC
 - Treasurer, Board of Managers - Dayton Physicians Network
 - Chair, Radiation Oncology Finance Committee – Dayton Physicians Network
 - IT Committee – Dayton Physicians Network
 - Medical Director, Radiation Oncology- Miami Valley Hospital
 - Chair, Oncology Committee – Good Samaritan Hospital
 - Co-Investigator – Dayton Clinical Oncology Program
 - Assistant Professor @ the Wright State School University, School of Medicine
 - Board Certified American Board of Radiology, Radiation Oncology
 - American Medical Society Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
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- Dr. Mridula P. Reddy, MD
 - Board Certified American Board of Internal Medicine, Medical Oncology
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- Dr. Mark D. Romer, MD
 - Pharmacy & Therapeutics Committee – Dayton Physicians Network
 - Board Certified American Board of Internal Medicine, Medical Oncology
 - American Medical Association Member
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 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
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- Dr. Tarek M. Sabagh, MD
 - Hematology & Oncology Finance Committee – Dayton Physicians Network
 - Pharmacy & Therapeutics Committee – Miami Valley Hospital
 - Family Education Committee – Miami Valley Hospital
 - Chair, Department of Internal Medicine at Miami Valley Hospital
 - President Elect of Medical Staff at Miami Valley Hospital
 - Cancer Liaison Physician at Upper Valley Medical Center
 - Associate Clinical Professor – Wright State University
 - Lung Tumor Board – Good Samaritan Hospital
 - Board Certified American Board Internal Medicine, Hematology, Medical Oncology, Hospice and Palliative Care
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
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- Dr. James H. Sabiers, MD
 - Medical Oncology - Clinical Leadership Committee – Dayton Physicians Network
 - Chair, Oncology Committee – Wayne Hospital
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 - American Medical Association Member
 - Montgomery County Medical Society Member
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- Dr. Guy Savir, MD,
 - Board Certified American Board of Radiology, Radiation Oncology
 - American Medical Association Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member
 - Wright State University Clinical Assistant Professor

- Dr. Ronald K. Setzkorn, MD
 - Radiation Oncology Finance Committee – Dayton Physicians Network
 - Cancer Committee Chair, Chief of Support Services, Upper Valley Medical Center
 - Board Certified American Board of Radiology, Radiation Oncology
 - American Medical Association Member
 - Dayton Clinical Oncology Program Member
 - Montgomery County Medical Society Member
 - Ohio State Medical Association Member

- Dr. Ketan S. Shah, MD
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 - CQI Committee – Kettering Medical Center
 - Cancer Committee – Kettering Medical Center
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- Dr. Ryan D. Steinmetz, MD
 - Board of Managers – Dayton Physicians Network
 - Marketing Committee – Dayton Physicians Network
 - Radiation Oncology Finance Committee – Dayton Physicians Network
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 - American Urological Association Member
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 - Secretary, Board of Managers - Dayton Physicians Network
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 - Director, BMTU – Miami Valley Hospital;
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■ Dr. Michael K. Yu, MD, FACS

- Urology Finance Committee – Dayton Physicians Network
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- American Medical Association Member
- American Urological Association Member
- American Association of Clinical Urologists
- Montgomery County Medical Society Member
- Ohio State Medical Association Member
- Ohio Urological Association
- Endourological Society
- The Society of Lapararo-Endoscopic Surgeons
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Barbara L. McAneny MD MACP FASCO
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As the recipient of the CMMI Community Oncology Medical Home ([COME HOME](#)) grant funded to [Innovative Oncology Business Solutions](#) Inc. in 2012, I applaud CMMI's new direction.

Previous attempts at ACOs have not generated sufficient savings, and have been a boon for the IT industry. Meaningful Use has brought about needed changes to EHRs, but the data systems needed for ACOs have been ineffective and expensive. Few physician driven ACOs and very few if any hospital based ACOs have generated enough savings to cover the IT costs required to manage the programs.

An unintended consequence of the Affordable Care Act (ACA) was an acceleration of the acquisition of practices into hospital based systems, moving practices from the Physician Fee Schedule (PFS) into the Hospital Outpatient Prospective Payment System (HOPPS), thus increasing the overall cost of care.

The consolidation of of physician practices into large tax-exempt systems has decreased access, decreased the tax base, and increased cost without increasing quality. In contrast, physician practices are local businesses purchasing services from other small businesses and contributing to the tax base. Many Americans live in small towns or rural areas, and rely on smaller practices for their care. Physician practices have long been part of the infrastructure of health care.

A restructured CMMI focused on increasing competition to deliver care in a more cost effective system will encourage systems and practices to compete for patients based on how patients judge their treatment, access, quality of care and cost. Simply making CMMI support accessible to smaller practices will provide the opportunity to create APMs that keep more health care in the less expensive PFS system rather than consolidating into HOPPS paid systems. For cancer care, the literature shows that HOPPS costs CMS approximately 50% more than PFS for the same services.

The regulatory environment has been accelerating the increases in costs of care without benefit in access or quality. The Administration is looking for examples of regulations that add cost without value: USP 800 regulations for in-office infusions seem to be reacting to the problem of contaminated drugs by one compounding pharmacy. In oncology practices, drugs are not mixed for administration until the physician has approved the treatment, the labs are reviewed, the consent is obtained and the iv is running. The drugs are simply too expensive to risk mixing a drug and then not using it. The current safeguards of personal protective equipment have resulted in a very safe environment, and there is no evidence that adopting the expensive construction of a USP 800 compliant pharmacy (around \$300,000 per location) will add to the safety. In fact, knowing that our small rural clinic in Ruidoso New Mexico (population 20,000) would never make enough profit to pay for the construction, we closed that clinic. Patients now drive for 3 hours one way on mountain roads for care. The safety of cancer patients

driving these roads or the decision to forego care was not considered by USP. Simply by rolling back that regulatory over-reach, costs of care will be lowered and access improved. We applaud the regulatory reduction direction taken by CMMI in this administration.

Ownership by patients

Patients often accept without question the referrals made by their physicians. However, in large integrated systems, most referrals go to the employed specialist without consideration of quality, convenience, cost or patient choice. Patients often do not even know that other options exist, and critically ill patients are not able to shop for care. Transparency as to the employment status and financial benefits to the referring physicians as well as the ability to compare quality and cost should be provided when the insurance vehicle is purchased by the employer or patient, not when care is needed.

Cost of care can easily be affected by transparency. If a patient is told they need a CT scan and there is a hospital based, American College of Radiology (ACR) accredited and a community based ACR accredited program available, patients should be made aware that the hospital based CT can cost up to 3 times as much for the same quality. These options should be included in networks, and physicians should have this information in order to better advise their patients.

Empowerment of patients to actively participate in their care requires significant patient and caregiver education. Providing this education requires personnel who are sophisticated enough to understand the options and the time to ensure patient understanding of complex choices. Currently this is an unpaid process, using expensive personnel, and therefore is not well done. Until patient education is valued enough to pay for the teaching process, practices will not be able to afford the expense.

The intent of CMMI to test innovations prior to attempting to change the entire health care system by decree is wise, and much appreciated by practices that must continue delivering care under the old system while transforming to a new system.

Recently, insurance companies and several hospital initiated health plans have suffered significant financial losses or were unable to stay in business, at least in part because they did not have the financial reserves to cover their actuarial risk. Yet the current CMMI proposals and the ACO model expect physician groups to manage actuarial risk without any reserves. OCM expects individual practices to manage actuarial risk with up to 8% of their Medicare revenue at risk in order to be an APM under MACRA. Most practices do not have an 8% margin on their Medicare book of business, and certainly do not have the reserves to manage this loss.

For example, the current Oncology Care Model (OCM) used some of the features of the COME HOME model, but the added features of risk, massive data collection, lack of ability to correctly attribute patients to physicians, and the inability to accurately correlate clinical conditions with costs of care, has made this model unwieldy. New Mexico Oncology Hematology Consultants, the lead practice in COME HOME,

and a participating OCM practice, should be well positioned to understand and accept risk. But we carefully studied this, and risk as defined by OCM would be a practice-ending event. Most practices participating share those concerns.

CMMI should not expect practices to take risk that could eliminate the practice, and the nation cannot afford to lose the medical infrastructure of physician practices. Yet it is reasonable to hold practices accountable financially for their choices or care options.

Therefore new mechanisms to hold physician practices accountable for manageable risk rather than actuarial risk must be developed. CMMI should be applauded for making this opportunity available.

If given an accurate target price corridor that reflects the actual experience of patients with specific clinical characteristics, and adequate real time data on resource use, physicians can manage patients to meet those targets. I define this as transactional risk, and it does not require reserves. Therefore an APM based on physicians managing transactional risk can result in savings without threatening the infrastructure of health care. It does require access to real time claims, but does not require adjudicated claims, because denials would simply reduce the amount spent. If the claims for a procedure or consultation ordered by the physician managing the patient were transparent to the ordering physician, selections of site of service or referrals could better reflect the value of the service. For example, if one surgeon requires excessive imaging before a breast biopsy and another does not, the referring physician would be able to compare the outcomes and costs of the two surgeons, and adjust referrals accordingly. The primary treating physician could develop a network that includes the more value conscious specialists.

CMMI is now very interested in consumer directed health care

Empowerment of patients to actively participate in their care requires significant patient and caregiver education. Providing this education requires personnel who are sophisticated enough to understand the options and the time to ensure patient understanding of complex choices. Currently this is an unpaid process, using expensive personnel, and therefore is not well done. Until patient education is valued enough to pay for the teaching process, practices will not be able to afford the expense. An Alternative Payment Model must include significant patient education to succeed.

The original COME HOME model, based on the CMMI grant received in 2012, by a company created for the purpose (Innovative Oncology Business Solutions), consisted of the creation of an oncology medical home. This requires expanded access to same day visits, guided by physician-written, nurse-administered pathways for managing patient symptoms. The nurse received a call from a patient that disclosed a symptom, and the triage process safely directed 29,000 patient encounters to the appropriate site of service. We decreased hospitalization usage by 40+% and savings by \$4000/patient. We documented quality by developing physician driven pathways and measuring adherence. Patient surveys demonstrated levels of satisfaction in the high 90's.

Based on COME HOME, NCQA has revised its accreditation process for the medical home, and the American Society of Clinical Oncology feels the process is sufficiently valuable that it has entered into a three year contract to promote the COME HOME process.

The major limitation of the COME HOME model is that the required additional infrastructure is an expense to the practices, but the revenue accrues to the payers. The OCM model incorporated COME HOME processes, and has attempted to couple it with a payment system. The OCM monthly payment partially covers the infrastructure costs, but the shared savings component is flawed by imprecise target payments, and the money is diverted into significant record keeping, data collection and reporting requirements and away from patient care, thus impairing practice transformation.

COME HOME fits the principles 1-6 as outlined in the RFI. However the OCM struggles from the lack of price transparency as well as accuracy and requires modification. In addition the OCM model only starts with the onset of chemotherapy. Much physician time, care coordination, and expense occurs at the time of diagnosis, staging and treatment planning when oncologists are ordering staging procedures, reviewing pathology, collaborating with Primary care, surgery, radiation oncology and many others, and spend much time educating patients and family members as to their options. None of that is rewarded by OCM. The American Society of Clinical Oncology, (ASCO), model of Patient Centered Oncology Payment, (PCOP), addresses this mismatch between physician work and physician payment. Both the PCOP and the OCM model include monthly payments for the Oncology Medical Home features that have been shown by COME HOME to create savings.

If a patient decides that radiation or no chemotherapy is their best option, none of the time spent in patient-centered decision support is credited or rewarded under OCM, but it is under PCOP. New models must include this feature to discourage a bias toward treatment.

The major flaw of the OCM is that the targets for shared savings and risk taking are not accurate. We compared actual Medicare costs for the COME HOME patients with the targets created by OCM and found a 0.34 R-squared value. A reliable model would have an R-squared around 0.75. The opportunity for an advanced, partially transformed practice to hit those targets is so small that many will drop out by 2018. Only hospital based practices that are already more expensive and who have admitted large numbers of patients and use the Emergency Department for extended hours care, will be able to hit targets. Therefore a new process is needed to support those efficient, lean practices that have heard CMS' call for transformation.

The redirection of CMMI will allow the development of a pilot project, bigger than COME HOME and incorporating its successes, and create a payment system that will sustain practice transformation. With a payment system that gives transformed practices the ability to accept risk on the individual care of patients while having sustaining revenue streams for the infrastructure of care, mostly nursing salaries, we can develop an alternative payment system that works for oncology.

If this process is as successful as COME HOME, it will provide a voluntary option for a new APM for the physicians who have already achieved the savings envisioned by OCM and have reached the limits of a shared savings program, or who do not have the volume to manage the actuarial risk of OCM patient assignment.

I have been working with the ASCO to create a model that combines PCOP with the Oncology Medical Home processes of COME HOME. We envision the maintenance of practice expense through a combination of FFS and PCOP payments, with a manageable risk component payable if and only if the quality metric of pathway adherence is proven and the targets met.

We call this pilot MASON: Making Accountable Sustainable Oncology Networks, and welcome the opportunity to describe it in the addendum to this document.

Thank you very much,

A handwritten signature in black ink, appearing to read "BL McAneny", with a stylized flourish at the end.

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ADDENDUM

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Alternative Payment Methodology Pilot Project for Oncology: Making Accountable Sustainable Oncology Networks ("MASON")

Introduction:

Alternative Payment Methodologies (APM) are essential for the sustainability of the Medicare system and the Health Care system as a whole. Transformation of the entire system from a fee for service payment method at a time of increasing physician shortages, consolidation of the industry and inadequate EMRs, is necessary but cannot disrupt the care given to current patients. All specialties and all practice settings must be included. There should be no requirement that the methods are the same for all as long as the payment is equitable and practical. Specialties have potential for achieving savings by efficient management of sicker patients, but have not had good APM options.

The Oncology Care Model (OCM) is a current option for Oncology practices, but in order to become an APM, two-sided risk must be accepted by the practices. Hospital practices that use emergency departments (ED) for managing the side effects of cancer and its treatment and have high inpatient usage, are often large enough to have sufficient reserves to be able to absorb adverse actuarial selection, and may do well under the OCM model. CMS will save money in this subset of OCM participants because they can make a small change in practice habits and hit the target prices for services.

Practices that see only a few thousand cancer patients per year, that manage patients with health disparities, who do not have hospital levels of reserves, and who have already decreased hospitalization and ED usage rates, will not be able to accept even one sided risk. CMS will see some of these practices either dropping out of OCM or failing to hit targets. We suspect that very few independent practices will be able to become an advanced APM with OCM because the targets reflect additional savings over those already achieved, are developed based on an actuarial assumption of the numbers and severity of patients with a given tumor type, and cannot account well for new therapies. The inclusion of the total cost of care as a target will be possible, if unlikely, for large institutions that have multiple specialties but not for single specialty or cancer only practices.

Practices that accept two-sided risk and fail to hit the targets of two-sided risk, would have to repay CMS money they cannot afford to lose. This can result in loss of the infrastructure of providing cancer care to smaller or underserved markets or the sale of practices to hospitals. Because hospital based cancer care is significantly more expensive, the loss of the leaner practices will cause an overall increase in the cost of cancer care, or decreased availability for some markets.

The OCM is perhaps overly optimistic that it has the ability to set target prices, given the variation in price and cost for different situations in the same tumor type. If all the variation were from physician choice of therapy, that assumption would be justified. However, the majority of the variation is from patient and disease related factors that determine therapeutic choices.

For example: if an 85 year old Medicare Beneficiary has T1 N0M0 ER+ HER Negative breast cancer, mastectomy and aromatase inhibitor therapy is a logical choice and is very inexpensive and will give excellent outcomes. If a 65 year old Medicare Beneficiary has T1 N0 M0 ER negative HER positive disease, appropriate therapy could include lumpectomy with radiation, adjuvant chemotherapy for 6 cycles with a year of Herceptin therapy, resulting in a much higher cost in order to achieve the same outcome. In a large sample of patients, the numbers of each type will be predictable so that a blended target for breast cancer could be accurate. The General Linear Model used by CMS to set targets shows that this occurs to some degree. However, as numbers get smaller, the possibility of a distribution of patients that do not correlate with the expected distribution becomes larger. Practices are unable to predict or control the distribution of patients who seek services, but must take care of all patients who present, regardless of adverse clinical characteristics.

Therefore, a practice will not hit the target if it sees more patients whose appropriate care is more expensive without being offset by sufficient inexpensive patients. Small numbers of expensive to treat patients, even with windsorization, will cause large variations year to year.

Target price setting must be made more granular to account for clinical characteristics not available in claims data. A combination of clinical and claims data is necessary.

Shared savings itself is not a sustainable model. Year after year, prices will not go down. Even without new drugs that provide remarkable outcomes and therefore must ethically be used, and without inflation of goods and services or giving raises to health care personnel, there is a lower limit to costs.

Practices must therefore have a sustainable reliable payment rate to cover goods and services including a margin for growth and investment. No business is viable otherwise. OCM partially recognized this with the Monthly Enhanced Oncology Services (MEOS) payment, but that does not take into account the actual costs of providing increased services, nor the diversion of much of the MEOS payment into necessary data collection.

Available funding for patient services is significantly impacted by overhead for practices and hospitals. The amount needed to document quality of care for CMS and other payers, and the costs of billing, paying for services, and other administrative costs, is currently excessive. Rather than decreasing administrative costs to provide for more savings in the health care system, OCM has significantly increased overhead costs. A new system ideally should divert savings back into patient care, rather than into IT costs as has occurred both with OCM and ACOs.

Cancer Care was perhaps an overly ambitious target for the first specialty care model, but the potential for savings is great. OCM is very large and therefore will have difficulty with the needed mid-course corrections.

We therefore suggest a pilot project with the following goals, with more specific detail provided in the Goals section below – click on any item to see its details:

1. [Combine clinical and claims data in an iterative fashion to create increasingly accurate cost targets.](#)
2. [Require practices to accept transactional risk \(appropriate management of specific patients\), but protecting them from actuarial risk.](#)
3. [Encourage practices to accept all patients without regard to their affect on the payment system.](#)
4. [Build on the success of COME HOME.](#)
5. [Care directed by physicians and guided by evidence based pathways is the ultimate quality measure, without excessive data entry overhead.](#)
6. [Create a sustainable payment system that reflects the actual care given without preventing the use of alternative methods such as technological monitoring.](#)
7. [Allows funding for essential services such as patient education, determination of patient choice, and care coordination without relying on cost shifting from a margin on drugs.](#)
8. [Create a system that is built on the fee for service system during the transition phase and gradually shifts the payment toward appropriately structured bundles, thus allowing the current configuration of payment processes to function.](#)
9. [Separate the costs of delivering chemotherapy from the costs of the drugs.](#)
10. [Create transparency in the payment system by combining claims and clinical data in a manner that is accessible to all participants.](#)
11. [Encourage practices to serve patients with health disparities.](#)
12. [Encourage physician choice of site and mode of practice to serve the needs of all communities, large and small.](#)
13. [Encourage and enable oncology practices to select care partners that provide the best care at the best price.](#)
14. [Have a group of practices willing to participate and share data to develop the model. The group would be of sufficient size and geographic diversity to make the model scalable.](#)
15. [Have a control group of similar practices to determine if the model itself was the cause of cost savings.](#)
16. [Have a rapid learning system to incorporate lessons learned during implementation.](#)

Overview:

We propose to use a set of practices, the National Cancer Care Alliance (NCCA), the majority of which have already expressed interest, and compare with a control group of similar practices currently enrolled in OCM, to serve as a pilot project to accomplish the goals outlined above. The NCCA practices would withdraw from OCM to participate in this pilot. In this multi-year pilot, the first year would be used to acquire claims data, look for cost clusters of patients with seemingly similar cancer and stage, and determine through the acquisition of clinical data extracted from the EMR whether the differences between clusters were related to clinical conditions or practice choices.

Through this process, Oncology Payment Categories (OPCs) would be created. These OPCs would be visible to the practices as a virtual account, and submitted claims would be subtracted from that account. As the lack of adjudication of claims would over-estimate the amount of money subtracted from the account, it would not be necessary to wait for adjudication. This would allow for real time management of current patients and comparison of the prices charged to CMS by care partners.

OPCs would be assigned to a patient based on clinical criteria, thus determining a realistic target. The OPC would be modifiable based on Hierarchical Clinical Categories, (HCCs), and other factors in a fashion similar to APCs and DRGs. If a patient developed an unrelated condition, such as trauma or an MI, it would not be included in the target, but if persistent comorbidities developed, the target would be modified. New non-drug therapies that change the standard of care would be added to the OPC.

NCCA would purchase reinsurance to manage the costs that over-run the OPC. A reinsurance captive would be created with each practice owning and funding a cell which covers the risk of patients who were slightly more expensive. The practice would therefore be at risk for some of the cost overrun if it occurred but protected from practice ending risk. The captive insurance company would purchase the reinsurance that covers excessive losses from extremely expensive patient outliers as well as cumulative risk from an adverse selection of slightly more expensive patients. Therefore the risk of managing an individual patient falls to the practice, rather than the actuarial risk of having too many of one type of patient seek care. Offloading risk to a reinsurance company eliminates the need for a practice to maintain reserves. (Practices generally do not have reserves, and we would prefer that the money be spent on patient services.) Reinsurance would be needed on years 2 or later, when the process is sufficiently developed to put practices at risk.

NCCA would monitor pathway compliance and expenses so that each practice would be held accountable for its behavior, and would not be able to coast on the good performance of other practices in the pool.

Practices would implement a pathways system, derived from the COME HOME diagnostic and therapeutic pathways. These pathways are a subset of National Comprehensive Cancer Network (NCCN) pathways, with regimens considered obsolete or those not considered to be the standard of care eliminated. The physicians, aided by appropriate academic support, would update the pathways at least quarterly. NCCA practices have agreed to do this.

Data would be extracted from the EMRs electronically to determine pathway compliance. This data would be submitted to CMS to prove the quality of care. Errors of commission and omission would be evident by lack of compliance. Pathway compliance is a more comprehensive method of determining quality than the current spot-checking provided by Physician Quality Reporting System (PQRS).

The practices will also use the triage pathways of COME HOME for managing the complications of cancer and its treatment. The triage pathways are designed for early intervention combined with ongoing caregiver and patient education, getting patients to the appropriate site of service for their care and preventing complications that would otherwise require hospitalization. This is the best form of patient feedback: patients who have a problem get immediate service through a decision support tool used by a practice nurse, and give immediate feedback on the care they received. Supplemented by patient satisfaction surveys, we can provide excellent data on the customer service part of care quality.

Participation in any shared savings would require pathway compliance as the quality measure.

In addition, therapy regimens that require additional interventions to manage the patient's condition can be tracked, and the costs of providing those interventions can be acquired from the claims data. This will allow the pilot program to consider not only the cost of the drug regimen, but include the cost to manage the regimen as part of the OPC. Eventually this will form the basis of an oncology bundled payment that is granular enough to account for and manage variations.

Outcomes data will become available over time. Relapse rates, death rates, hospitalizations and toxicity can help physicians select appropriate regimens. This data can also be entered into CancerNet for big data studies.

Software vendors would have to allow extraction of the needed data. This is required in statute, but the definition of data blocking would need to be clarified to force vendors to allow access to the data. COME HOME developed software that was able to extract the data from the vendors in use during the grant, but current vendors are not allowing extraction.

Practices are currently paid under fee for service, and the change from that process must be gradual to allow for adoption of new models without threatening practice stability. For the first year of data collection, the practice is paid fee for service plus a Patient Centered Oncology Payment for care coordination, plus a facility fee for the overhead of having chemotherapy administration and pharmacy costs plus the acquisition cost of the drugs. The expense of implementing the triage and the diagnostic/therapeutic pathways would need to be covered as part of the pilot project.

With the rapid escalation of chemotherapy drug pricing, and the fact that the new expensive drugs are often significantly better in terms of outcomes and toxicity, putting drugs into a bundle is not currently practical. There are standardized regimens embodied in the evidence based pathways for choices of chemotherapy, and we do not want

physicians avoiding more effective chemotherapy regimens based on financial considerations. The major discretion is in the order of usage in the metastatic setting where performance status is maintained.

If drugs were in the bundle, a perverse incentive to deny patients the expensive drugs might exist, and we should guard against that. The new drugs are put in the pathways at the appropriate place in the treatment paradigms, and measuring pathway compliance will prevent both over and underuse. The pathways should be vetted by the American Society of Clinical Oncology (ASCO) and by CMS.

However, support drugs should be part of the bundled payment. If a drug is truly better at preventing delayed nausea and vomiting, it would be cost effective, even if the drug itself were more expensive. Most of the drugs where the physician has discretion are the support drugs for nausea, growth factors, and maintaining bone density.

In the second and third year, as the OPCs are shown to be accurate, the practices can go at risk for meeting the OPC target. The OPC would include the FFS payment, care coordination (PCOP) payment, and the facility payment for chemotherapy administration but not the drug payment. This allows the practice to have cash flow for expenses such as payroll, as it is not possible to wait for shared savings at the end of the episode. However, in year 2 or 3, shared savings could be possible. The baseline level of the OPC, and therefore the PCOP payments would have to be tied to the Medicare Economic Index (MEI), and should reflect the market average. Rebasing should not be tied to the performance of the individual practice, as that is a race to insolvency. For each practice, the metric to work against should be what the market would charge if that practice were not present.

Eventually, as both CMS and the practices gain experience with the models, payment could be paid in advance when a patient is enrolled and an OPC is assigned. Then the practice would have to manage the money as well as the care, and still submit quality data. Ideally the practice would then pay the other members of the care team out of that bundle, which would encourage the use of cost effective providers of services. This would require additional infrastructure development for contracting with surgeons, hospitals, hospices, primary care etc.

Goals:

1. Combine clinical and claims data in an iterative fashion to create increasingly accurate cost targets:

- 1.(a) The practice would register a patient in the pilot, by giving demographics, diagnosis, staging, intent of therapy (i.e. neoadjuvant, metastatic, etc) performance status and plan for therapy. A pathway would be assigned to that patient. For the first year, claims data would be collected and the payment put into a virtual account as it is paid in the usual fashion. The practice would have access to that account to see the use of funds in real time.

- 1.(b) As CMS develops a range of costs for similar patients registered in a given pathway, an OPC would be developed. We have data models that will facilitate this process.
 - 1.(c) The practice would perform against the OPC but with a feedback loop to make sure the OPC remains accurate.
 - 1.(d) Comorbidities would be used to risk adjust that OPC.
 - 1.(e) If the patient develops comorbidities during therapy, the OPC would be modified.
 - 1.(f) Working with the Innovative Oncology Business Solutions data scientist, we would use a model called Density Based Spatial Clustering of Applications with Noise (DBSCAN). This model starts with the description of each patient encounter with demographic information, and adds the clinical information. The clinical information starts with a collection of all the HCPCS codes found in the episodes ranked by frequency. This generates a synthetic episode that can then be made more precise as more data is collected. Preliminary work shows good correlation with claims data. J codes for drugs would be evaluated separately. A current problem with OCM is that the drug development outpaces the ability to modify the model. Separating drug codes from the rest of care allows the model to work without the variation produced by new drugs. Comparing the drug usage independent of the other codes allows better monitoring of drug usage and therefore cost.
 - 1.(g) The practice would evaluate outliers for causation and could apply for additional payment if the cause of the underpayment was unavoidable. (for example, if a patient develops a DVT or becomes diabetic)
 - 1.(h) CMS would monitor similar patients in the geographic area and would monitor costs of care over the entire pilot. This might be a sufficient volume to compare with the control group, particularly in years 2 and beyond.
- 2. Require practices to accept transactional risk, (appropriate management of specific patients) but protecting them from actuarial risk:**
- 2.(a) In year 2 and beyond, each patient would have an OPC assigned that was appropriate for the clinical situation of the patient. Therefore a practice that happened to have a healthier subset of patients would have lower targets to work towards and a practice would not be penalized for caring for sicker patients. Because each OPC is specific for the patient, the practice would not risk financial catastrophe from adverse actuarial selection.
 - 2.(b) However, the practice would need to manage to the target as the patient receives care. This means that the practice would have to identify patients at higher risk of ED usage and admissions and provide additional services to avoid excess expense.
- 3. Encourage practices to accept all patients without regard to their affect on the payment system:**
- 3.(a) Under a system like OCM where the targets are created from the combined costs of a variety of patients, the OPC assigned is specific to

the patient's clinical situation. When a more complex patient with more expensive care presents to the practice, the OPC assigned reflects the average costs for patients with that condition. The OPC is modified by the patient's comorbidities, so sicker patients have a higher OPC than patients with the same cancer diagnosis and stage but no comorbidities.

4. Build on the success of COME HOME:

- 4.(a) COME HOME showed that early aggressive intervention with decision supported nurse triage and same day visits led to decreased hospitalization rates and savings. These triage pathways would be implemented in the NCCA practices that were not already using them. In addition the COME HOME diagnostic and therapeutic pathways are now owned by NCCA and can be implemented. The EMR vendors of the NCCA practices would need to allow the data extraction tools created by COME HOME to have access to the data so that the dashboards could be created. The dashboards allow individual physicians as well as the practice administrative team to monitor the performance of the model. We have vendors who can provide this function.

5. Care directed by physicians and guided by evidence based pathways is the ultimate quality measure, without excessive data entry overhead:

- 5.(a) Currently, data entry is complex with multiple manual data entry points required. The personnel to provide this data must be RNs, advanced practice clinicians or physicians, making data entry both expensive and frustrating. Clinical personnel should not be distracted from clinical work, so data entry must be electronic.
- 5.(b) Similarly, the data extracted are very limited to a few tumor types and a very few clinical situations and do not reflect the overall quality of the clinical care.
- 5.(c) We believe quality of care has 2 major components:
- 5.(c)i. Technical quality to know and perform the right procedure or therapy for the right patient at the right time.
- 5.(c)ii. Patient centered quality is determining optimal care for each patient, and providing that care with respect for the patient's time, money, emotional status and symptoms.
- 5.(d) Extracted pathway compliance data demonstrates at the practice level, the physician level, the disease level and the patient level whether or not the technical quality is present. Pathway compliance includes the proper selection of imaging techniques at the appropriate time, the proper surgical and radiation interventions and the evidence based choice of therapy. Whereas PQRS measures only one specific subset of one tumor type, pathway compliance measures all tumor types in all clinical settings, and is therefore a more specific measure of quality.
- 5.(e) Patient satisfaction surveys add some value, but patients get tired of being surveyed and patients are reluctant to criticize their care team. Extraction of triage pathway data demonstrates that the practice has structured the care to provide rapid response to the patients needs. Patient satisfaction with the COME HOME practices was very high.

- 5.(f) If quality measures based on pathway compliance are not met, the practice would not be eligible for shared savings.
- 6. Create a sustainable payment system that reflects the actual care given without preventing the use of alternative methods such as technological monitoring:**
- 6.1. Fee for service systems require face-to-face encounters between physicians and patients for payment and is not sufficient to support additional services. In an efficient Medical Home constructed practice, many services are provided without face-to-face encounters. Either cost shifting to cover the costs of the services must occur, or the value of the services must be built into the episode payment.
 - 6.2. Because these services are performed by people who are salaried, the payment must be prospective to be sustainable. The ASCO Patient Centered Oncology Payment system reflects the non-face-to-face work performed both by the oncologist and the team to provide the appropriate education, decision support, implementation and monitoring of therapy. The continued fee for service payments reflect the face-to-face work. The combination is essential for the Oncology Medical Home. The additional payments would allow for the needed support services such as education of caregivers, assisting patients in finding community support, copay support, psychosocial support and other needed functions, and would allow some of those to be delivered by telemedicine or electronic monitoring.
 - 6.3. Shared savings will diminish over time, and therefore are not appropriate for the ongoing expense of the practice, but can be a bonus used to expand the practice capabilities and design new processes.
 - 6.4. Without the combination of fee for service for basic in office functions, MEOS or PCOP type payments for the non-face-to-face encounters, and shared savings for an incentive program and for the capital needed for innovation, practices can not transform while continuing to provide current services.
 - 6.5. Chemotherapy is addressed in [item nine](#).
- 7. Allows funding for essential services such as patient education, determination of patient choice, and care coordination without relying on cost shifting from a margin on drugs.**
- 7.(a) There are no codes other than the transition of care codes that pay for non-physician face-to-face encounters for patient teaching and discussions with caregivers. The transition of care codes attempt to address this but are limited to specific functions.
 - 7.(b) Ongoing physician discussion with patients, family members, and other members of the care team are essential to determine patient goals as the clinical situations change. These are rarely face-to-face as presumed by the family conference codes, but are frequently by phone.
 - 7.(c) Ongoing education processes by pharmacists, oncology nurses, triage nurses, social service and others are far more extensive and expensive than expected or compensated under current codes.

- 7.(d) The social determinants of health, such as assisting patients when they are forced to choose between copays and food, or who cannot arrange travel or child care, require significant interventions and staff time.
 - 7.(e) With the current system requiring coinsurances or large copays for oral chemotherapy, and with the difficulty of accessing the copayment foundations, pharmacists are spending unreimbursed time obtaining drugs for patients.
- 8. Create a system that is built on the fee for service system during the transition phase and gradually shifts the payment toward appropriately structured bundles:**
- 8.(a) Current billing systems for both practices and payers are based on fee for service. Patients currently under therapy for cancer cannot have a disruption of their care, and practices cannot have disruptions of their cash flow. The current system must act as a safety net for both during the transition to value based payment.
 - 8.(b) Until sufficient clinical and claims data have been aggregated to create the OPC system, FFS must continue.
 - 8.(c) The FFS claims system is a reasonable way to keep track of the services provide and the costs. Payer software is designed to do this, and one barrier to alternative payment methods would be a requirement for different software structures for payment. When the OPC is determined, the FFS claims are subtracted from the OPC payment. The virtual OPC account is visible to all the participants. The claims do not need to be adjudicated, as a denial would add to rather than subtract from the remaining funds in the OPC account. Practices would manage to the worst case scenario, if all the submitted claims were paid in full.
 - 8.(d) The practices would have to provide reinsurance in years where risk is taken, to avoid putting a practice that could not perform for whatever reason out of business, but would allow for a second chance and continues transformation for success.
 - 8.(e) Fee for service codes are also useful tools for internal management of practice expense and staff compensation.
 - 8.(f) Oncology practices have an increasingly slim margin, as evidenced by the number who have been forced by economic factors to sell to hospitals. Interruption of cash flow can be fatal to a practice. Oncology practices are an important part of the infrastructure of providing cancer care. If that infrastructure is disrupted, patients with cancer are at risk of dying.
 - 8.(g) The current system is unable to devise a bundle with sufficient accuracy and granularity to cover costs. Until practices are comfortable knowing they will be paid fairly and sufficiently to cover expenses, they will resist transformation to a bundle.
 - 8.(h) Current computerized systems for paying claims are based on the Fee for Service model. It will take significant time and resources for payers to develop computerized systems for payment.

- 8.(i) This model preserves the fee for service model as the base, but recognizes that the personnel costs of the Medical Home model must be paid on top of the payment for those services covered by the FFS system. Payment for these services is covered by the decreased rates of hospitalization.
 - 8.(j) As the model collects data and continues to refine OPCs, codes can be developed that pay the OPC amount for a given patient with all the services needed bundled into that payment, except chemotherapy. (Codes cannot change fast enough to keep up with the changes in options for new chemotherapy.) Once practices become accustomed to and successful at monitoring costs to stay within an OPC, the individual FFS payments become less important. Once CMS becomes comfortable that the OPC is a fair price for the value delivered, FFS payments are less necessary.
 - 8.(k) Both sides must recognize that with bundled payment systems, transparency is sacrificed for efficiency.
- 9. Separate the costs of delivering chemotherapy from the costs of the drugs.**
- 9.(a) Drug prices are rising rapidly, but neither CMS nor the practices currently have to the ability to negotiate for better prices. As new drugs, effective but expensive, are developed, the J codes system is currently very effective for accurate payment.
 - 9.(b) ASP has proven problematic as there is currently a 6 month lag when a drug price goes up before the ASP payment catches up. New drugs are often "underwater" for the practices until the ASP catches up, thus delaying patients' access to new and effective therapies. In addition, ASP includes rebates such as prompt pay and GPO rebates that are not available to practices. Therefore, from the practice standpoint, purchasing at ASP+0% to ASP+2% is often the best price available, and that is inadequate to cover the cost of care. With the current sequester and especially with the proposed sequesters, practices will lose money treating Medicare patients. We do not want any barriers to accepting Medicare Beneficiaries in our model. We would therefore propose payment at acquisition cost plus 6% to cover variation in price, and drug specific pharmacy issues such as special storage or tubing.
 - 9.(c) By using acquisition pricing, CMS will gain significant data as to the true amount paid for the drugs.
 - 9.(d) Much chemotherapy is now oral, and waste of unusable drug is a good target for savings. We would propose that oral chemotherapy be handled the same as iv chemotherapy so that the practices are not paying to incinerate hundreds of thousands of dollars worth of drugs annually. (In New Mexico, where we have a prescription drug recycling program, we have collected over \$200,000/year worth of drugs from patients, and given those drugs to other patients. Without that law, these drugs would have been destroyed.)
 - 9.(e) The process of safely delivering chemotherapy has become increasingly expensive and is no longer covered by the infusion codes, even with the added 4.3% to drug purchasing. We therefore suggest that an evidence

based evaluation of the costs of infusion be performed, and that a facility fee for infusion be created. This can be done by the same data extraction techniques as described, and over the first year, the accuracy can be tested, and adjusted as needed.

- 9.(f) The costs of acquisition, storage, education for both oral and IV chemotherapy is significant but should be relatively constant across different practice settings. Therefore we propose an evidence based facility fee to cover these expenses instead of assuming the ASP system covers them. Once the reimbursement for pharmacy costs and infusion costs are accurately paid, modification of the payment over invoice price can be reconsidered.

10. Create transparency in the payment system by combining claims and clinical data in a manner that is accessible to all participants.

- 10.(a) Bundles lose the transparency of a FFS payment where each payment is clearly allocated to a given service. The major costs of oncology care delivery are the drugs, the infusion, the imaging and the radiation oncology delivery. The cost shifting process that was created when CMS instituted the 95% of Average Wholesale Price (AWP) system to cover the costs of infusion plus drugs became a windfall profit to oncologists. The attempt to shift to ASP+6% (now 4.3% with the sequester) has made the payment pendulum swing too far such that Medicare patients are often costing the practices more to treat than CMS pays the practice.
- 10.(b) Transparency requires fair price setting. Understanding the technical costs of providing a service, and having the infrastructure available for patient use is key to providing evidence based payment. This requires both data that is accurate and trust on the part of payer and provider that neither party is gaming the system. It also requires understanding by payers that a margin is necessary for all businesses, and by providers that a margin is not a license for greed.
- 10.(c) Costs change over time. This process must be iterative to stay accurate and will require significant data collection on the part of the practices as to what their actual costs are. Data collection is expensive, so the data set must be carefully constructed. New data fields are needed to estimate time used by personnel providing a service. We propose to work with our vendors to collect this data.

11. Encourage practices to serve patients with health disparities.

- 11.(a) Requiring practices to aim for a target price that is an average of the costs of patients with differing clinical situations and those with health disparities – both from the socioeconomic factors and other health factors – puts practices at risk of not hitting the cost targets. Cherry picking for healthy or low cost patients is the best way to hit a general target.
- 11.(b) Having an OPC that is adjusted for the health and socioeconomic factors for an individual patient removes the risk of accepting that patient into the practice. Oncology practices prefer to accept any patient who presents for care. Our model will remove the disincentives to do so.

12. Encourage physician choice of site and mode of practice to serve the needs of all communities, large and small.

- 12.(a) By providing accurate targets and assisting practices with the data collection and the analytics formerly only available to large systems, physicians in small practices can continue to function in their existing practices.
- 12.(b) Many oncology practices have closed remote satellite clinics that served communities too small to support a full time oncologist, much less a large system. With recognition that overhead that is required regardless of size must be shared among fewer patients, the current system of cost shifting has made satellites unsustainable. With a facility fee, this barrier is removed.

13. Encourage the oncology practices to select care partners that provide the best care at the best price.

- 13.(a) The virtual account attributed to every patient through the OPC will allow the practices to see which partners of care cost more than others. For example, if a CT scan is done in a hospital and costs three times as much as one in a freestanding center, the practice will encourage patients to use the lower cost facility. For quality purposes, American College of Radiology, (ACR), accreditation would be required, as it is for all Medicare patients.
- 13.(b) Surgeons who exhibit lower lengths of stays in the hospital and fewer complications would be recognized and would receive more referrals.
- 13.(c) Giving the practice real time data on submitted charges is sufficient. Charges will either be accurate when adjudicated, or will decrease if the charge is denied. Practices would manage to the higher cost possibility and might do better after adjudication, so there is no need to delay debiting the virtual account when the charge is submitted.

14. Have the model developed by a group of practices willing to participate and share data. The group would be of sufficient size and geographic diversity to make the model scalable.

- 14.(a) CMMI is right to test major policy changes on smaller pilot groups prior to making changes in the entire delivery system.
- 14.(b) The [National Cancer Care Alliance](#) (NCCA) is a group of 16 practices from coast to coast, each in a different market. These practices are already advanced in terms of electronic infrastructure, Oncology Medical Home processes and pathway usage, and data analysis. Management of NCCA is currently by Innovative Oncology Business Solutions, Inc, (IOBS) a company formed for the purpose of managing the CMMI award, COME HOME. IOBS is very familiar with managing projects of this magnitude.

15. Have a control group of similar practices to determine if the model itself was the cause of cost savings.

- 15.(a) An alternative control group would be to use the practices currently enrolled in OCM.

16. Have a rapid learning system to incorporate lessons learned during implementation.

- 16.(a) The development of the OPC is by nature iterative and will require constant adjustment. That is actually part of the data model.
- 16.(b) Pathways will be updated quarterly as medical science advances. A pathway that is not current provides inferior care. The effect of a pathway change on the OPC could be in either direction.
- 16.(c) As new non-chemotherapy drugs are adopted, that expenditure would be added to the OPC. Chemotherapy will be paid separately.
- 16.(d) Pathways will also allow for outcomes analysis. As data is collected throughout the process, measurements of efficacy of drug regimens as well as toxicity will be made. If a regimen is found to be more toxic or less effective, usage of that regimen would probably be minimized.
- 16.(e) Changes in regimen usage will change the cost of the episode of care, by requiring more or less intervention. OPCs will need to be modified.
- 16.(f) New regulatory requirements that increase the cost of providing services would add to the facility fees that would have to be adjusted. This administration's focus on minimizing regulatory burden would minimize this adjustment, but having a mechanism to cost out the new regulatory requirement would provide valuable information to CMS as well.
- 16.(g) If practices learn which other care partners are most effective, providers who are not selected to participate in care may change their business plan to become more cost effective and competitive. This would lower the overall cost of care and therefore lower the OPCs.
- 16.(h) Care must be taken to ensure that OPCs do not become too low to sustain innovation. There are costs to the data collection and the quality processes that must be included.

Conclusion:

A new pilot is needed to meld the health care delivery processes created by COME HOME with pathway driven quality metrics, and give it a sustainable method of payment that supports and promotes the level of care physicians want to deliver. The creation of a payment system that merges claims data, clinical data, and pathway adherence with a form of accountability can lead to the evolution of the fee for service model into care that is truly accountable. Risk must be kept in proportion to the ability of physicians to manage without loss of the infrastructure of the delivery system. The new payment method must provide both ongoing sustainable payment while encouraging innovation that meets the triple aim.

Innovative Oncology Business Solutions is partnering with the American Society of Clinical Oncology to create this model and will be submitting a proposal to the PTAC.

MASON is that model.

Thank you for your consideration,

A handwritten signature in black ink, appearing to read "BE McAneny". The signature is fluid and cursive, with the first name "BE" written in a larger, more prominent style than the last name.

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Introduction

MASON is an innovative attempt to solve a very complex problem by using data science to develop new tools, integrating claims data and clinical data.

Cancer diagnosis, treatment and management is increasingly complex and is not well served by the payment tools that are currently available. Attempts to tweak the current fee for service system have not been effective at achieving the triple aim. ACOs and other shared savings programs have generally created minimal savings and minimal changes in care, so entirely new systems are needed. A simple system will never be able to adapt to the complexity of care. An effective system will never be “completed” but must be adaptable to changes in the science of health care. Data science, also referred to as cognitive computing, has the ability to rapidly incorporate changes in standards of care.

The variables that affect the costs of cancer care include:

- 1) the classic factors of tumor site of origin, stage, and grade;
- 2) patient specific factors including co-morbidities, personal preferences, tolerance for side effects, personal resources both physical, emotional and financial;
- 3) genomic factors that defy classification into the usual paradigms of therapy;
- 4) physician factors of preferences for care modalities from training, availability of modalities in the local referral arena and practice economics;
- 5) health system factors including what the payment system will allow.

A successful system will need data science to manage all of these independent variables, and will need to be flexible to manage the change. It must also be able to sort out which factors cannot be modified, like genomics, and which can, like practice economics.

All of these factors are changing so rapidly that the current payment system is inadequate. This is evidenced by the rising costs of care, acquisition of practices by hospitals because the reimbursement is better, and the closing of independent clinics that cannot afford the buy and bill processes that worked well in simpler times. As the consolidation of markets has shown us, loss of the independent, Physician Fee Schedule practices has increased the costs of care without increase in quality, decreased patient choice and increased physician dissatisfaction.

A new system will need to preserve the existing delivery infrastructure at the same time that transformation occurs.

Current payment systems lack the flexibility needed for modern cancer care. There is only payment for E&M codes for face to face encounters between the physician and the patient, for procedures like radiation and surgery, for infused drugs and for imaging. Prior to the OCM and COME HOME, there were no payments for the care coordination, management of the social determinants of health including nutrition and exercise, patient and caregiver education, and the time for the oncologist to review the complicated genomic reports, search for literature or trials

or even discuss the care with the rest of the care team. Lack of payment for these essential parts of care is a disincentive for physicians to provide these services, or to maximize covered services to increase revenue.

Medical Home processes include those unfunded patient centered services, and have been shown to decrease costs and increase patient satisfaction and are included in OCM and Mason.

I will show the payment estimates for those functions as provided with COME HOME. The OCM underfunded those costs and unfortunately diverted that money into data collection. Data collection in Medicare products has expanded the traditionally low administrative costs of the program into levels approaching commercial payers.

A new successful payment system must adequately pay for the care given and must adjust for changes in care that add value, and resist changes that simply add expense. Data collection must be electronic and not require the use of scarce resources like physician time. Any new system must acknowledge that the collection of data is an overhead cost and must provide value to be worth the time, effort and expense.

The cost shifting that occurs from commercial payers to governmental payers, and from services that are well reimbursed to cover the shortfall for unpaid or underpaid services, has led to a culture of maximizing revenue generating services and lack of transparency. Poor transparency, in turn contributes to our lack of knowledge about the actual costs of delivering care, a lack of trust between payers and providers, and the incentive to provide services for which value is limited but payment is obtained. The lack of transparency has led to silos of information, so that no one entity has all the data needed to accurately predict costs.

Cost savings are currently possible, but have a limit, as cancer care will never be free. A shared savings program provides an incentive for change, but is not a sustainable funding source. A new payment model must be depended on to pay fairly and accurately for the legitimate costs of care. An ideal model should be able to establish a predictable cost that can eventually be pre-paid, so that the physicians are at risk for the appropriate management of the patient, but not for items not under their control, and so that the infrastructure of care delivery is not threatened.

A new payment system must be transparent, trusted by both payer and provider to cover costs, provide a margin for cost of living changes and transformation, but ensure that the value is given in proportion to the amount spent.

The development of a new system will require a group of physicians and the selection of a trusted payer, preferably CMS, to share data that will be used to build the new tools we need. The complexity of the system and the disease means that standard computing processes will be ineffective in creating a better system of understanding cost and care. Data science is a tool used to manage large amounts of variable data with ever-changing inputs so that complex systems can be managed. It is time for this science to be applied to health care, and MASON is a pilot project

that will combine the clinical data from a volunteer group of advanced oncology practices with the claims data provided by the payer, using data science to create a model can not only solve the payment problems of oncology but can be generalized to much of health care.

Once the initial data is obtained, updates occur at the speed of computing ability. Because the pathways are based on NCCN guidelines used as the gold standard by all oncologists in all practice settings, the OPCs can be rapidly applied to all practices of oncology.

The processes used to create the OPCs will be useful to provide cost and value data and payment systems for any specialty managing chronic diseases.

Overview of MASON

Phase 1, Development of the Oncology Payment Categories (OPCs)

The first phase of MASON will be to develop the OPCs using data science partners, claims data and clinical data from National Cancer Care Alliance (NCCA) practices.

In the claims data, the same cancer with the same stage can have markedly different expenses, and currently we do not know if those differences are related to characteristics of the cancer, the patient or the physician choices. Using data science, the characteristics of the patients who fall into a claims cluster can be determined by extracting data from the clinical record. (Currently physicians have a disincentive to accurately code data: it slows them down, is irritatingly difficult with current EMRs, and only benefits the payers or the people who sell the data to the payers). NCCA practices have agreed to accurately code needed data elements, because they will see their accuracy reflected in the payment processes. The OPC is the amount of money needed to cover the legitimate expenses of the care for that particular clinical situation. The concern that it will not save money because it reflects a FFS payment is mitigated by the compliance with pathway recommendations for appropriate patient care management. If a physician is adding additional services, the cost will be over the OPC target.

Current accurate targets to predict costs of care have been elusive. Even successful ACOs such as the primary care Medicare Advantage ACO, New West in Denver, have avoided trying to predict costs for any but the most simple types of oncology care. There is no evidence that more attempts to use the current tools for care will be any more successful than they have been in the past. The Oncology Care Model (OCM) is finding that its inability to provide physicians with an accurate cost target is threatening the viability of the model. Practices of any size would be foolish to accept actuarial risk without verifiably accurate target prices. Any attempt to create a bundled payment model for oncology will fail without accurate data on the actual costs of optimal care. The cost of failure would be the destruction of the infrastructure of cancer care delivery. A pilot project to develop a new system is needed, before it is rolled out to the country as a whole.

Therefore the NCCA oncology practices are willing and able to work with IOBS and the data science partners and CMS or other commercial payers to develop a new, adaptable, accurate model.

The most successful model in oncology to save money while improving care is COME HOME, the oncology medical home. Several of the participants in NCCA are NCQA certified oncology medical homes, and therefore have demonstrated their commitment to improving quality and lowering costs.

The most successful part of COME HOME was the use of nurse driven, EMR embedded, Triage pathways providing decision support to take patient reported problems, and find solutions at the lowest cost appropriate site of service. NORC (University of Chicago) has attributed the cost savings to the use of the nurse driven triage system. MASON makes use of the pathway system.

Pathways for diagnostic evaluation and therapeutic decision-making have been shown to document the quality of care and possibly save money by avoiding ineffective care or unwise choices. MASON will use pathways to demonstrate the quality of care and make documentation of that quality electronic, thus sparing physician time for patient care. The pathways include all the components of care, and then the cost of those components build the OPC.

Once sufficient numbers of patients have been accumulated that the data scientists are confident that enough of the necessary data elements have been included and the unnecessary ones excluded, that list with costs becomes the OPC. The methodology for creating the OPCs already exists and awaits the data.

Different diseases will take different lengths of time to develop their OPC depending on the number of patients in the category and the number of variables affecting the outcomes. The limiting factor is accumulating the patient data. The computing processes are extremely fast.

An evaluation point should be the development of a number of OPCs over the 6 months to one year time frame, with the appropriate validation.

Phase 2 Use of the OPCs

The OPC is a list of expected interventions and billing events for a patient with a designated clinical situation. The list of interventions is created from the pathways, based on the NCCN guideline set, which is the gold standard for cancer care, and from the claims data showing what codes appear in conjunction with a given tumor diagnosis. The list and the clinical characteristics are determined by the data science. Because of previous discussions with the PTAC and concerns about the OPCs, I have spoken with several data companies who assure me this not only can be done, but that they would like the opportunity to do it.

When a patient comes to the practice as a new patient, data begins to be entered as the staging and diagnostic part of care occurs. Once the patient's data shows that he or she belongs in a given OPC, that patient is registered with CMS as being in that OPC. CMS establishes a virtual account, so that all charges attributed to the patient's cancer, with the exception of drugs, are attributed to that account. The account is visible to the practice and CMS and if the patient wishes, the patient. The target for care cost is the OPC, the virtual account is the reality of what is billed.

A quality withhold is subtracted from all payments. (Originally I had suggested 2% but would be willing to increase that to 4%. The 2% sequester was painful for cash flow, so I was originally hesitant to use more than 2%. More than 4 % would be difficult for practices to manage, as discussed below.)

The practices, through NCCA, will have purchased re-insurance to function as a stop loss to allow for two sided risk without threatening the viability of the practices.

As the patient undergoes procedures to treat the cancer, all of the submitted bills except drugs are attributed to the virtual account. This includes the medical home payments, all E&M codes, hospitalization and ED costs, lab, pathology, imaging, radiation therapy, surgery, home health and infusion.

Because all of these expenses with the exception of the medical home payments and Patient centered oncology payments (PCOP) are currently paid by CMS as fee for service, those costs would be the same. The Medical Home costs have been shown to cause the cost savings of COME HOME so adding those in is balanced by subtracting hospital and ED costs. The Medical home costs are billed to CMS like the OCM MEOS payment, and included in the virtual account. The PCOP payments pay for the physician work that is done between and before patient face to face encounters.

Drugs remain out of the OPC because the cost of the drugs is so high that inclusion would put physicians in a situation where denying a new drug to a patient would guarantee shared savings. While we would like to believe that physicians do not make any therapeutic choices based on economics, data seems to suggest that some do. Therefore we would pay for the drugs separately at invoice price and keep them out of the OPC. This provides the transparency of drug costs, and removes any incentive, positive or negative, for physicians to make decisions on anything other than patient need.

Drug margins have been used to cover infusion costs and other services through a cost shifting process. Elimination of the drug margin will require that other costs be paid directly. An infusion facility fee with drug specific infusion payment codes covers the process of safely administering chemotherapy. The infusion facility fee covers the fixed costs of an infusion center and the infusion codes cover the variable costs. Previously, margins from drugs also funded the work done by physicians as outlined in ASCO's Patient Centered Oncology Payment (PCOP) system,

and the medical home work done by nurses and pharmacists in care coordination and patient/caregiver education.

Elimination of the drug margin requires payment for needed but unreimbursed services by the infusion facility fee, the PCOP payments and the medical home payments, making these costs transparent to CMS. Infusion codes are currently paid, so that is not a change.

Each of these charges are submitted to CMS in the usual fashion, paid in the usual fashion, but are attributed to the virtual account.

If a patient has HCCs attributed to them from before the cancer diagnosis, services provided with the HCC diagnoses are not attributed to the virtual account.

Charged incurred for illnesses unrelated to the cancer diagnosis but occurring after the diagnosis are also not attributed to the virtual account. Collecting the data from the EMR and using the data science processes will help correlate which intercurrent illnesses are associated with the cancer and which are not. For example, most infections should be considered related, but trauma should not. Data scientists can evaluate the frequency that a given code is associated with a cancer diagnosis. Codes appearing infrequently in the data set are unlikely to be part of the cancer care, and commonly appearing codes should be attributed to the cancer, and therefore to the OPC.

This represents a change based on the conversation with the PTAC evaluation committee. Because of the concerns expressed, I discussed this problem with several of the proposed data science partners, who expressed that using the frequency of codes associated with the index code solves the problem.

A dispute resolution process may be useful in the beginning but as the numbers of patients being monitored increases, the data scientists tell me that attribution becomes data driven. This also provides a great byproduct. As physicians learn which regimens are associated with more intercurrent problems, they will be able to work with patients to avoid those regimens, assuming alternatives exist, or manage them prospectively.

Charges submitted by members of the care team who are not part of the practice are billed and paid in the usual fashion, but attributed to the virtual account.

Adjudication of the claims usually occurs within a few weeks, but occasionally claims are held for other reasons, so we would prefer to have the un-adjudicated claims. If the claims change, the amount is usually less, so the amount left in the virtual account would be higher. This allows the practice to manage to the worst case (most expensive) scenario, but admittedly does not solve the problem of delayed claim submission by other providers. Fortunately this is an uncommon problem, and the omission of an expected charge would be noted by the practice management.

At the end of the episode of care, the amount in the virtual account is compared with the OPC. If the amount is lower, ie less was spent, then the savings are shared with the practice. If the amount is higher, the practice pays CMS the difference with the help of reinsurance. After a period of time, if the OPCs are as accurate as we think they will be, the difference will be minimal which opens the opportunity for a bundled payment.

If the quality measures are not met, there are no payments for shared savings.

There is concern about the time to create the OPCs as for each tumor subtype it will be necessary to have sufficient patients for an accurate calculation. Once data is acquired, time for computation and updates is minimal, given the speed of modern computers.

Criterion based Comments:

Criterion 1: Thank you.

Criterion 2 rated as does not meet:

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.

Pathway based compliance is an excellent measure of the technical quality of care. The committee was concerned that 80% was too lenient. There is no literature on the correct level for pathway adherence, but pathway developers, implementers and payers have cited 80% as the accepted level, as pathways are written for the average patient, and no patients are average. For example, because pathways are written for patients without complications, appropriate management of complications with additional imaging and therapy will not be reflected by the pathway. The gold standard for pathways are the National Comprehensive Cancer Network guidelines. Dr. Robert Carlson is the CEO of the NCCN. Payers use the NCCN guidelines to determine payment, but off guideline payment occurs with the medical Literature. I include, with his permission, an email from Dr. Carlson commenting on the 80% level:

Hi Barbara,

It was good to see you and hear your presentation at the CAC meeting.

I have been aware of your PTAC proposal and have heard discussions of it at a several meetings, so am generally aware of what you are trying to do.

The 80% concordance with guidelines/pathways benchmark is to my knowledge not an evidence-based benchmark. However, 80% is the number that multiple guidelines/pathways developers have independently landed on. That is what we've used at NCCN. I do know that the McKesson Specialty Health CV+ pathway implementation also uses 80% as

the expectation of those who use their tool. So, you will find support, although not necessarily published evidence.

There is another layer of complexity here, also. For recommendations that are based upon high level evidence, the concordance should be higher than in those situations where only low-level evidence is available. We found that in the (now defunct) NCCN Outcomes Database where there was typically 90%+ concordance with GL recommendations supported by high level evidence, but lower concordance in those with lower-level evidence and uniform consensus, and still lower concordance with low-level evidence and less uniform consensus. That makes sense, and is what we should expect. But even in the settings with high-level evidence there will be patients who refuse therapy, comorbidity that alters the risk/benefit considerations, or financial or access issues that will lower the concordance numbers independent of the quality of care provided.

Hope that this is helpful!

Bob

Robert W. Carlson, M.D.

Chief Executive Officer

National Comprehensive Cancer Network® (NCCN®)

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Deviations from guidelines must be accompanied by a clinical rationale. We currently measure this from a drop down list or a free text box in the EMR.

There was concern mentioned in the comments that the OPCs are not yet developed, which is true. However, the older, simpler methods of creating targets for cost and payment are not adequate, and never will be able to manage the complex, multi-variable situations found in clinical cancer care. It is time to take a data science approach to determining the optimal appropriate interventions and treatments by clinical and patient characteristics and determine the current costs for optimal treatment. It requires a group willing to share clinical data with a payer and a payer willing to share claims data with the team. The OPCs will never be a finished product but will always require modification based on changes in optimal care. This is actually a strength of the methodology, as a payment system that does not evolve with the changes in clinical practice will soon become a hindrance to providing optimal care. Leaving the drugs out in favor of invoice pricing minimizes the largest variable. Pathways are updated very frequently by NCCN and other pathways developers whenever a pertinent study is published and confirmed. As new therapies become part of practice, the OPC generating methodology will adjust the OPC.

The NCCA has taken ownership of the diagnostic and therapeutic pathways. Part of MASON will be the agreement to incorporate NCCN changes as they become part of the standard of care.

The methodology to develop the OPCs already exists, and once the data is acquired the computation is very fast. The limiting steps are the incidence of various types of cancers, so less common cancers will have slower data acquisition than more common cancers. The impact of the less common tumors on CMS' spend for cancer care is much less than the common types, so impact will be minimally affected by the data acquisition time for the less common tumors.

The problem of acquiring clinical data will never be overcome with the current EMRs and the lack of benefit to the physicians for taking the extra time to enter data. The NCCA offers a unique opportunity to have a group of oncologists willing to participate in a pilot to create the OPCs. The data scientists have the ability to pull data from multiple sources to minimize duplicative data entry and the computing ability to proceed rapidly once data begins to be acquired. As mentioned, OPCs will need to be revised as the science changes, and the data processes already set up will be able to catch meaningful changes and react appropriately.

One comment was that savings will not be generated because claims from practices are the basis for the OPC. Hospital and ED care are the low hanging fruit for cost savings, and part of the MASON project is to use the Oncology Medical Home COME HOME triage pathways. According to NORC, nurse managed, decision supported triage was the part of COME HOME that generated the savings. The United Health Group project found that aggressive management of side effects of cancer created the savings they saw as well.

Imaging is a major expense, and the pathways include the appropriate use of imaging. The virtual account will allow the practice managing partners to monitor the use of imaging and the software will notify the ordering and the managing physician when imaging is ordered off pathway. There may be a very good clinical reason for additional imaging off pathway, such as pain suggesting disease progression, but without a good clinical reason, excess imaging will be measured and managed.

In addition for the first time, the oncologists managing the patients will be able to see the charges submitted by other unaffiliated providers. Comparison of outcomes—physicians know which surgeons get the best biopsies or operate with fewer complications—can now be correlated with costs. Imaging varies from low cost free standing facilities to expensive hospital outpatient departments, but this data has always been hidden in the claims data and especially by the higher cost entities. The transparency of the virtual accounts gives practices a tool to select care team members based on value. This will contribute to savings.

The shared savings component will ultimately determine whether costs of care go down. Eventually the targets will be sufficiently accurate that no further savings will occur. There will be a baseline price below which service cannot be provided. So the goal is not year after year savings, but stabilization and accurate pricing that guarantees value.

Concerns for the ability to scale affect every pilot project, and the NCCA practices range from solo oncologists to groups of over 100, and are from coast to coast. They are independent, and therefore less expensive than hospital based practices. NCCA practices are advanced, motivated practices that wish to provide optimal care and keep costs down. NCCN guidelines are used across the country, and will help to standardize care. It seems to me that this is what you want, and if we can provide a gold standard for quality and cost, then other practices need to adapt. It would not make sense to select poor performing practices with high costs.

Therefore I request reconsideration, as MASON has the ability to improve care and decrease cost.

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.

A major goal of MASON is to build on structures that already occur in the CMS payment processes to minimize disruption to CMS and other payers. MEOS (medical home nursing care) payments, G codes for PCOP payments, facility fees and invoice pricing are all concepts familiar to CMS and easily adaptable to MASON as a pilot project. The FFS payments for existing codes and for other providers not part of the pilot proceed without disruption. MASON will measure the costs of infusion and monitor the medical home and physician work (PCOP) processes and report to CMS. The development of the OPC target is done by MASON, validated by CMS, leaving only the creation of a virtual account as a task for CMS or payers. However, currently charges for unique patients are attributed to that patient, so the major difference is providing read only access to the account.

A request was made for documentation of the care management amounts and other reimbursed services. During COME HOME, we were requested by Dr. Patrick Conway to quantify the costs associated with the implementation of the Triage pathways in particular and the care management processes in general.

Implementing practice modification requires implementing new software, changing patient flow, training the personnel. Implementing a triage program that gives the nurses the power to bring patients into the practice based on their judgment requires hiring training and paying them, and providing computers, phones and a place to work. We kept records of the expenses of the 7 COME HOME practices and submitted this to Dr. Conway and CMS. This is the document we provided:

COME HOME Triage Demand, Staffing and Costs v5 1/6/15

As we move toward the end of the grant-funded portion of the COME HOME Program, we are in the process of quantifying the costs associated with implementing the Triage Program and the Extended Hours. This report focuses on the costs associated with implementing and staffing the triage system, in the most efficient way possible.

Part 1: Labor Costs

This analysis consists of three parts: determining the number of anticipated triage calls, determining the number of triage nurses required to manage those calls and the labor costs for those triage nurses.

In addition to the ongoing labor and system costs, there are some one-time fixed costs associated with the triage system. These are:

One time IT costs:

PMS interface:	\$1,750/practice
NantHealth Setup Fee:	\$1,200/practice
System Training:	\$720/practice
Total:	\$3,670/practice

To determine the first part, the number of required triage nurses, we have calculated the number of triage calls per month, per 1000 active patients for each COME HOME Practice. From this analysis, shown in the table below, we determine that the average practice receives approximately 15 calls per 1000 active patients per month. This ratio can be affected by patient engagement, patient education, and the availability of other providers, particularly primary care providers.

	ACC	CCBD	DPN	NECS	NGOC	NMCC	SCCC	CH Total
Number of Active Patients	3,900	18,200	21,400	17,300	4,100	7,800	6,900	79,600
Number of Triage Calls/Month	51.7	207.6	475.4	242.4	24.1	180.0	37.4	1,218.6
Calls/1000 Active Patients/Month	13.2	11.4	22.2	14.0	5.9	23.1	5.4	15.3

The second part of the analysis involves determining how many calls each triage nurse can manage. At many of our practices, the triage nurses have many duties, in addition to managing the Triage phone lines, such as care coordination. However, at one of the COME HOME practices, Cancer Center for Blood Disorders, the triage nurses are responsible only for phone triage. At this practice there is a dedicated triage department whose sole responsibility is to handle all triage and medication refill calls. For the purpose of this analysis, we assume that half of their time is spent on triage and half on medication

refills. Using that assumption, we conclude that one triage nurse can manage 200 triage calls per month. Using a ratio of 15.3 calls per 1000 active patients per month, this translates to one triage nurse per 13072 (~13000) patients.

The final portion of this analysis concerns salaries. The triage nurses consist of RNs, LPNs and, in the state of Georgia, Medical Assistant IIIs. Salaries vary widely by title and by geography, and will significantly impact the total cost of the program. Additionally, each practice requires one First Responder (phone operator) per Triage Nurse, and one Patient Care Coordinator (scheduler) per practice. The median triage nurse salary in the COME HOME Program is \$41.21/hr, the median First Responder salary is \$20.20/hr. and the median Patient Care Coordinator salary is \$18.81/hr.

Part 2: Infrastructure Costs

There are two parts to the infrastructure. The first is a charge for the Triage System. This is a pass through cost that IOBS will collect from the practices and pay to NantHealth on their behalf. Currently, this charge is \$120 per physician, per month. The second infrastructure cost is to support the IOBS infrastructure, including triage system maintenance, custom reports, helpdesk services and administration. The monthly costs to support the IOBS infrastructure are detailed below.

Service	Hours	Hourly Rate	Total Monthly Cost
Administration	1	\$250.00	\$250.00
Finance	1	\$150.00	\$150.00
Reporting	1	\$150.00	\$150.00
System Maintenance	1	\$150.00	\$150.00
Helpdesk	1	\$100.00	\$100.00
Overhead	NA	NA	\$400.00
Total	5		\$1200.00

Part 3: Total Costs

Projected total costs for the program are given below. We've used median salaries in this analysis, but the salaries for any given practice or geographical area could be substituted in the calculation. This analysis represents our current assumption that one triage nurse could manage 200 calls per month (median call length of 60 minutes) or approximately 13,000 active patients.

Number of Active Patients	0 - 6500	6500 - 13000	13000-19500	19500 - 26000
Number of Physicians (approx)	4	8	12	16
Number of Triage Nurses	0.5	1	1.5	2
Number of First Responders	0.5	1	1.5	2
Number of Patient Care Coordinators	1	1	1	1
Triage Nurse Hourly Salary	\$41.21	\$41.21	\$41.21	\$41.21
First Responder Hourly Salary	\$20.20	\$20.20	\$20.20	\$20.20
Patient Care Coordinator Hourly Salary	\$18.81	\$18.81	\$18.81	\$18.81
Monthly Triage Labor Costs	\$10,440.59	\$16,914.96	\$23,389.33	\$29,863.70
Triage System License (\$120/physician)	\$480.00	\$960.00	\$1,440.00	\$1,920.00
IOBS Costs	\$1,200.00	\$1,200.00	\$1,200.00	\$1,200.00
Total Infrastructure Costs	\$1,680.00	\$2,160.00	\$2,640.00	\$3,120.00
Labor PMPM	\$3.21	\$1.73	\$1.44	\$1.31
Infrastructure PMPM	\$0.52	\$0.22	\$0.16	\$0.14
PMPM (Midpoint # of active Pts)	\$3.73	\$1.96	\$1.60	\$1.45

Definitions:

Number of Active Patients – Count of unique patients with face to face encounters at the practice in the past twelve months.

Number of Triage Calls/Month – Average calls/month from June 2014 through November 2014.

In addition, we based the payments for the non covered services on work done with ASCO in their patient centered oncology payment, PCOP.

These payment rates were developed over consultation with multiple oncology physicians looking at the time spent on the various parts of unreimbursed care and is best explained by the set of powerpoint slides entitled “Reducing Cancer Care Costs”, separately attached.

In my own practice in New Mexico, I have a contract with BCBS Medicare and TrueHealth (formerly New Mexico Health Connections, the exchange cooperative health insurance company) using these rates. This provides validation of the costs by two separate insurance companies.

Concerns about the use of HCCs and the ability to separate cancer related claims from non-cancer related claims were expressed, both in this document and in the previous verbal discussion. Since that time, I have discussed this problem with the data scientists and have learned that it is a solvable problem. First all HCCs will be useful to determine pre-existing conditions and the pre-existing costs of those conditions prior to the diagnosis of cancer.

The process of examining the cluster of codes surrounding each cancer diagnosis will also measure the frequency of the submission of that code. So if a significant number of the patients being treated for a specified cancer also have codes submitted for another condition, the likelihood of causation is high. If a code is very rare it is far more likely to be an outlier, unassociated problem. So for example, if a given cancer, treated with an anthracycline, has codes submitted by multiple practices both for the anthracycline and for echocardiograms and for congestive heart failure, this can be statistically designated as a cancer related complication, and should be included in the cancer cost of care. However if a small number of patients also have codes submitted by EDs for motor vehicle accidents, those rare codes can be determined to be an outlier and excluded from the cancer cost of care. Checking against the previously submitted pre-existing HCCs provides a statistical double check for accuracy.

I appreciate the PTAC committee bringing up this weakness in the proposal, as it caused me to do some additional work to find a solution. The data science solution should replace the case by case adjudication, which I agree is difficult to scale.

I would propose a change to the 2% add on to invoice price for drugs as suggested in the PTAC comments. My concern was that all vials of medication and all oral chemotherapy must be inspected by a pharmacist or a specially trained nurse, so that any damaged or inaccurate shipments can be returned. I understand from the PTAC comments that the concerns that drug selection will be based on the 2% is a weakness of the proposal.

The cost for a pharmacist to inspect a vial, given current pay scales for oncology trained pharmacists or nurses of approximately \$45-\$50/hour is approximately \$20.

The cost to return a vial to the vender is variable depending on the contract, but also is about \$20.

So I propose to delete the 2% add on and replace it with a \$40 flat fee for handling costs.

In addition, the 2% withhold is felt to be too low. Our experience with the sequester showed me the impact in my practice on cash flow, and that is how I chose the 2% amount. Given that over time the cash flow issue stabilizes and the goal is to provide some risk to the practices so that they focus on meeting the quality measures, 4% would be manageable.

OCM has made the assumption that practices can put 8% of revenue at risk. The NCCA practices discussed this aspect of OCM, and it was a major deterrent in consideration of accepting two sided risk. There is not an 8% margin in treating Medicare patients, in fact the margin is often negligible and the highest margin we saw was in practices that could negotiate rates well over Medicare for MA plans, and that was less than 8%. The practices in states with lower GCPIs are paid less for Medicare patients than those in higher GCPI states, so the higher level disproportionately harms practices serving poorer people.

Therefore I propose changing the risk withhold for quality to 4%.

Criterion 4:

Value over Volume.

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

I was surprised by the Subcommittee's determination that we are not focused on value over volume. The concern seemed to be that we were segmenting cancer care from other medical care and not integrating sufficiently with the rest of the oncology care team.

As mentioned above in the discussion about using data science to determine what conditions are cancer related and what are not, the OPC goal is to hold oncologists accountable for the care that they either provide or manage. Having care for patients' other medical conditions carved out of the payment to oncologists would tend to encourage, not discourage oncologists from requesting that their patients continue receiving care for other conditions.

In the current total cost of care system of OCM, a patient who has a pre-existing condition of inflammatory disease such as rheumatoid arthritis, and is on a biologic or requires frequent joint injections or surgical interventions, has the costs for those conditions and interventions attributed to the oncologist. The oncologist would never hit the OCM target price. This could lead to oncologists participating in OCM refusing to accept patients with expensive pre-existing conditions into the practice.

Under MASON, the pre-existing rheumatoid arthritis related care would be carved out, but the cancer related care would be included.

Under OCM the drug for the RA would be included and would price the care well over the OCM target, so the oncologist would be penalized for accepting that patient. Under MASON, there is

no disincentive to accepting these complicated patients as both the care and the drugs are not in the OPC.

Surgical care, palliative care and radiation oncology charges are all included in the therapeutic pathway and therefore in the OPC, so the medical oncologist has the incentive to coordinate care with the other specialists involved in the care. If the oncologist were to try to game the system by denying access to radiation, the pathway compliance software would document that omission and make it unlikely that the physician would hit the quality target and regain the withhold.

I would appreciate discussion with the PTAC team to better understand this conclusion and to request reconsideration.

Criterion 5: Thank you.

The software that monitors pathway compliance allows physicians a limited number of clinical reasons for refusal, which are listed in a drop down menu. If for example, the physician marks “patient refusal” or “poor performance status” the software deletes the “off pathway” report.

Criterion 6:

Evaluation of the MASON model **Have evaluable goals for quality of care, cost, and any other goals of the PFPM.**

In the original proposal 13 evaluation endpoints were suggested. Several of these are process measures, including development of the OPCs, and facility fees but several are outcome measures including hospitalization rates compared to similar patients treated by OCM practices:

Criterion: Goals of MASON, Ability to be Evaluated

- a. Development and maintenance of standard of care pathways embedded in EHRs.
- b. 80% compliance rate with diagnostic and therapeutic pathways.
- c. Achieve patient satisfaction scores of over 90%.
- d. Development of OPCs starting with the 7 tumor types for which pathways exist from COME HOME, and expanding to include 95% of oncology diagnoses.
- e. Set up an automated mechanism for CMS to approve OPCs, both initially and with ongoing modifications based on data collected from claims and clinical systems.
- f. Implement OPC virtual accounts so that each practice can monitor every patient’s use of resources.
- g. Development and implementation of a facility fee for infusion centers, both independent and hospital based, that covers the fixed costs including costs from the regulatory requirements. This will increase the transparency of costs, allow for cost accounting of new regulatory requirements, and help level the playing field between independent practices and hospital based practices.
- h. Change drug reimbursement to a 2% over invoice based system to allow for greater

transparency and relieve the concerns of payers that drugs are selected for financial gain rather than value to patients. This will also transfer some of the 340B discounts given to hospitals back to CMS when MASON is expanded beyond the pilot phase.

- i. Transfer some infrastructure support from Emergency Departments to the less expensive physician office setting so that oncology patients have a more cost effective option for urgent oncology care. The MASON oncology medical home payments (the MASON version of PCOP) accomplish this goal. Emergency Departments would see decreased payments from decreased utilization.
- j. Decrease hospitalization rates and length of stay and readmission rates by implementing the COME HOME proven processes that intervene early in the complication of cancer and its treatment. Patients prefer to be home, so patient satisfaction is improved. Patients treated at home are less likely to develop adverse hospital acquired infections, thrombotic complications or the de-conditioning of lying in a hospital bed.
- k. Decrease cost of oncology care beyond the \$2,500/patient savings achieved by COME HOME.
- l. Compare the savings achieved by MASON with the savings from the Oncology Care Model using a comparison of costs for patients matched by clinical criteria. In addition, NCCA practice costs should be compared with the costs of patients matched for clinical criteria but treated at other facilities within the market of the NCCA practice.

Quality measures for the technical quality of care are best measured by pathway compliance. This is far superior to the current measures that only evaluate a tiny subset of cancer care.

Patient satisfaction surveys measure the customer service quality of care.

Cost of cancer care for MASON practices compared to other practices treating similar patients is a significant evaluation goal. I selected OCM as it has the most data provided to CMS. Another option would be to have an independent evaluation team like NORC select practices similar to the NCCA practices as occurred in COME HOME.

The ideal measurement would be the cost and outcomes of care from the MASON practices compared to the rest of the community, so that we can measure what the effect would be on the cost of care if the MASON practice did not exist. This can be done in states with an all payer database, and may be possible if CMS makes both Medicare FFS and Medicare MA data available.

I would appreciate input from the PTAC committee on what measurements would strengthen the proposal.

Criteria 7: Thank you.

Criteria 8: Thank you.

We have found that for subjects as complicated as cancer, shared decision making begins with patient and family/caregiver education. For the first conversation, patients usually retain very little as the emotional levels are overwhelming. Repetition, often through multiple different people, results in the development of understanding of the possibilities and limitations of treatment. This usually occurs during the staging process. At the subsequent visits with the oncologist, the care plan is developed with the patient and family as active participants.

Criteria 9: Thank you.

Criteria 10: Thank you.

Most of the interoperability required to develop the OPCs will either require cooperation of the EMR systems (the majority of NCCA practices are on the same EMR), and much of the work to operationalize the virtual accounts will be in the practice management software which has many fewer barriers to communication.

PRT comments and closing:

I appreciate the time and effort of the PRT in evaluating this complex proposal.

I hope that I have assured you that the data science processes to determine the OPCs already exist, and that the data entry from patient care will proceed rapidly, especially for the common, most expensive cancers. NCCA sees approximately 75,000 new patients per year and has around 500,000 patients under treatment. This is sufficient volume to provide to the data scientists, and once the model is being computed, updates are extremely rapid.

Given previous PTAC questions about the requirement to use the specific vendor, I have investigated several other data companies to reassure PTAC, myself and the NCCA practices that what we propose can be accomplished. In addition, having several proposed partners allows us confidently evaluate the qualifications, experience, track records and costs of competing data scientist vendors.

Several of the data companies competing for this opportunity would be glad to provide the Committee with assurances as to the feasibility of creating the OPCs. Here is a letter from RS21, a data science company interested in participating:



August 4, 2018

Barbara L. McAneny MD, MACP, FASCO
Innovative Oncology Business Solutions, Inc.
4901 Lang Avenue NE, Ste. 204 Albuquerque NM 87109

Dear Dr. McAneny:

On behalf of RS21, I am pleased to offer our full endorsement of the Making Accountable Sustainable Oncology Networks (MASON) model. Further, we would like to commit fully to participate in the development of the model, offering our full suite of data science models and methods to help your team transform this exciting idea from concept to reality.

RS21 is ideally suited to support this project. Designed to tackle the world's most complex challenges, we bring together a robust blend of data scientists, computer programmers, and designers to create platforms that uncover unique insights and drive innovative solutions. We have the capacity, know-how, and technology to work across the disparate big data sets, both unstructured and structured, that will be required to combine claims data and clinical data to create Oncology Payment Categories (OPCs). Further, we have deep experience working with researchers and healthcare professionals to create interactive, data-driven platforms that drive insights to difficult problems that are actionable, intuitive, and intellectually honest.

We believe the MASON model has the potential to transform oncology, moving from volume to value, and will ultimately lead to much better outcomes for patients. We look forward to participating.

Sincerely,

Charles R. Rath
RS21
President & CEO

In closing, what we are currently doing for cancer patients is not satisfactory. It is increasingly impersonal and expensive, in part because of the consolidation of the market in oncology. Hospital based care has had a market basket increase every year, while practices under the Physician Fee Schedule have been disadvantaged by nominal changes In closing, what we are

currently doing for cancer patients is not satisfactory. It is increasingly impersonal and expensive, in part because of the consolidation of the market in oncology. Hospital based care has had a market basket increase every year, while practices under the Physician Fee Schedule have been disadvantaged by nominal changes in payment since 2003. This has led to the acquisition of practices and therefore the increase in costs of care.

If we are to reverse this, we need to fairly cover the costs of care in all clinical settings. If we are to accomplish that, we need to have accurate cost and clinical data with strong assurances of quality. We will not accomplish this with the current tools. Data science has the ability to analyze very large data sets to provide answers to important questions, and has the flexibility to manage change over time.

The opportunity to partner with a large group of oncologists is unique, and is necessary to create a new system of care and payment.

MASON offers an aggressively innovative solution, which I believe should be tested.

I greatly appreciate your interest and your consideration

Respectfully submitted,

A handwritten signature in black ink, appearing to read "BE McAneny", written in a cursive style.

Barbara McAneny MD FASCO MACP

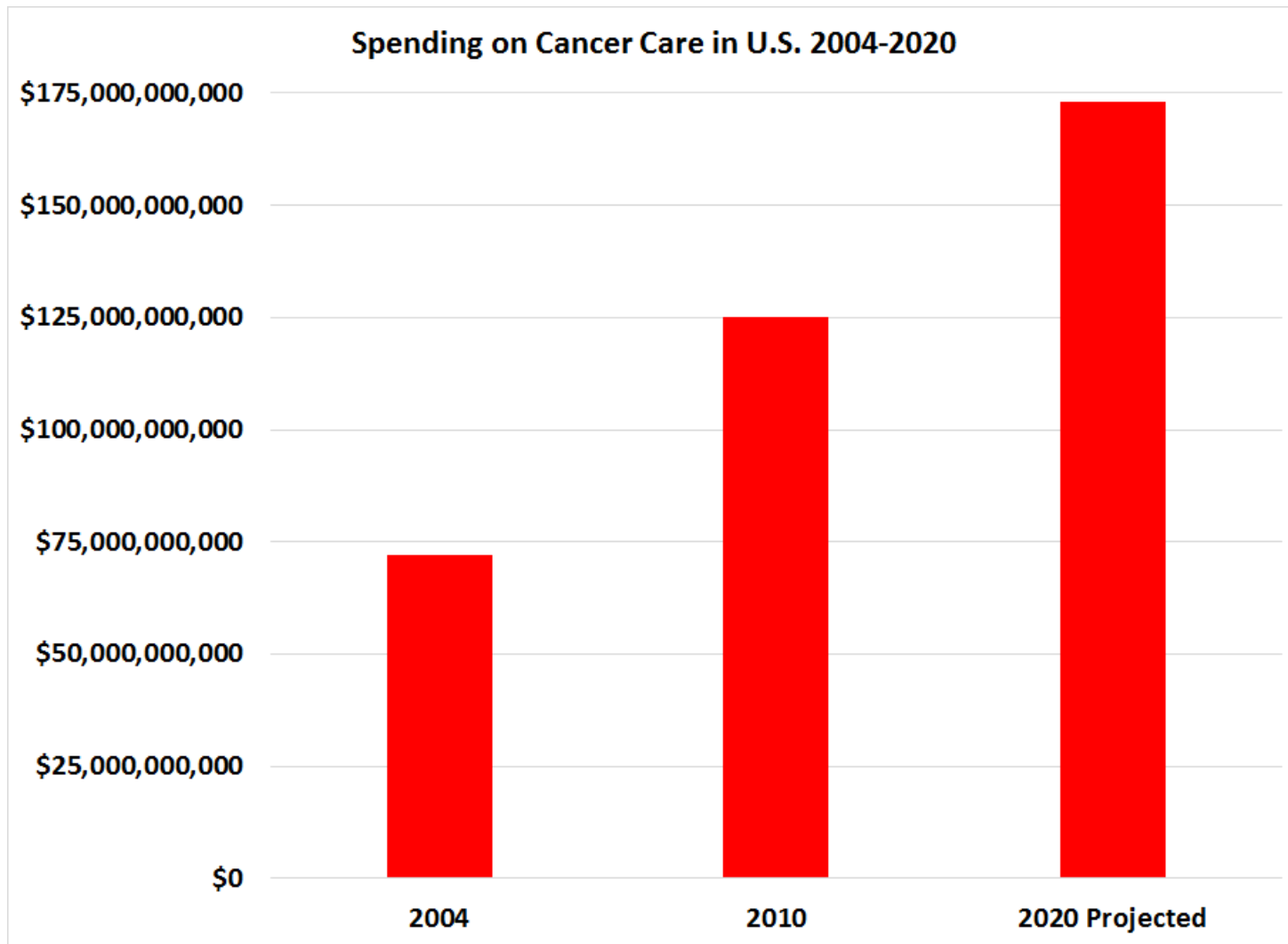


**BETTER CANCER CARE
AT LOWER COST**

**Patient-Centered Oncology Payment
That Supports Higher Quality,
Lower Spending, and
Financially Viable Oncology Practices**

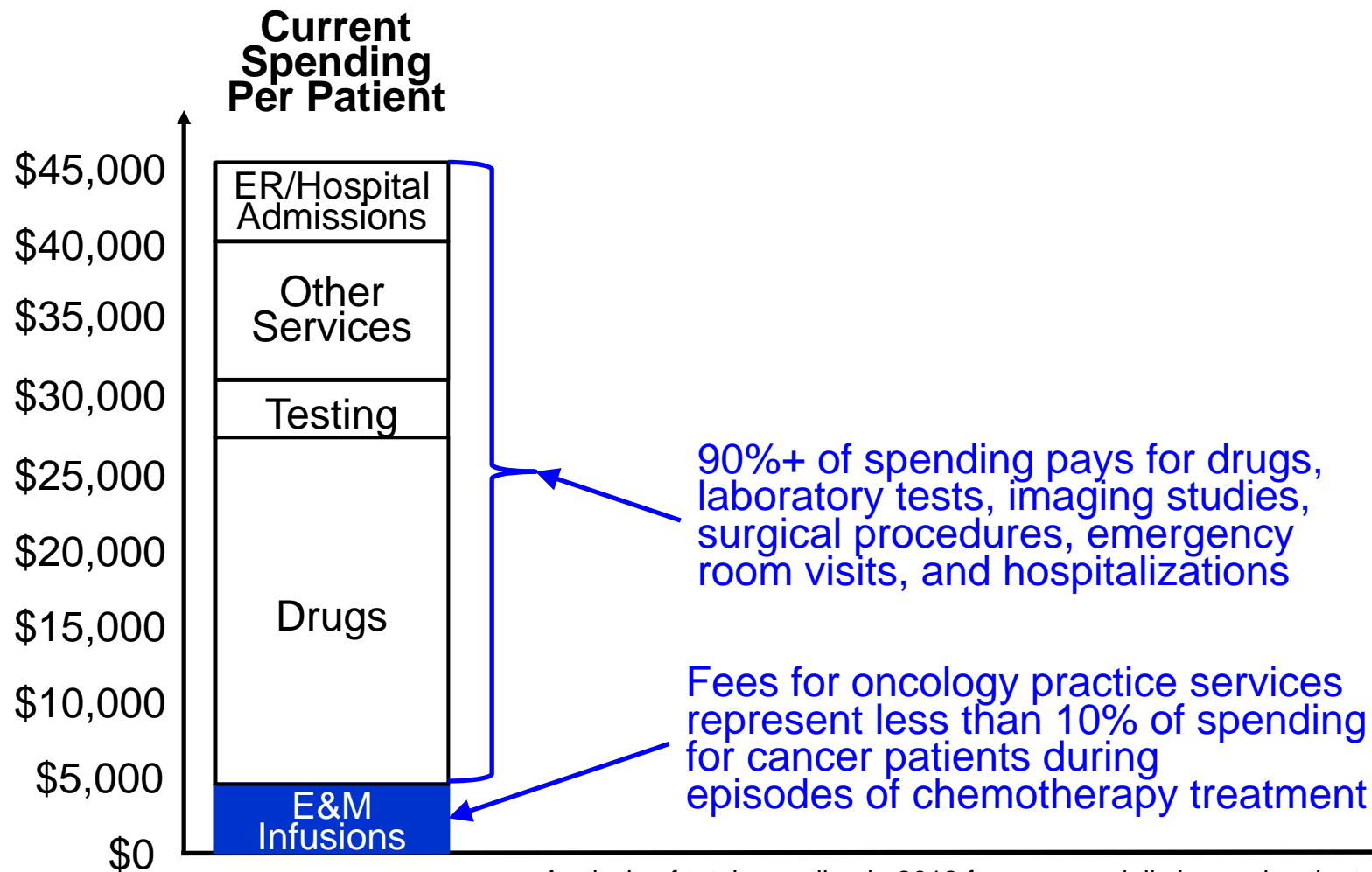


How Can You Control Cancer Spending w/o Harming Patients?





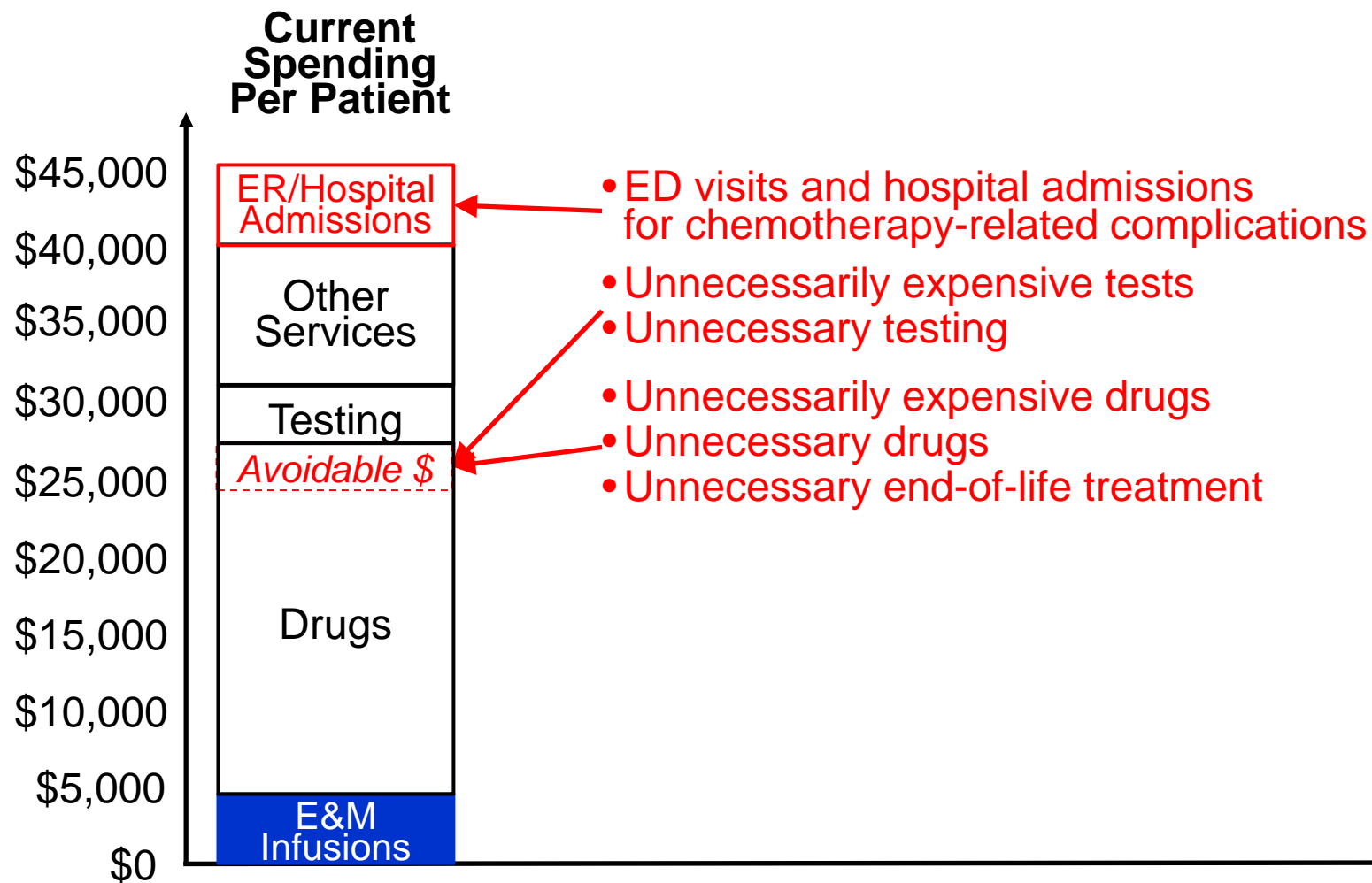
Drivers of Oncology Spending



Analysis of total spending in 2012 for commercially insured patients during an "episode" of chemotherapy treatment (treatment months through the second month after treatment ends)



Opportunities to Reduce Spending Without Harming Patients





Large Savings Possible From Reducing Avoidable Spending

Avoiding Emergency Room Visits and Hospitalizations

- An oncology medical home project used clinical nurse triage management and enhanced access to care in the oncology practice to reduce (total) emergency room use and total hospital admissions by over 50%.

(Sprandio JD, Flounders BP, Tofani S. Data-Driven Transformation to an Oncology Patient-Centered Medical Home. *Journal of Oncology Practice* 9(3):130. May 2013.)

Improving Appropriate Use of Drugs

- Chemotherapy spending for Medicare patients ranged from \$11,059 per patient for oncology practices in the lowest spending quartile to \$18,044 per patient for practices in the highest-spending quartile, a range of \$6,985. Over 1/3 of the variation (\$3,600) stemmed from variation in the use of just two drugs – Neulasta (pegfilgrastim) and Avastin (bevacizumab).

(Clough JD et al. Wide Variation in Payments for Medicare Beneficiary Oncology Services Suggests Room for Practice-Level Improvement. *Health Affairs* 34(4): 601. April 2015.)

- A study of the use of Neulasta (pegfilgrastim) at an outpatient oncology clinic found that approximately half of all cases using pegfilgrastim for primary prophylaxis were not consistent with published guidelines, representing an avoidable cost of \$8,093 per patient.

(Waters GE et al. Comparison of Pegfilgrastim Prescribing Practice to National Guidelines at a University Hospital Outpatient Oncology Clinic. *Journal of Onc. Practice* 9(4):203. July 2013.)

- A study of the use of myeloid colony-stimulating factors (CSF) such as pegfilgrastim in lung and cancer patients found that 96% of CSFs were administered in scenarios where CSF therapy is not recommended by evidence-based guidelines.

(Potosky AL et al. Use of Colony-Stimulating Factors With Chemotherapy: Opportunities for Cost Savings and Improved Outcomes. *J. National Cancer Inst.* 103:979-982. June 22, 2011.)

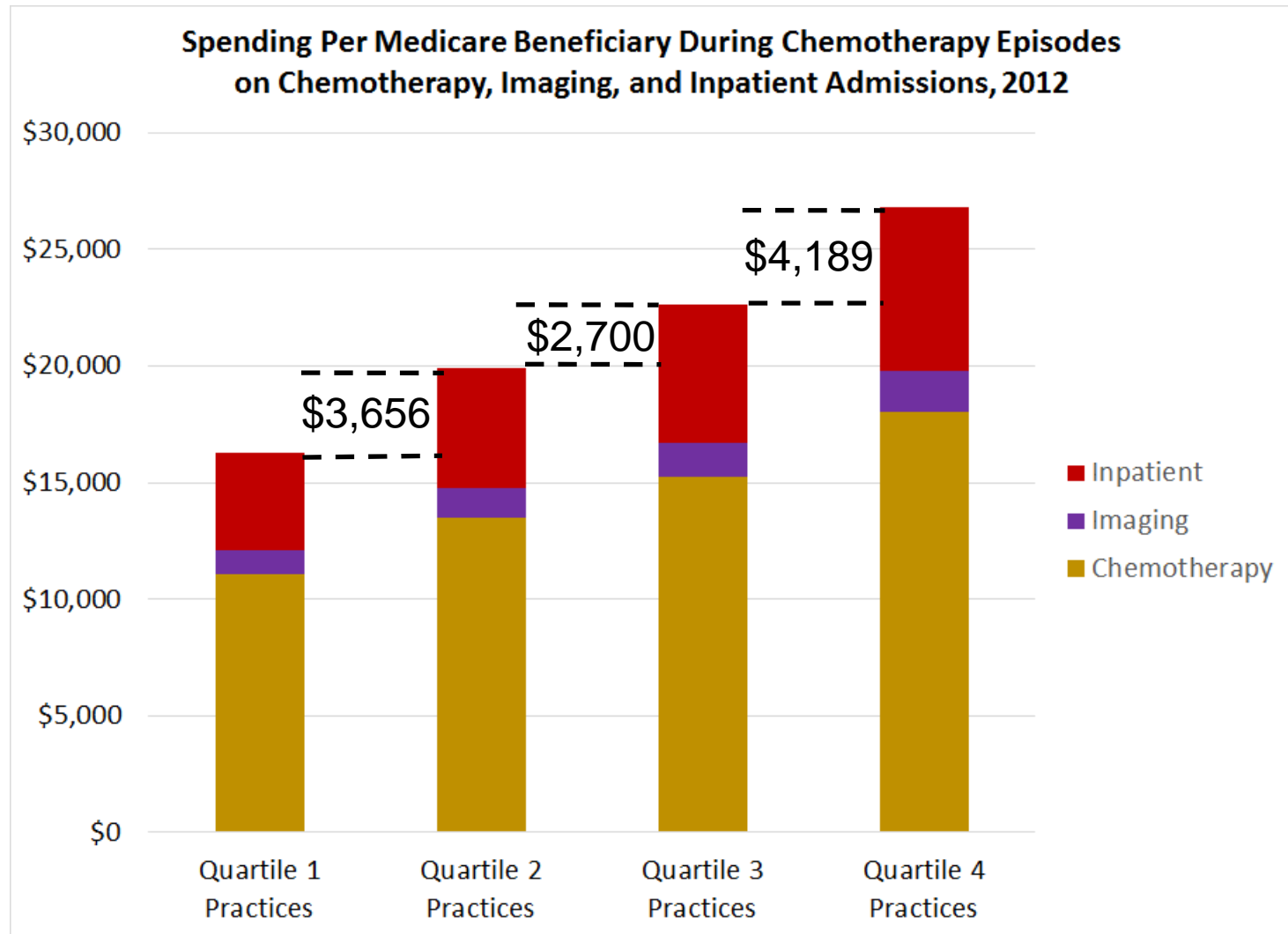
Improving End of Life Care

- A study of commercially-insured cancer patients found that patients incurred an average of \$74,212 in cancer-related expenses in the six months before death and \$25,260 was spent in the final month of life.

Chastek B, et al. Health Care Costs for Patients With Cancer at the End of Life. *Journal of Oncology Practice* 8(6s):75s. November 2012.



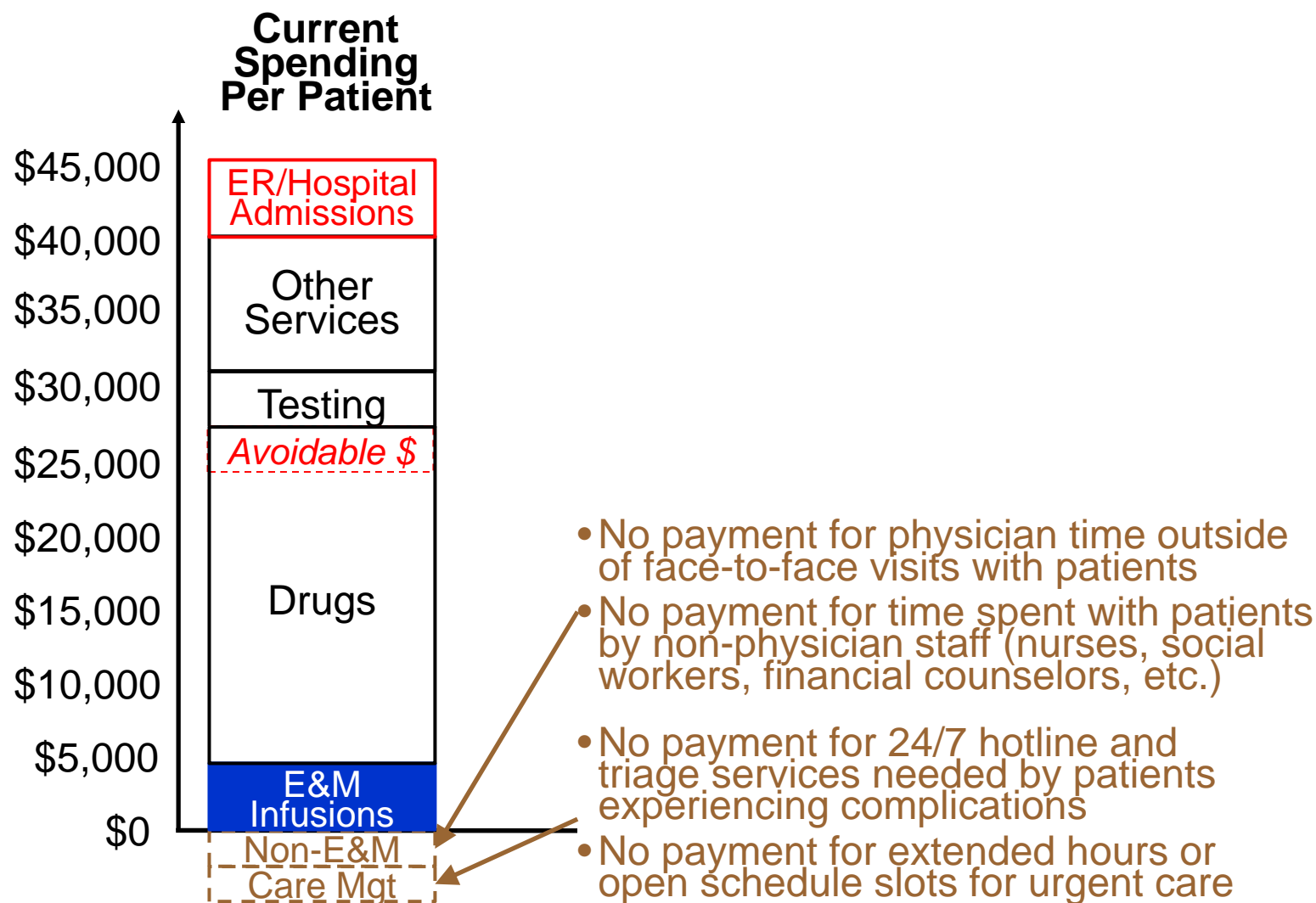
Spending on Drugs, Imaging, and Hospitals Varies by More Than 60%



Source:
Clough, Patel, Riley,
Rajkumar, Conway,
Bach.
"Wide Variation in
Payments for
Medicare
Beneficiary
Oncology Services
Suggests Room for
Practice-Level
Improvement."
Health Affairs,
April 2015

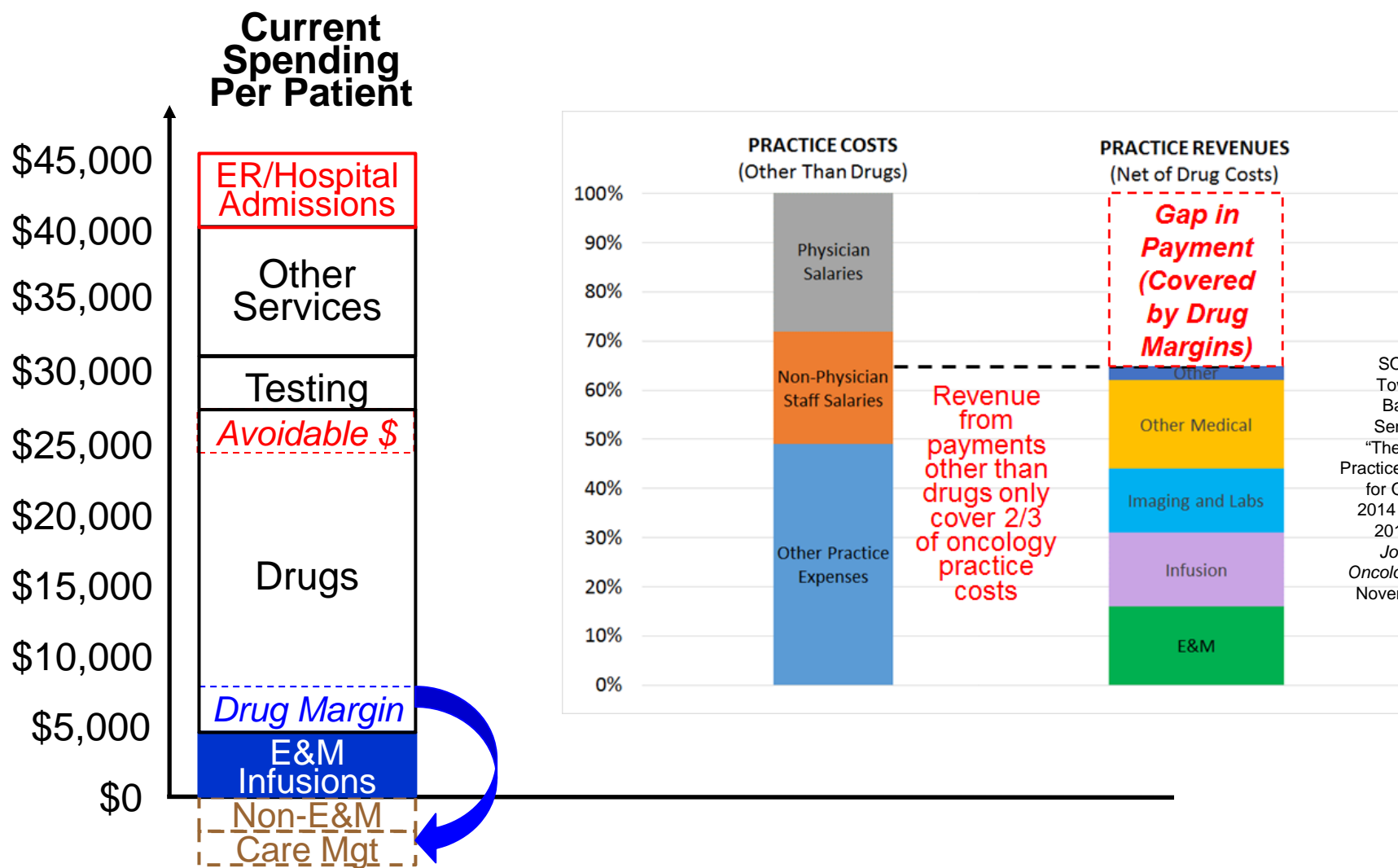


Current Payments Do Not Support Patient-Centered Cancer Care





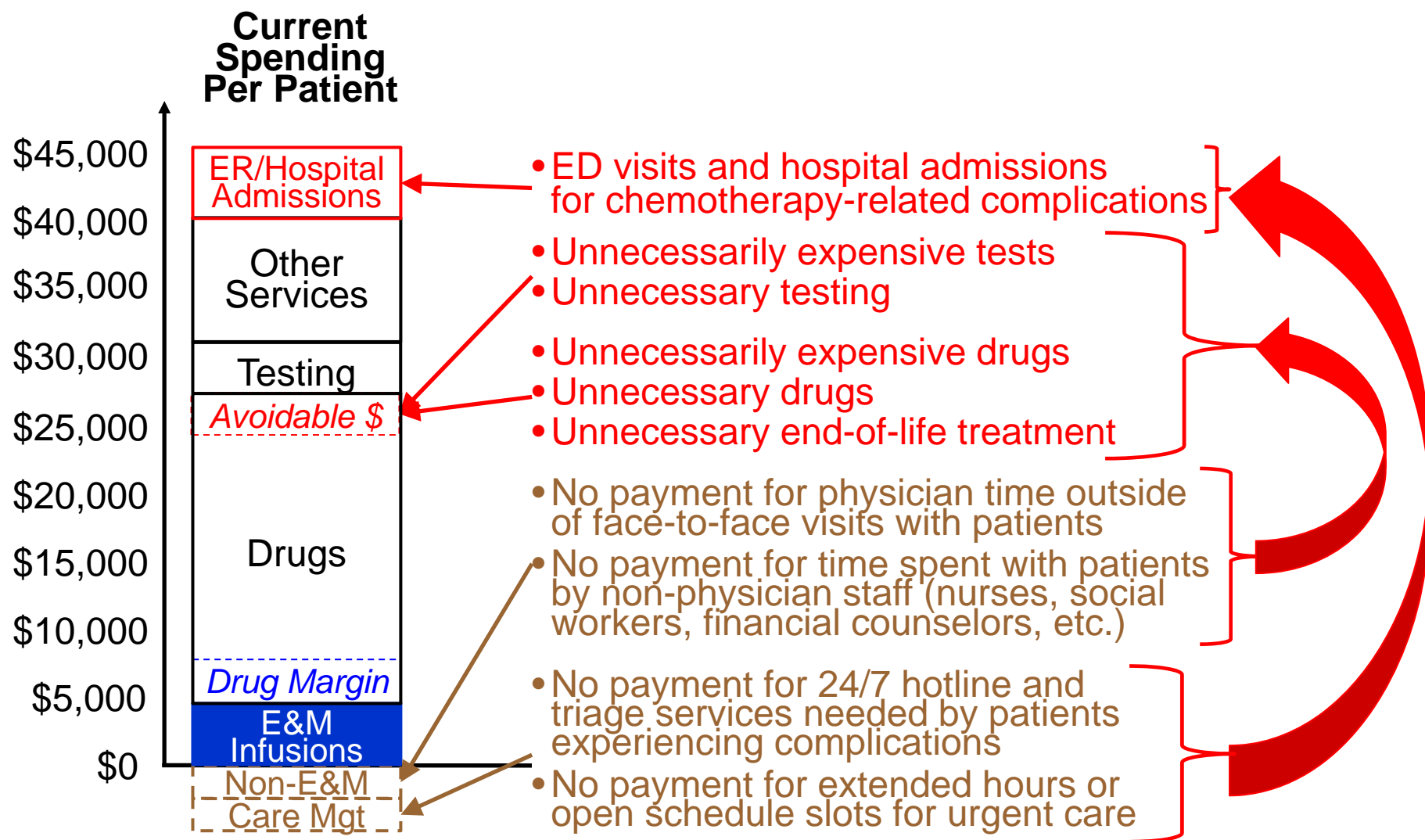
Practices Depend on Drug Margins to Support Unbillable Services



SOURCE:
Towle EL,
Barr TR,
Senese JL,
"The National
Practice Benchmark
for Oncology,
2014 Report on
2013 Data"
Journal of
Oncology Practice
November 2014

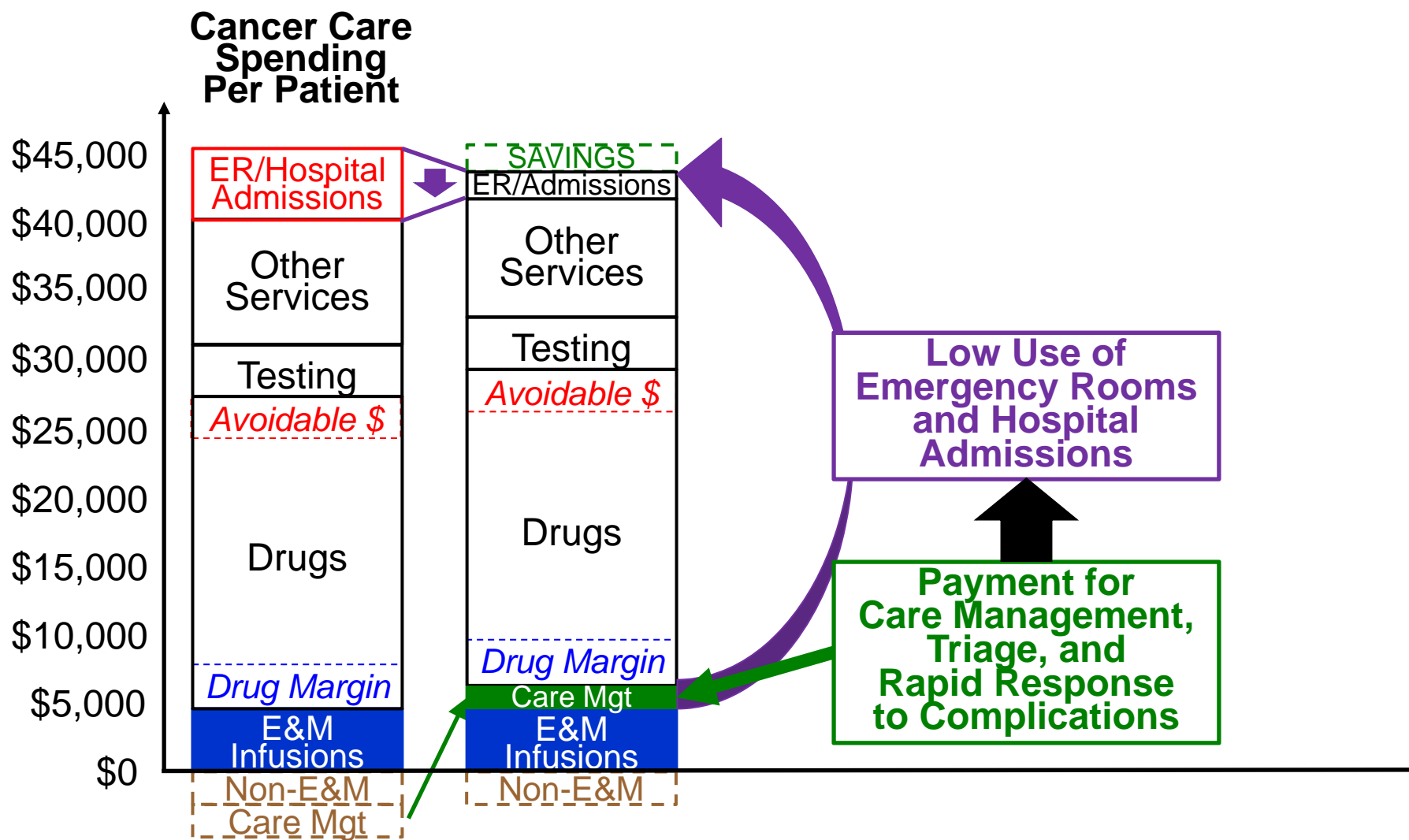


Failure to Pay for Good Care Leads to Costly, Low-Value Services



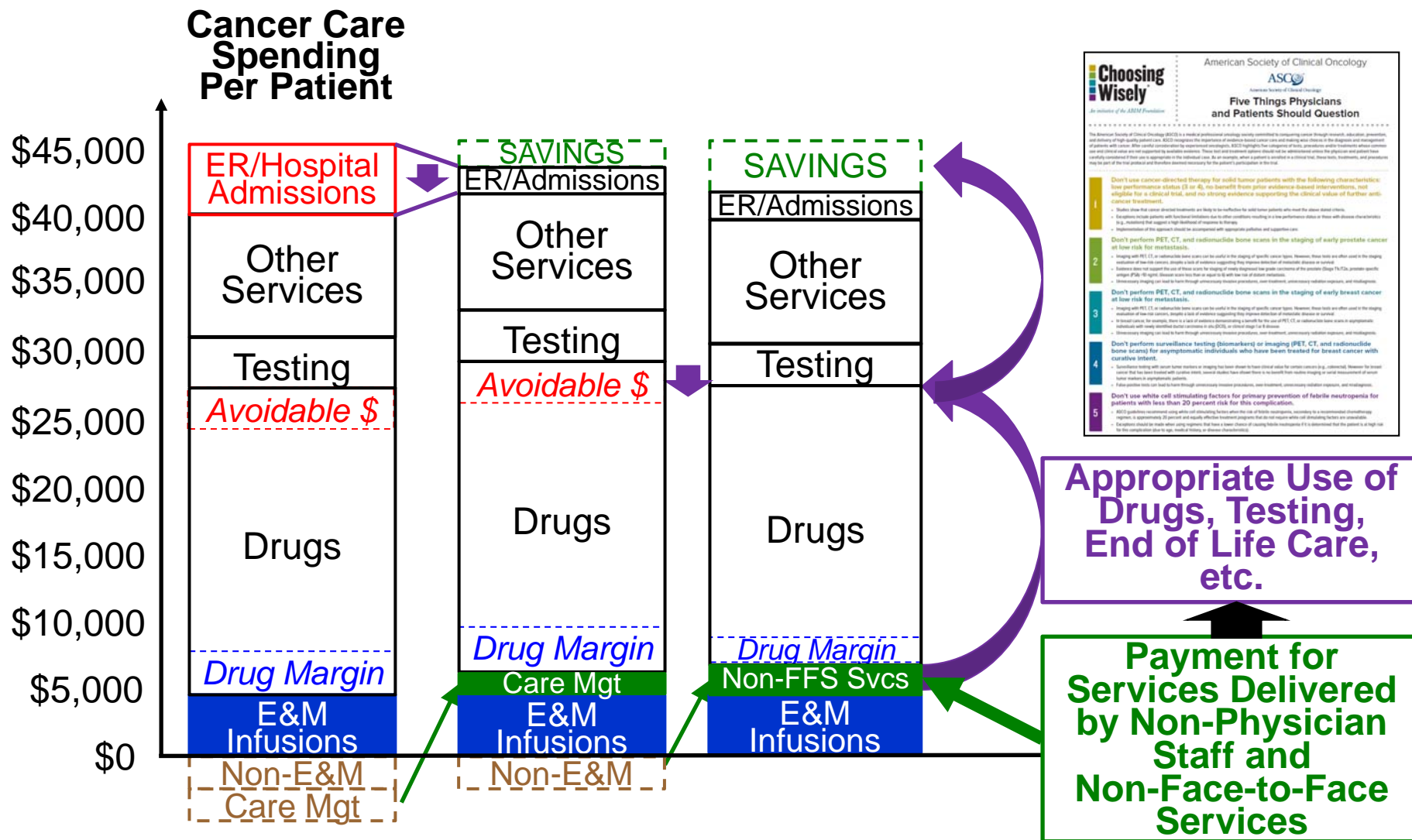


Goal #1: Pay for Care Mgt to Prevent ER Visits & Admits





Goal #2: Pay for Services Needed to Support Value-Based Treatment



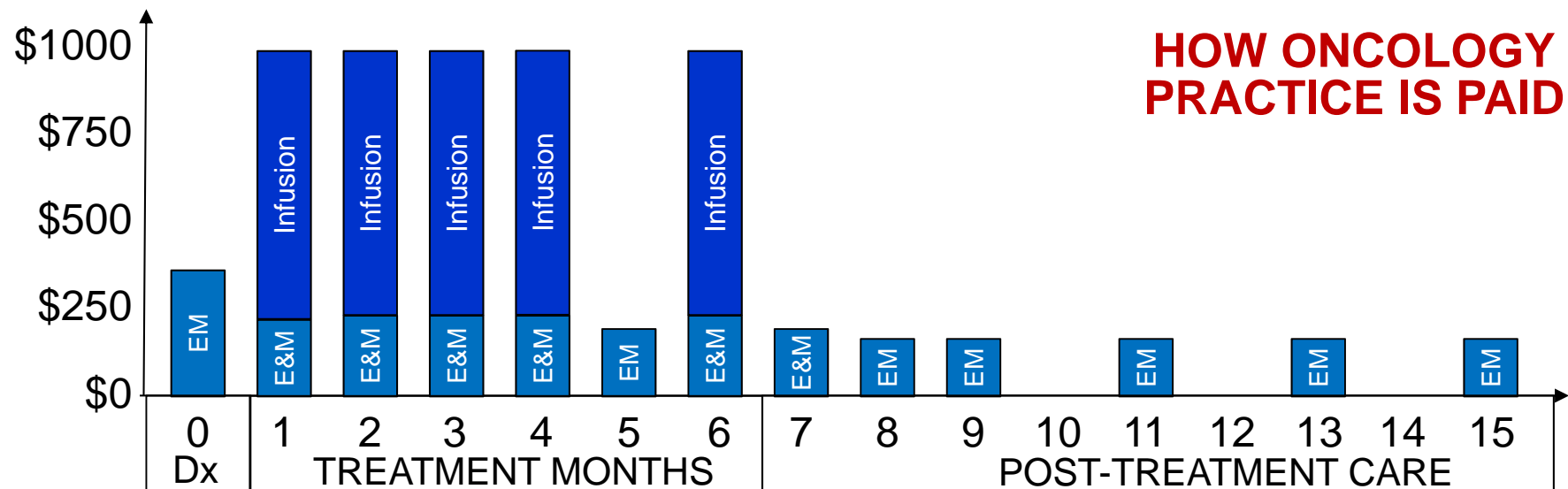
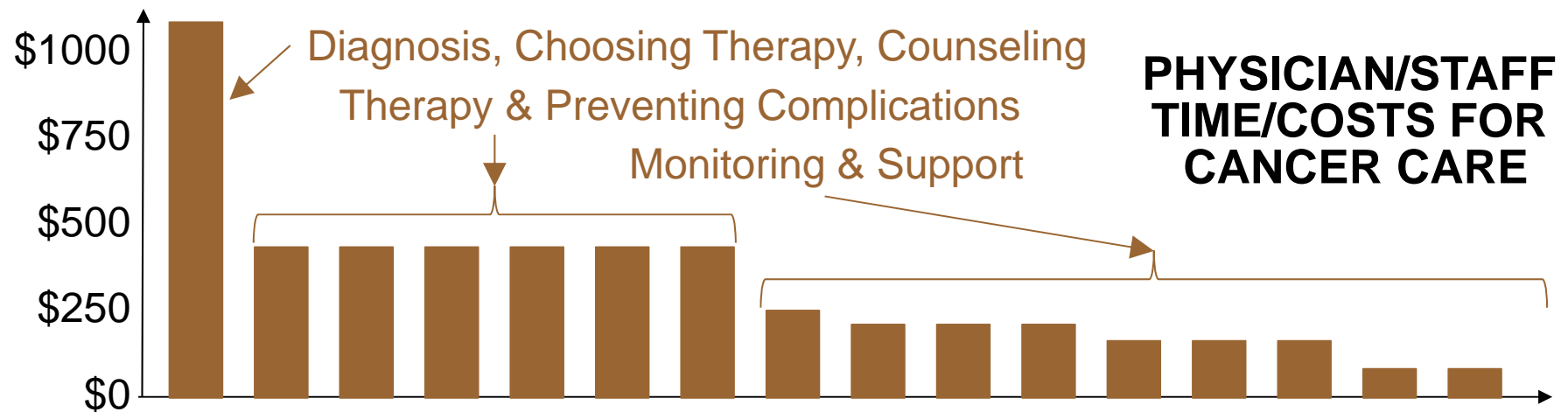
Choosing Wisely
American Society of Clinical Oncology

Five Things Physicians and Patients Should Question

1. Don't use cancer-directed therapy for solid tumor patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment.
2. Evaluate how the cancer directed treatment are likely to reflect on solid tumor patients who meet the above stated criteria.
3. Evaluate which patients with low-risk prostate cancer can be spared the toxicity of prostatectomy or radiation therapy.
4. Don't perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.
5. Don't use while cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20 percent risk for this complication.

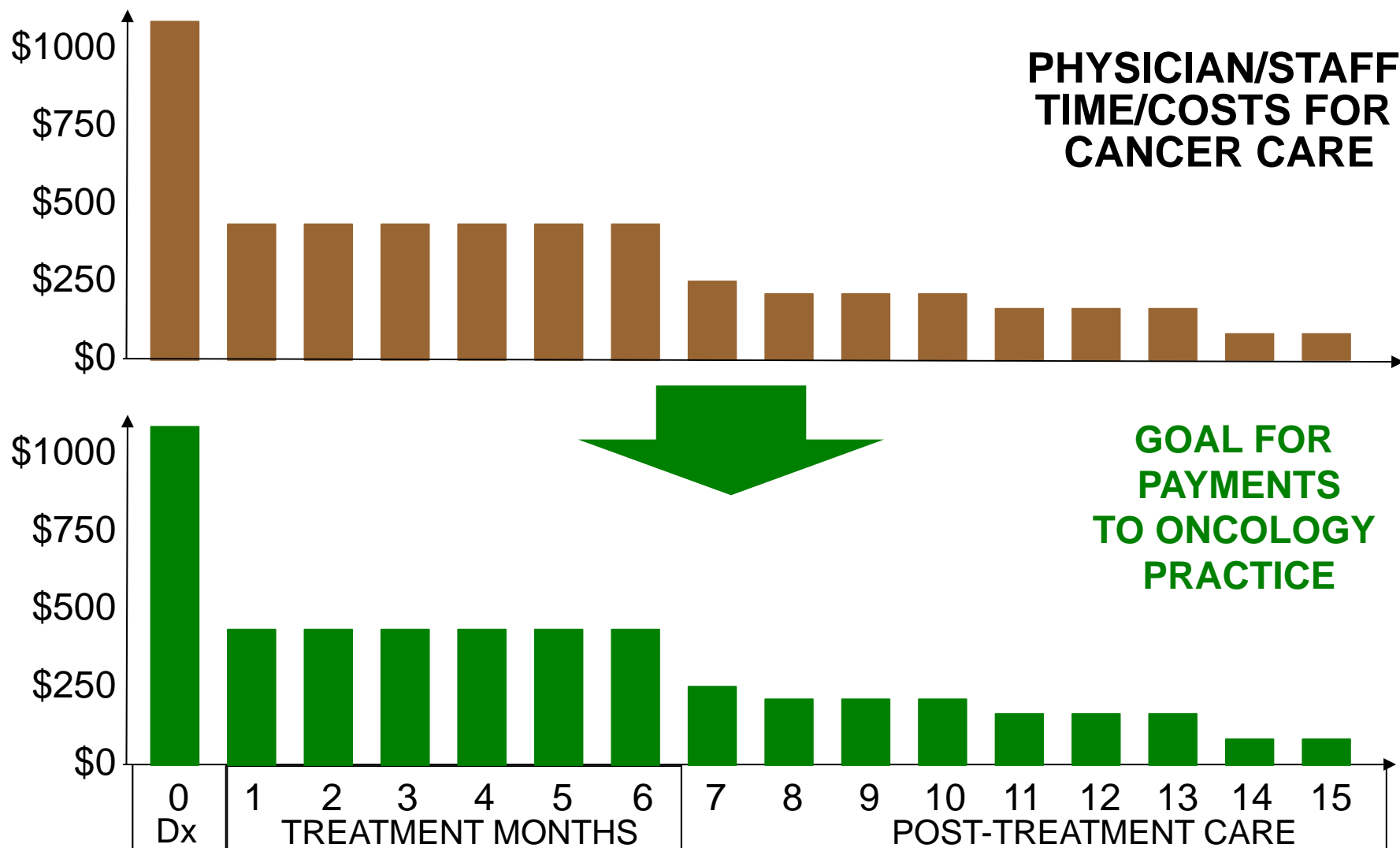


Practices Are Underpaid for Services Before & After Treatment





Goal #3: Align Payments With How Services Are Delivered

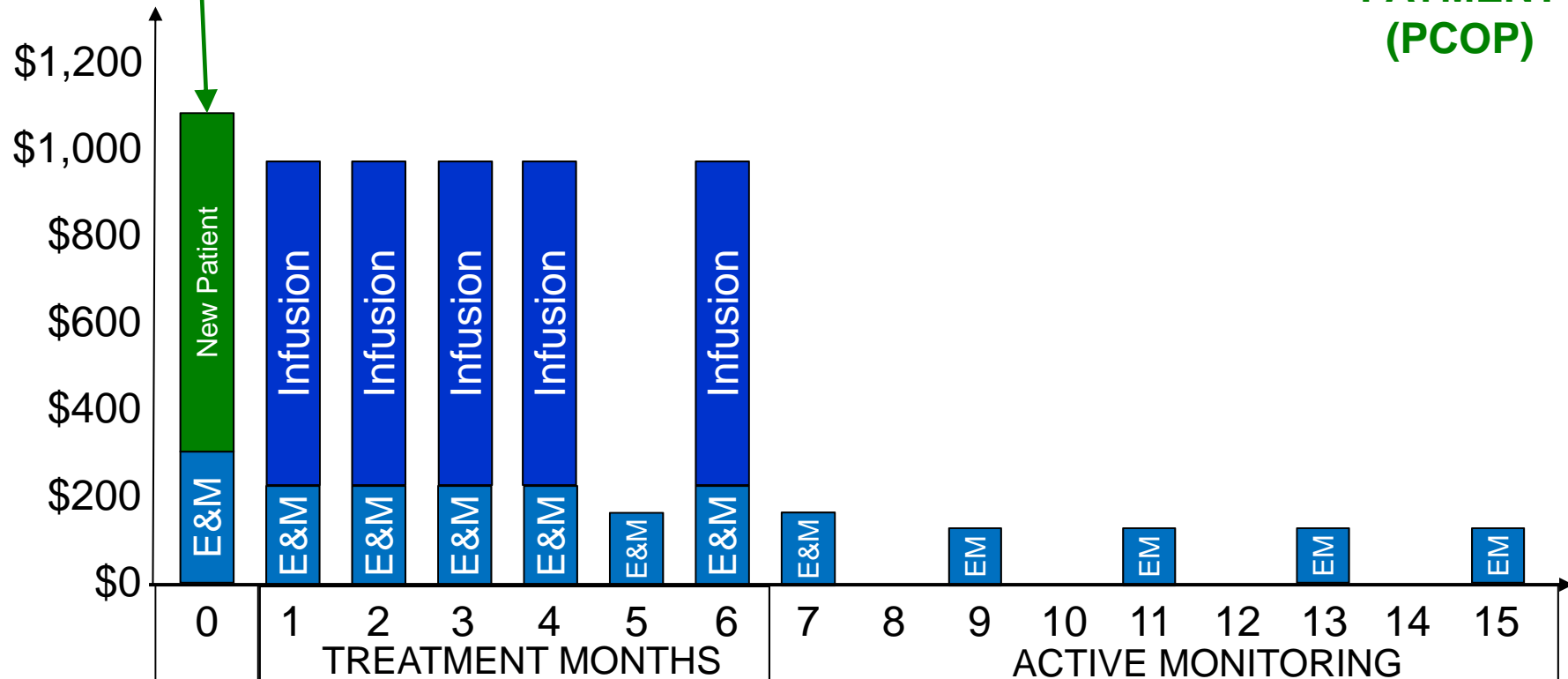




Step 1. Significant New Payment During Crucial Planning Stage

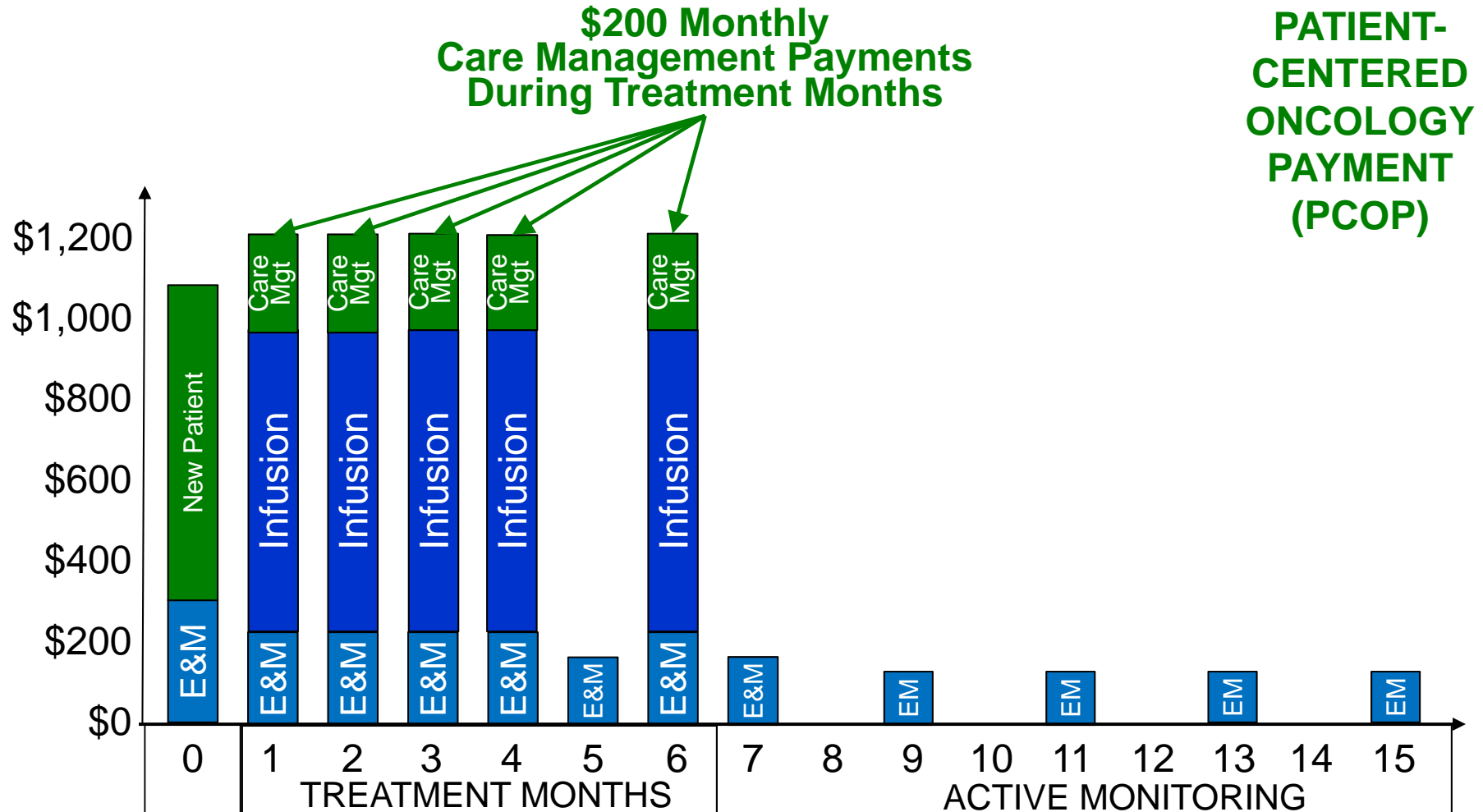
Additional \$750
One-Time Payment
for Each New Patient

PATIENT-CENTERED
ONCOLOGY
PAYMENT
(PCOP)



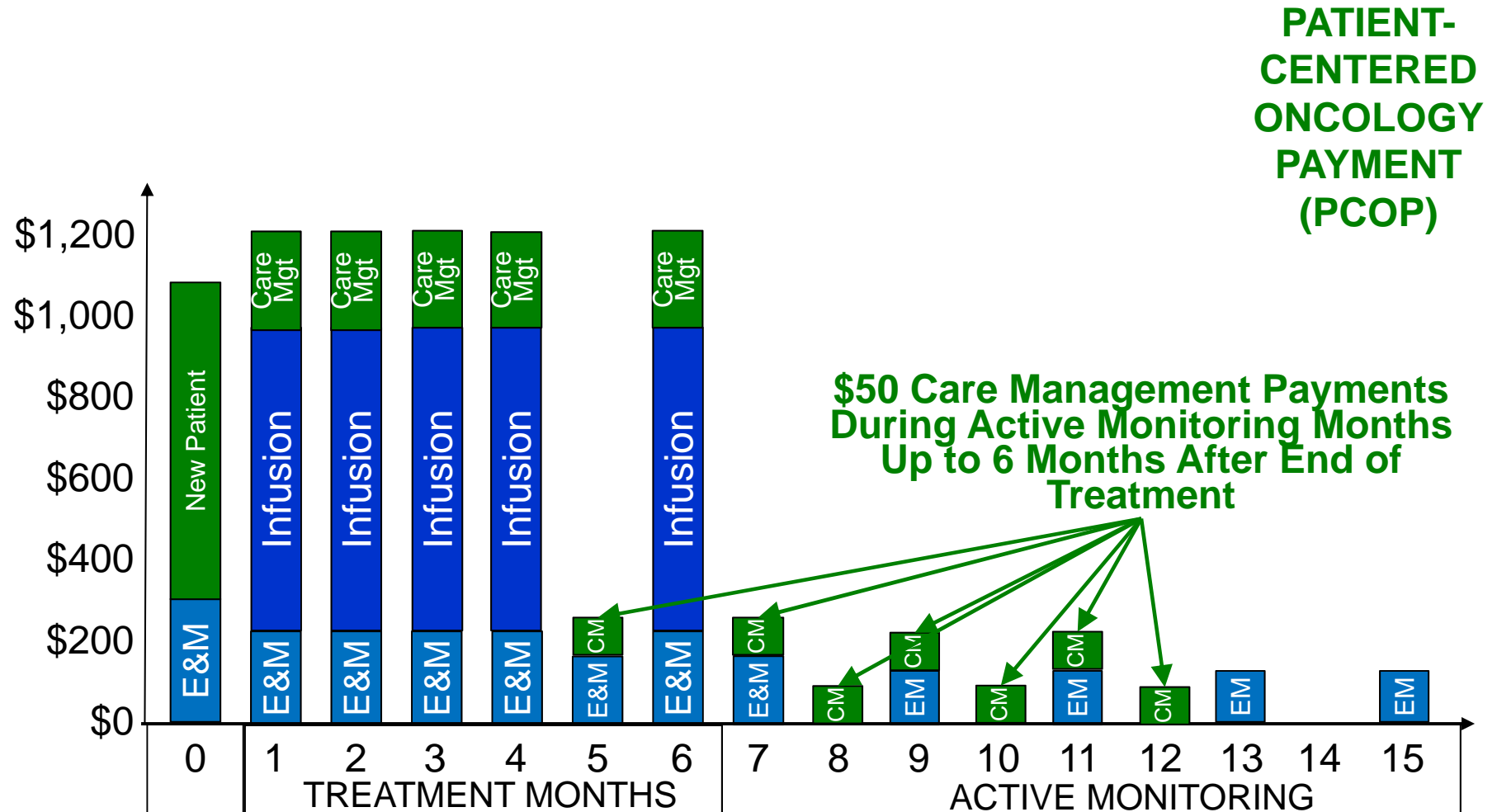


Step 2. Flexible Care Management Payments During Treatment



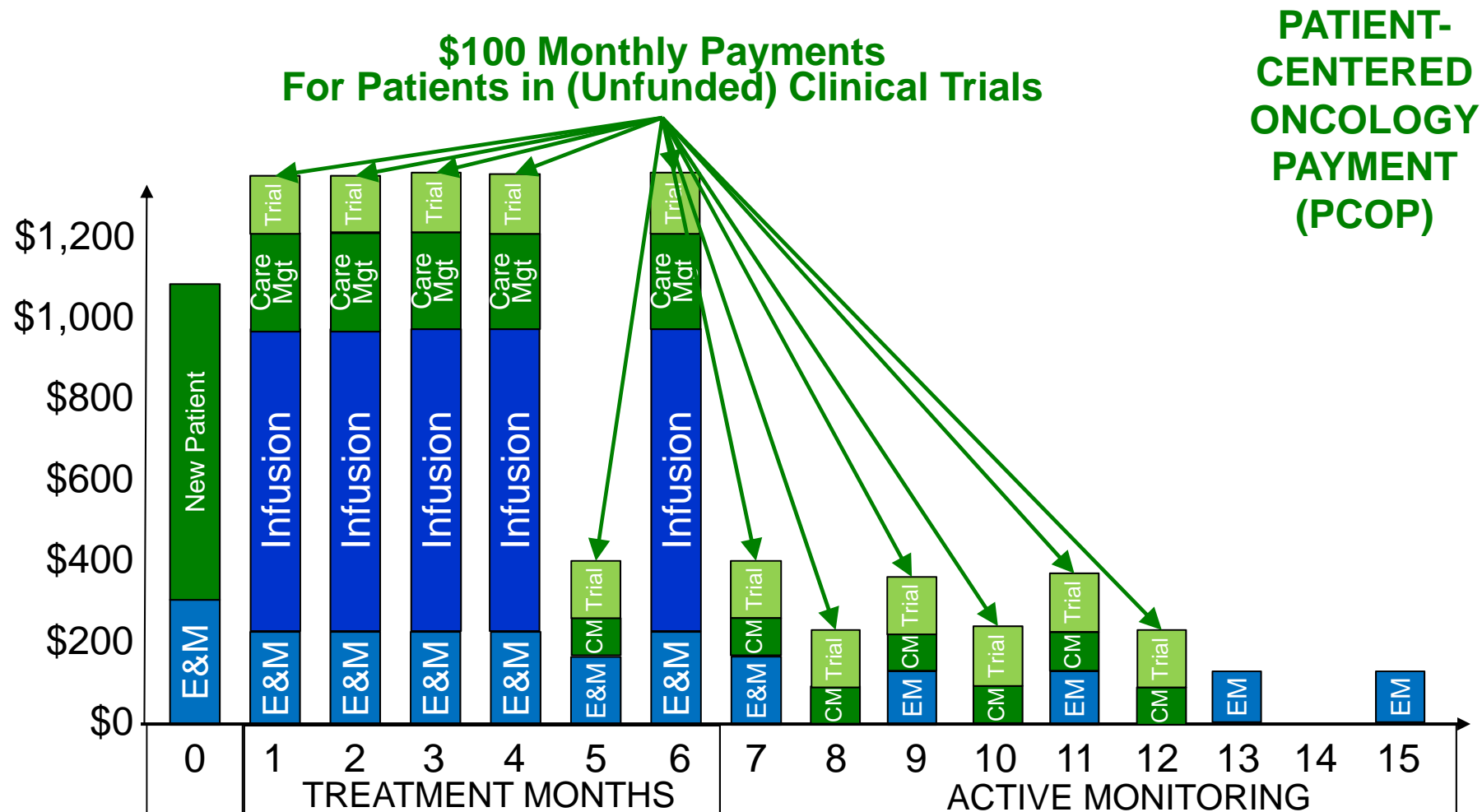


Step 3. Smaller Care Management Payments After Treatment Ends



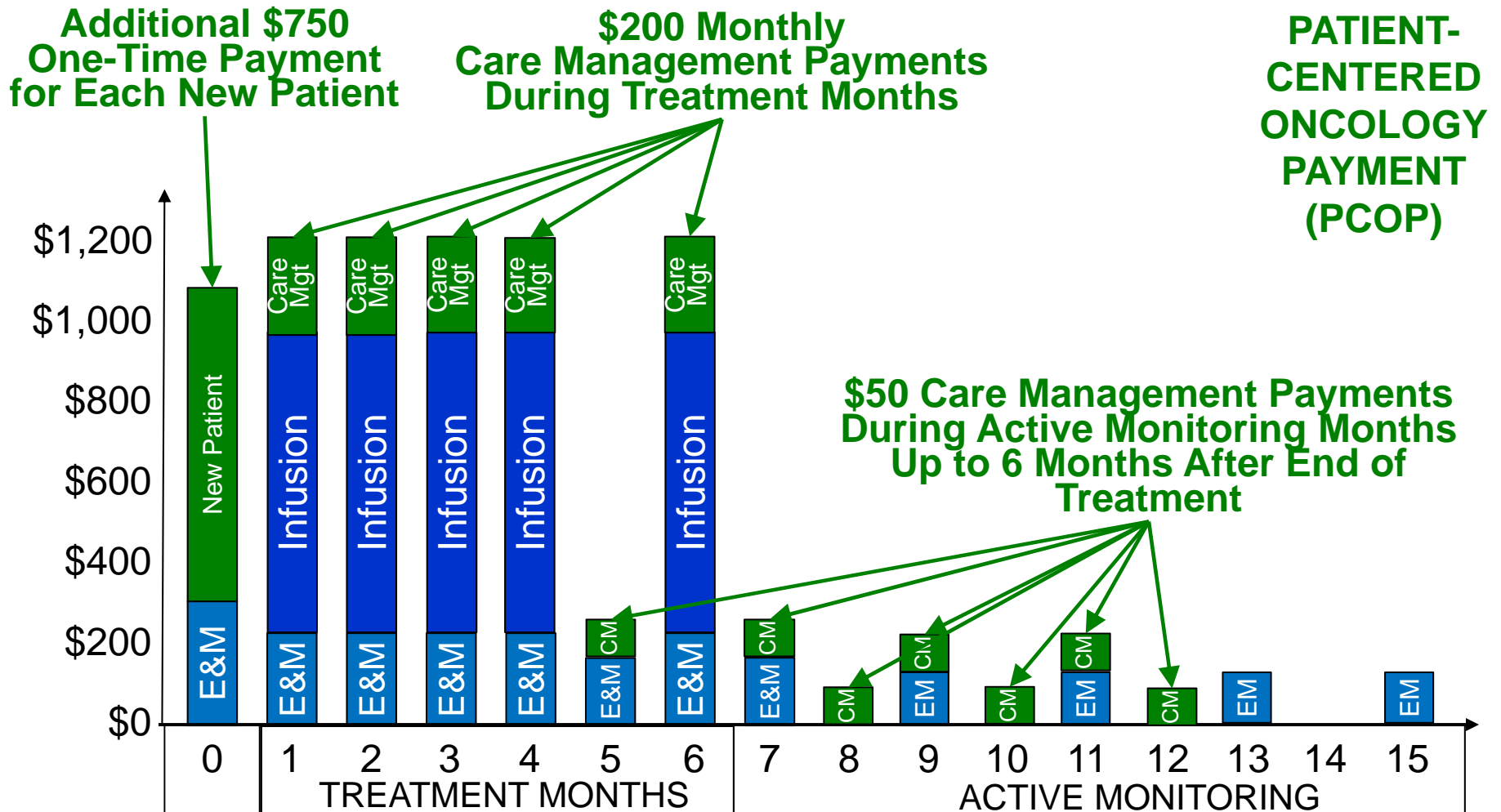


Step 4. Monthly Payments for Patients on Unfunded Clinical Trials



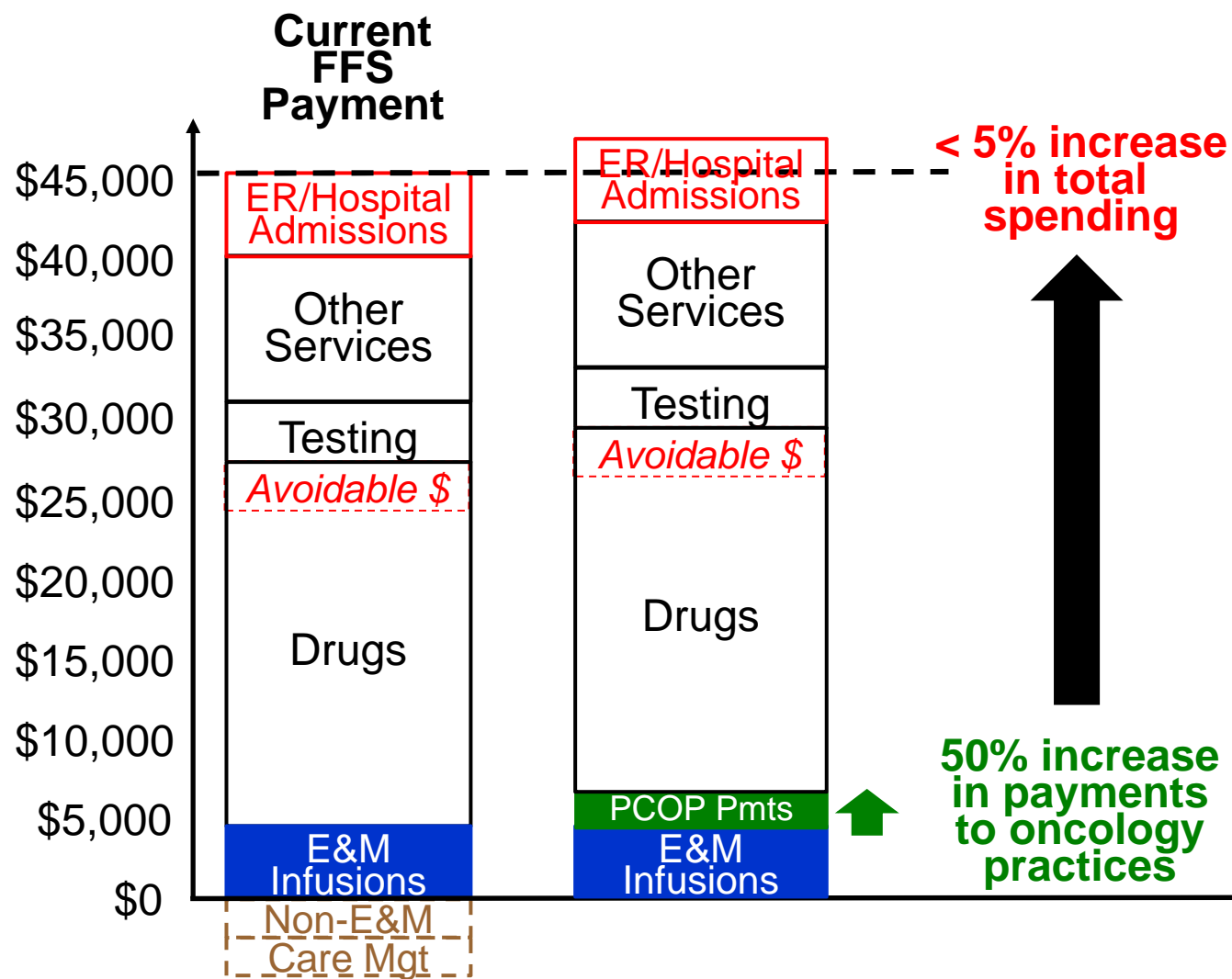


~\$2,100/patient more from PCOP; 50% Increase from FFS Today



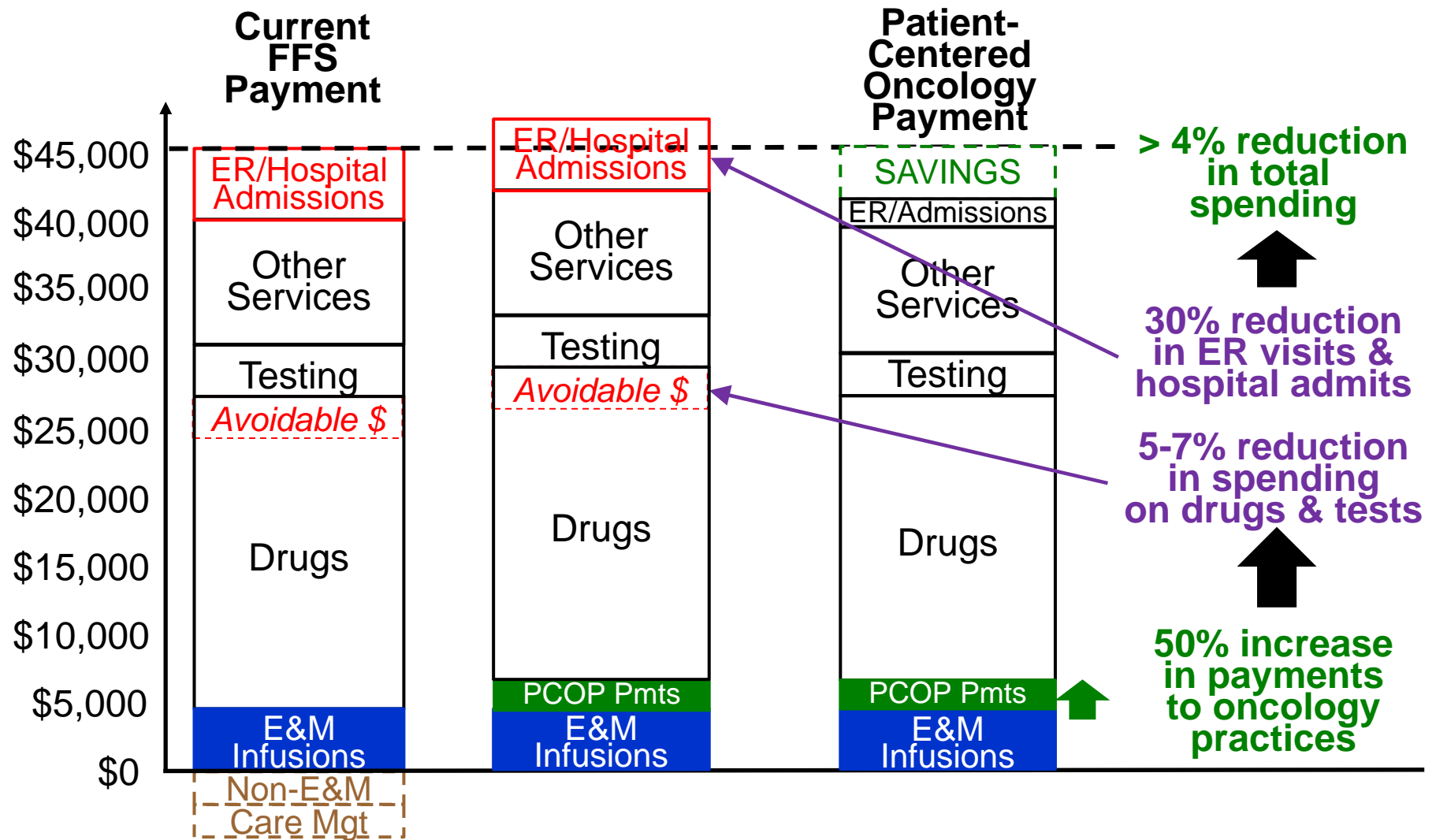


Large Increase for *Practices* is a Small Increase in *Total* Spending





Reductions in Avoidable Spending Will More Than Offset New Pmts






Analysis of PCOP Shows Large Net Savings from Better Payment

THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

PATIENT-CENTERED ONCOLOGY PAYMENT

Payment Reform to Support
Higher Quality, More Affordable Cancer Care

May 2015



American Society of Clinical Oncology

www.asco.org/paymentreform

Costs and Savings from Patient-Centered Oncology Payment			
	Current Average Spending Per Beneficiary	With Proposed New Payments and Estimated Savings	% Change
Month Prior to Treatment			
E&M Services	\$296	\$296	
PCOP		\$750	
During and 2 Months After Treatment			
E&M Services	\$2,071	\$2,071	
Infusion Services	\$1,904	\$1,904	
PCOP		\$1,190	
Chemotherapy/Drugs	\$25,131	\$23,372	-7%
Lab Tests	\$583	\$553	-5%
Imaging	\$1,503	\$1,428	-5%
ED/Ambulance	\$421	\$295	-30%
Inpatient	\$7,100	\$4,970	-30%
Other	\$10,920	\$10,920	0%
Months 3-6 After Treatment			
E&M Services	\$120	\$120	
PCOP		\$220	
Total	\$50,048	\$48,089	-3.9%

For 500 New Patients:	
Additional Practice Revenues	\$1,080,000
Net Payer Savings	\$979,802



New Billing Codes Will Be Easy for Payers & Practices to Implement

- **New Billing Code for New Patient Treatment Planning**

The oncology practice would bill the payer for a \$750 payment for each new oncology patient who begins treatment or active management with the practice.

- **New Billing Code for Care Management During Treatment**

The oncology practice would bill the payer for a \$200 payment for each month in which an oncology patient is receiving parenteral or oral anti-cancer treatment prescribed by the practice. This payment would also be made for patients who are in hospice if the oncologist is the hospice physician.

- **New Billing Code for Care Management During Active Monitoring**

The oncology practice would bill the payer for a \$50 per month payment when an oncology patient was not receiving anti-cancer treatment but was being actively monitored by the practice. This would include any months in which treatment was not received before a treatment regimen was completed and up to six months after the completion of treatment.

- **New Billing Code for Participation in Clinical Trials**

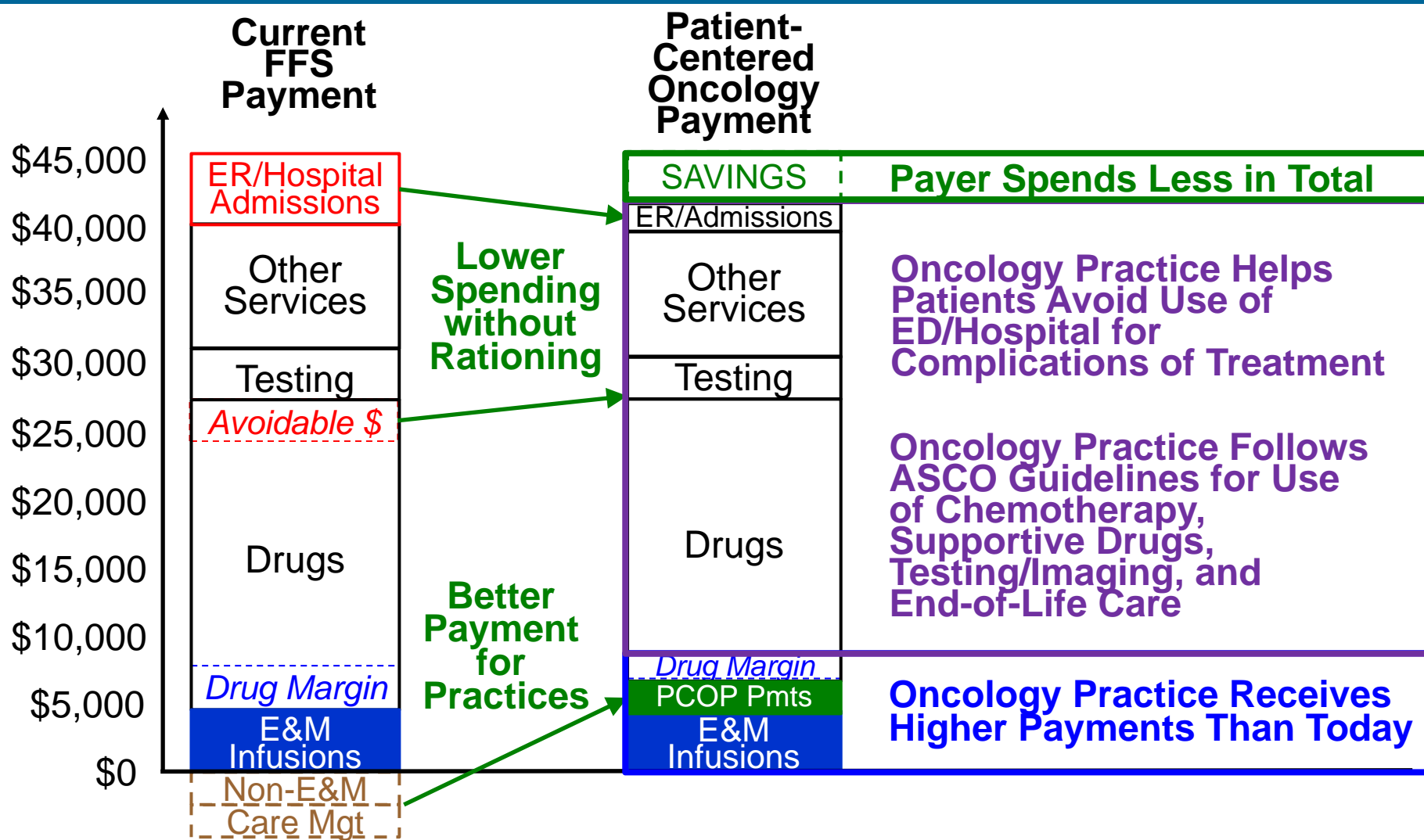
The oncology practice would bill the payer for a \$100 payment for each month in which a patient was participating in a clinical trial (for treatment or follow-up) if the trial sponsors do not provide support for practice expenses related to participation in the trial. This would be in addition to the New Patient Treatment Planning and Care Management Payments.

- **Continuation of Current Billing Codes for Services**

The practice would continue to bill the payer for all existing CPT and HCPCS codes (e.g., E&M services, infusions, drugs administered in the practice, etc.)



PCOP is a Win-Win-Win for Patients, Payers, & Practices





Comparison of PCOP to Other Payment Reforms

	Significant and Predictable Resources for High-Value Oncology Care	Payments Match Costs By Phase and Type of Care	Payment Tied to Appropriate Use, Not Savings <i>Per Se</i>
Quality P4P	No	No	Yes
Shared Savings	No	No	No
CMMI OCM	Yes	No	No
United “Episodes”	No	No	Yes
Anthem Cancer Care Quality	Yes	No	Yes
PCOP	Yes	Yes	Yes



Why PCOP Is a Better Approach Than Shared Savings

“Shared Savings” Payment Models

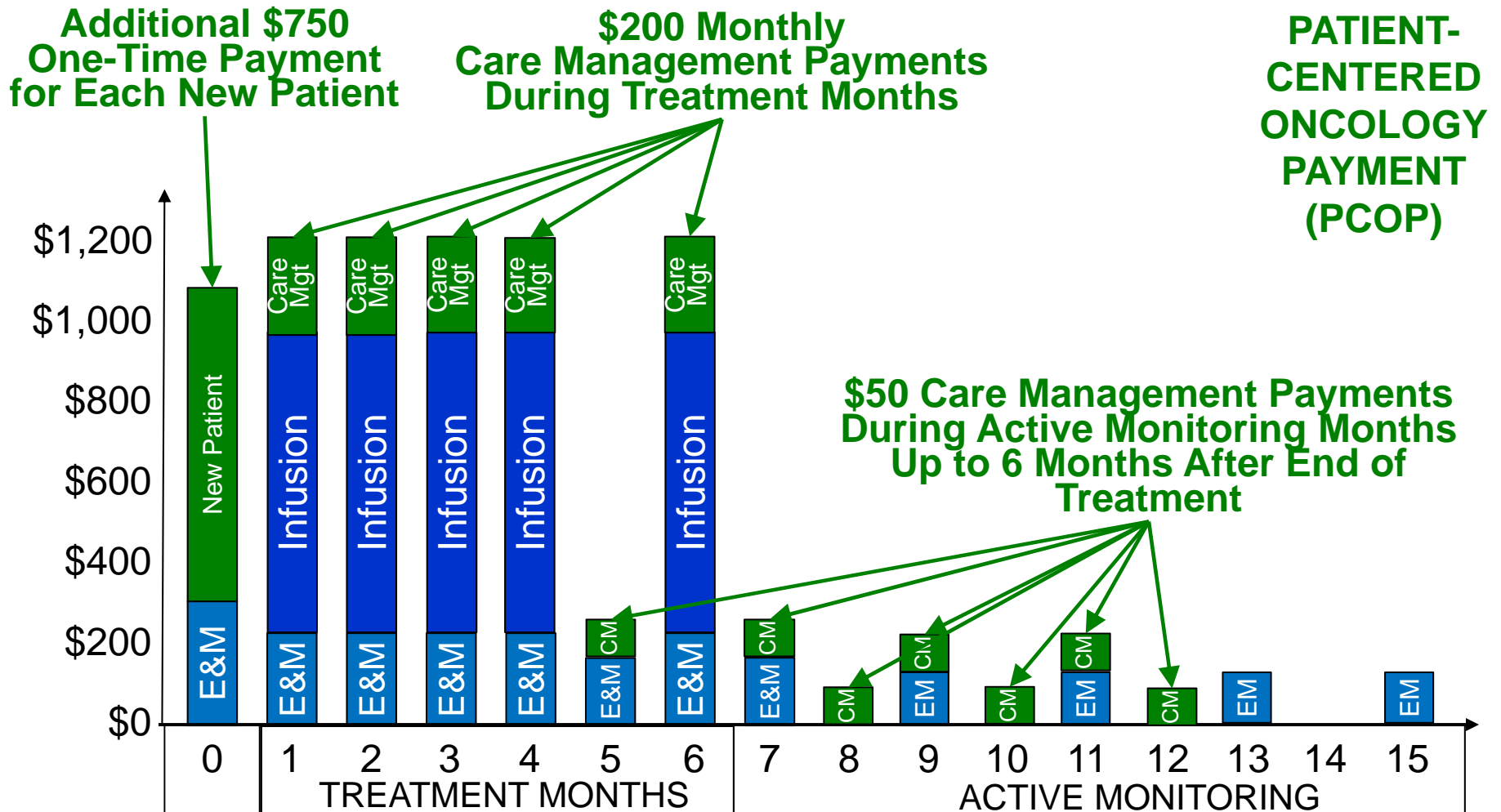
- Oncology practices only receive higher payment for improved care management if they can reduce spending
- Already efficient practices receive little or no additional revenue and may be forced out of business
- Practices that have been practicing inefficiently or inappropriately may receive more revenue than they need
- Practices could achieve savings by stinting on care as well as by reducing overuse
- Practices are placed at risk for costs they cannot control and random variation in spending

Patient-Centered Oncology Payment (PCOP)

- Oncology practices receive adequate payment to cover costs of high-value patient services regardless of total spending
- Already efficient practices are able to continue operating and showing what is possible from high performance
- Practices that have been practicing inefficiently or inappropriately generate significant savings for payers
- Patients are protected because savings are generated by delivery of appropriate care
- Practices are only accountable for services/costs they can control

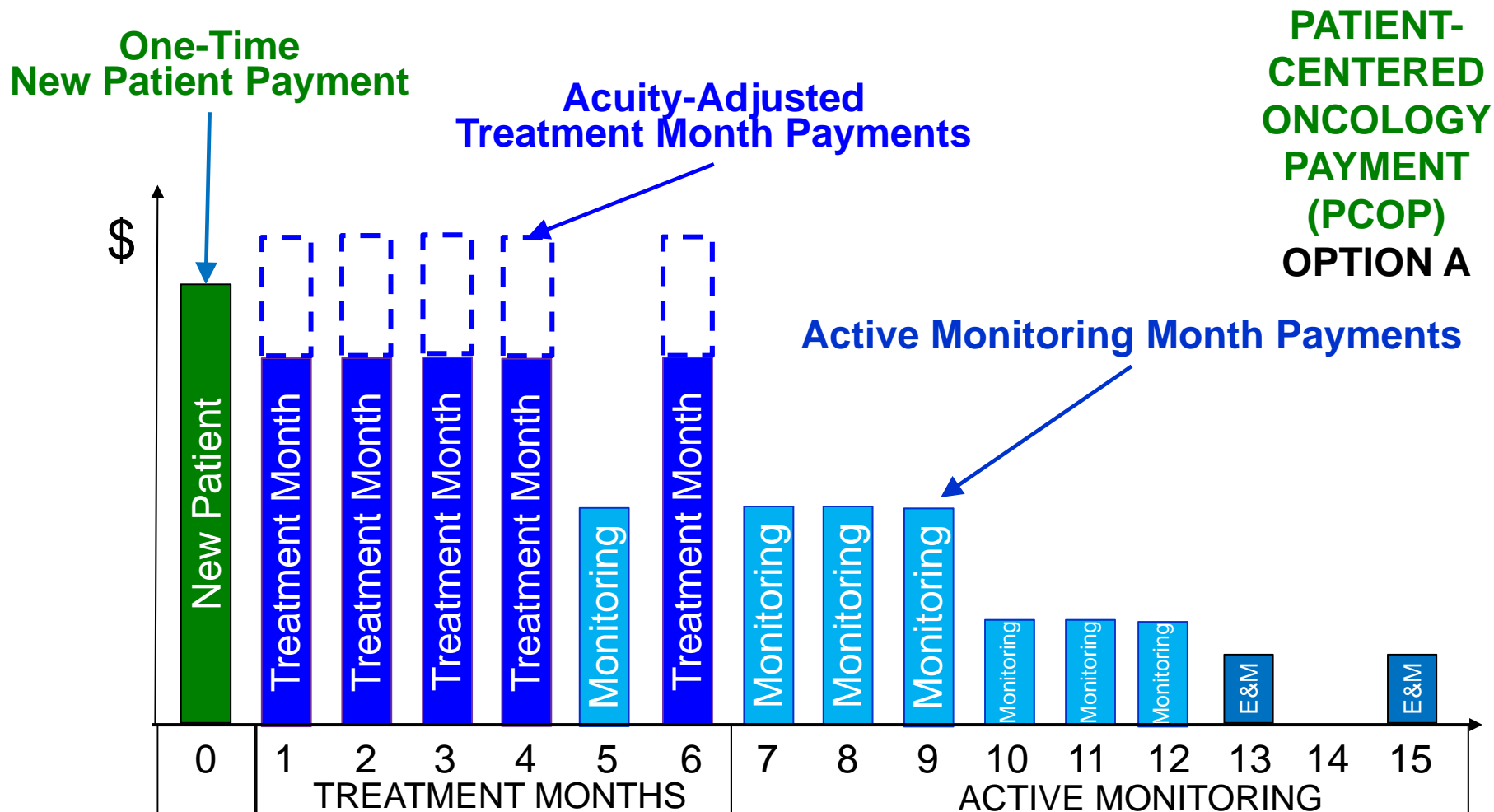


Basic PCOP Model Improves But Does Not Replace Current FFS





PCOP Option A: Consolidate Existing and New Payments





Dramatic Simplification of Coding and Billing

50+ Current Billing Codes

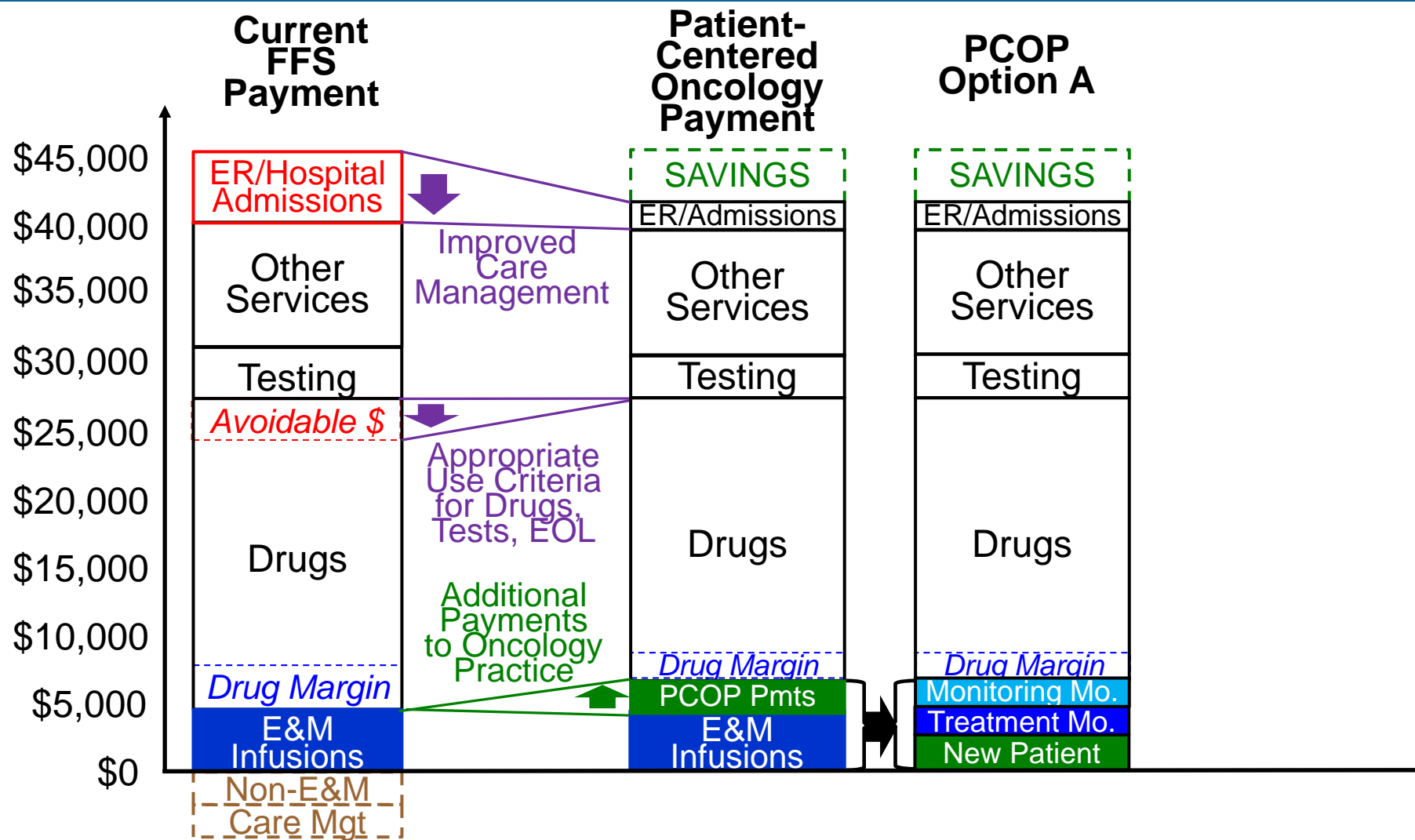
99211 Established Patient Office Visit – Level 1	96521 Refilling and maintenance of portable pump
99212 Established Patient Office Visit – Level 2	96522 Refilling and maintenance of implantable pump
99213 Established Patient Office Visit – Level 3	96523 Irrigation of implanted venous access device
99214 Established Patient Office Visit – Level 4	96542 Chemotherapy injection via subcutaneous reservoir
99215 Established Patient Office Visit – Level 5	96549 Unlisted chemotherapy procedure
99231 Subsequent Hospital Care – Level 1	79005 Oral radiopharmaceutical therapy
99232 Subsequent Hospital Care – Level 2	79101 Radiopharmaceutical infusion
99233 Subsequent Hospital Care – Level 3	79200 Radiopharmaceutical intracavitary administration
96401 Subcutaneous chemotherapy administration	79300 Radiopharmaceutical therapy
96402 Subcutaneous chemotherapy administration	79403 Radiopharmaceutical therapy infusion
96405 Intravesical chemotherapy administration	96365 Intravenous infusion, non-chemotherapy
96406 Intravesical chemotherapy administration	96366 Intravenous infusion, non-chemotherapy
96409 Push chemotherapy administration	96367 Intravenous infusion, non-chemotherapy
96411 Push chemotherapy administration	96368 Intravenous infusion, non-chemotherapy
96413 Infusion chemotherapy administration	96369 Subcutaneous infusion, non-chemotherapy
96415 Infusion chemotherapy administration	96370 Subcutaneous infusion, non-chemotherapy
96416 Infusion chemotherapy administration	96371 Subcutaneous infusion, non-chemotherapy
96417 Infusion chemotherapy administration	96372 Injection, non-chemotherapy
96420 Intra-arterial push chemotherapy	96373 Intra-arterial injection, non-chemotherapy
96422 Intra-arterial infusion chemotherapy	96374 Intravenous push, non-chemotherapy
96423 Intra-arterial infusion chemotherapy	96375 Intravenous push, non-chemotherapy
96425 Intra-arterial infusion chemotherapy	96376 Intravenous push, non-chemotherapy
96440 Pleural cavity chemotherapy	96379 Unlisted injection or infusion, non-chemotherapy
96446 Peritoneal cavity chemotherapy	96360 Intravenous infusion, hydration
96450 CNS chemotherapy	96361 Intravenous infusion, hydration

< 10 New Codes

- New Patient Payment
- Treatment Month (4-6 Levels)
 - Patient characteristics
 - Treatment characteristics
 - Transitions
 - Clinical Trials
- Active Monitoring Month (2 Levels)

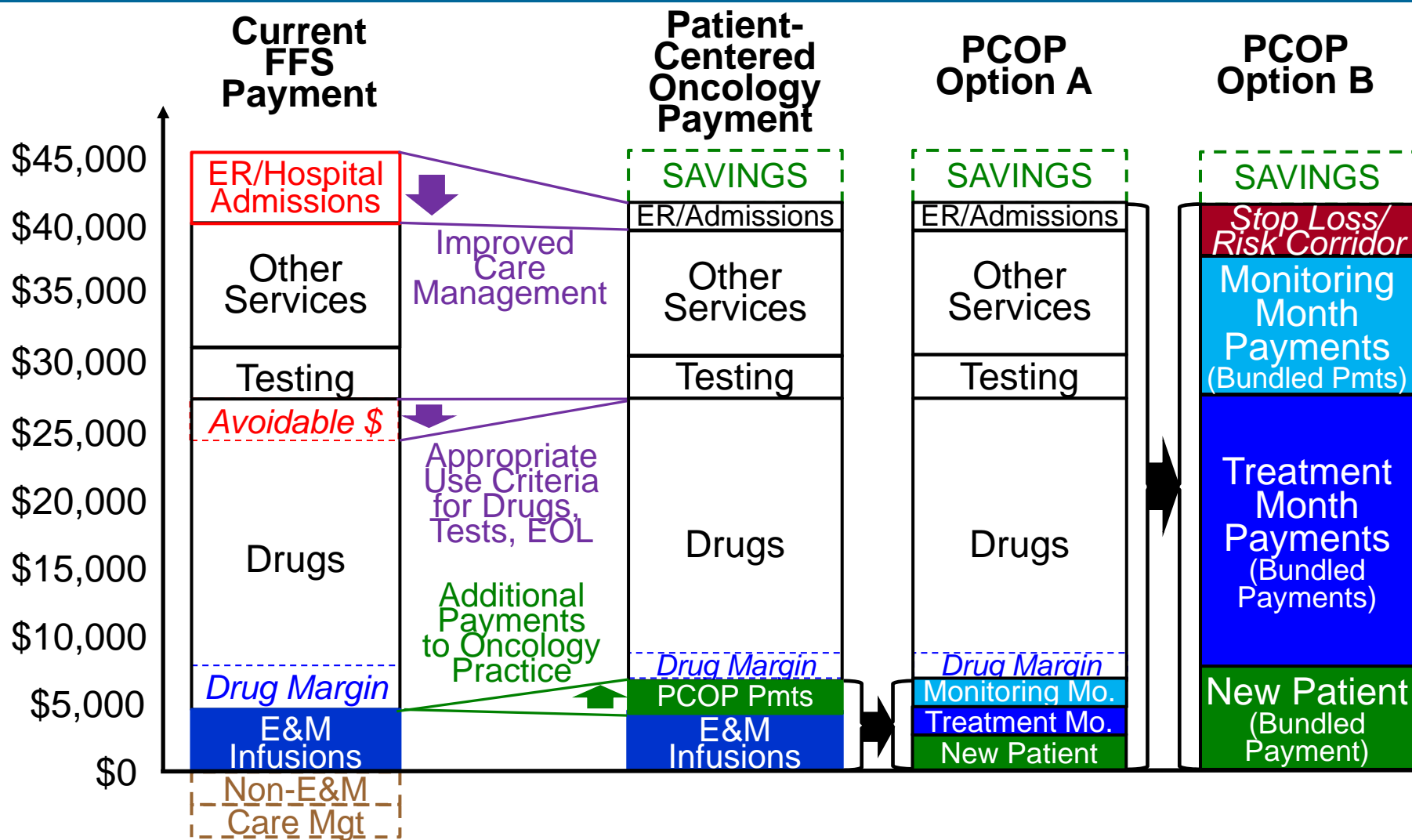


Same Accountability Components But Simpler, More Flexible Pmt





PCOP Option B: Bundled Monthly Budgets





Quality Measures in All Options Focused On Avoiding Underuse

QUALITY MEASURES

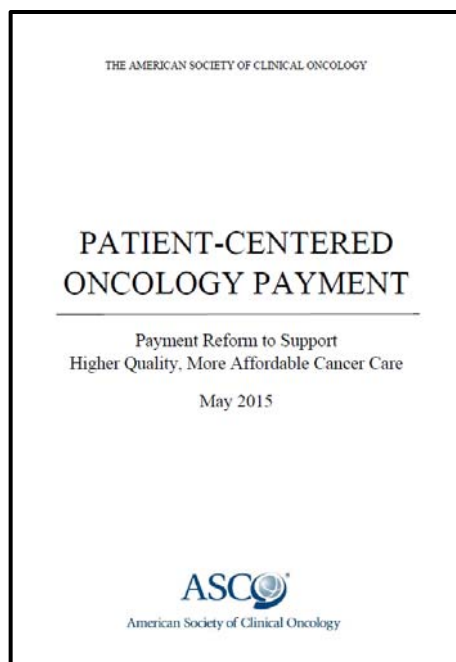
- **Quality of Treatment Planning for a New Patient**
 - QOPI Measures
 - Patient ratings of their experience of care
- **Quality of Care During Treatment**
 - QOPI Measures for All Patients and Cancer-Specific
 - Patient ratings of their experience of care
- **Quality of Care Following Completion of Treatment**
 - Patient ratings of their experience of care

PAYMENT ADJUSTMENT

- **Range of Acceptable Performance Defined in Advance Based on Levels Achieved by Other Practices**
- **Reductions in Payments if Performance Fell Below Minimum of Acceptable Range**



ASCO's Approach to Oncology Payment Reform



www.asco.org/paymentreform

ASCO Purchaser/Payer Partners Needed

- Oncology practices can't change the way they deliver care unless payers agree to pay them differently
- Oncology practices can't even estimate potential savings from avoided ED visits, hospitalizations, and tests/imaging without data from payers on utilization and prices
- There is uncertainty on both sides:
 - Can the oncology practice meet performance targets?
 - Will the savings offset the higher payments?
- A true partnership is needed to create a win-win-win approach

APPENDIX:
Gaps in Current
Fee-for-Service Payments
to Oncology Practices



Before Treatment Begins... ...Practices Are Underpaid

WHAT ONCOLOGY PRACTICES DO

Diagnosis and Treatment Planning

- Review tests & pathology reports
- Determine type and stage of cancer
- Identify and evaluate treatment options
- Identify clinical trial options
- Discuss treatment options with patient
- Develop plan of care
- Educate patient about treatment
- Provide genetic counseling
- Provide psychological counseling
- Provide nutrition counseling
- Provide financial counseling
- Determine insurance coverage and obtain pre-authorization
- Document information in records
- Etc.

HOW PRACTICES ARE PAID

- E&M payments for face-to-face visits with physicians

(No payments for services delivered by nurses, social workers, financial counselors, etc.)

(No payments for time spent by physicians on phone calls with patients and other physicians, researching treatment options, etc.)



When Oral Therapy is Used... ...Practices Are Underpaid

WHAT ONCOLOGY PRACTICES DO

Oral Therapy

- Prescribe drugs
- Order tests
- Evaluate patient progress
- Meet with patient to discuss progress
- Answer calls from patients
- Respond to complications
- Manage patients' pain
- Document information in records
- Keep detailed records for clinical trials
- Discuss end-of-life planning with patient
- Etc.

HOW PRACTICES ARE PAID

- E&M payments for face-to-face visits with physicians

(No payments for services delivered by nurses, social workers, financial counselors, etc.)

(No payments for time spent by physicians on phone calls with patients and other physicians, etc.)



If Parenteral Therapy is Given... More Payment, But Linked to Drugs

WHAT ONCOLOGY PRACTICES DO

Parenteral Therapy

- Administer IV therapy
- Order tests
- Evaluate patient progress
- Meet with patient to discuss progress
- Answer calls from patients
- Respond to complications
- Manage patients' pain
- Document information in records
- Keep detailed records for clinical trials
- Bill insurance companies
- Discuss end-of-life planning with patient
- Etc.

HOW PRACTICES ARE PAID

- E&M payments for face-to-face visits with physicians
- Payment for in-office infusions
- ASP+x% - acquisition cost of drugs

(No payments for services delivered by nurses, social workers, financial counselors, etc.)

(No payments for time spent by physicians on phone calls with patients and other physicians, etc.)



No Payment to Support Oncology Medical Home Services

WHAT ONCOLOGY PRACTICES DO

Parenteral Therapy

- Administer IV therapy
- Order tests
- Evaluate patient progress
- Meet with patient to discuss progress
- Answer calls from patients
- Respond to complications
- Manage patients' pain
- Document information in records
- Keep detailed records for clinical trials
- Bill insurance companies
- Discuss end-of-life planning with patient
- ~~Care management services~~
- ~~24/7 triage and response~~
- Etc.

HOW PRACTICES ARE PAID

- E&M payments for face-to-face visits with physicians
- Payment for in-office infusions
- ASP+x% - acquisition cost of drugs

(No payments for services delivered by nurses, social workers, financial counselors, etc.)

(No payments for time spent by physicians on phone calls with patients and other physicians, etc.)



After Therapy Ends... ...Practices Are Underpaid

WHAT ONCOLOGY PRACTICES DO

Post-Treatment

- Develop a survivorship or end-of-life plan
- Order and review tests
- See patient to address needs
- Answer calls from patients
- Respond to post-treatment complications
- Manage patients' pain
- Document information in records
- Keep detailed records for clinical trials
- Etc.

HOW PRACTICES ARE PAID

- E&M payments for face-to-face visits with physicians

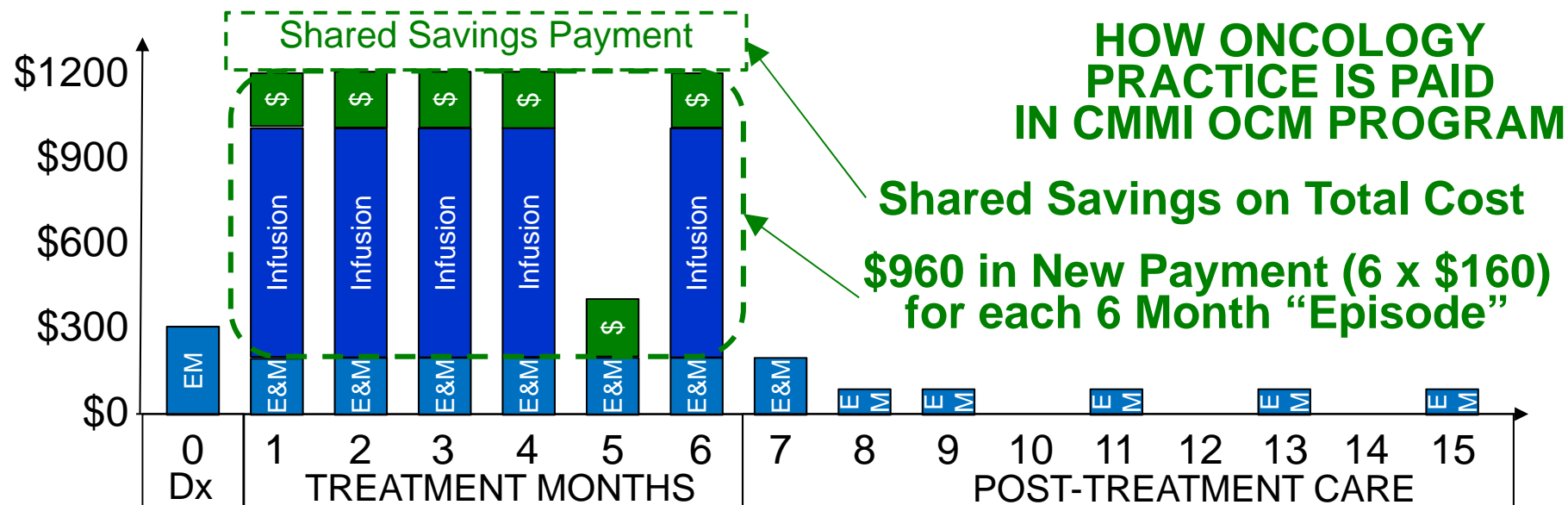
(No payments for services delivered by nurses, social workers, financial counselors, etc.)

(No payments for time spent by physicians on phone calls with patients and other physicians, etc.)

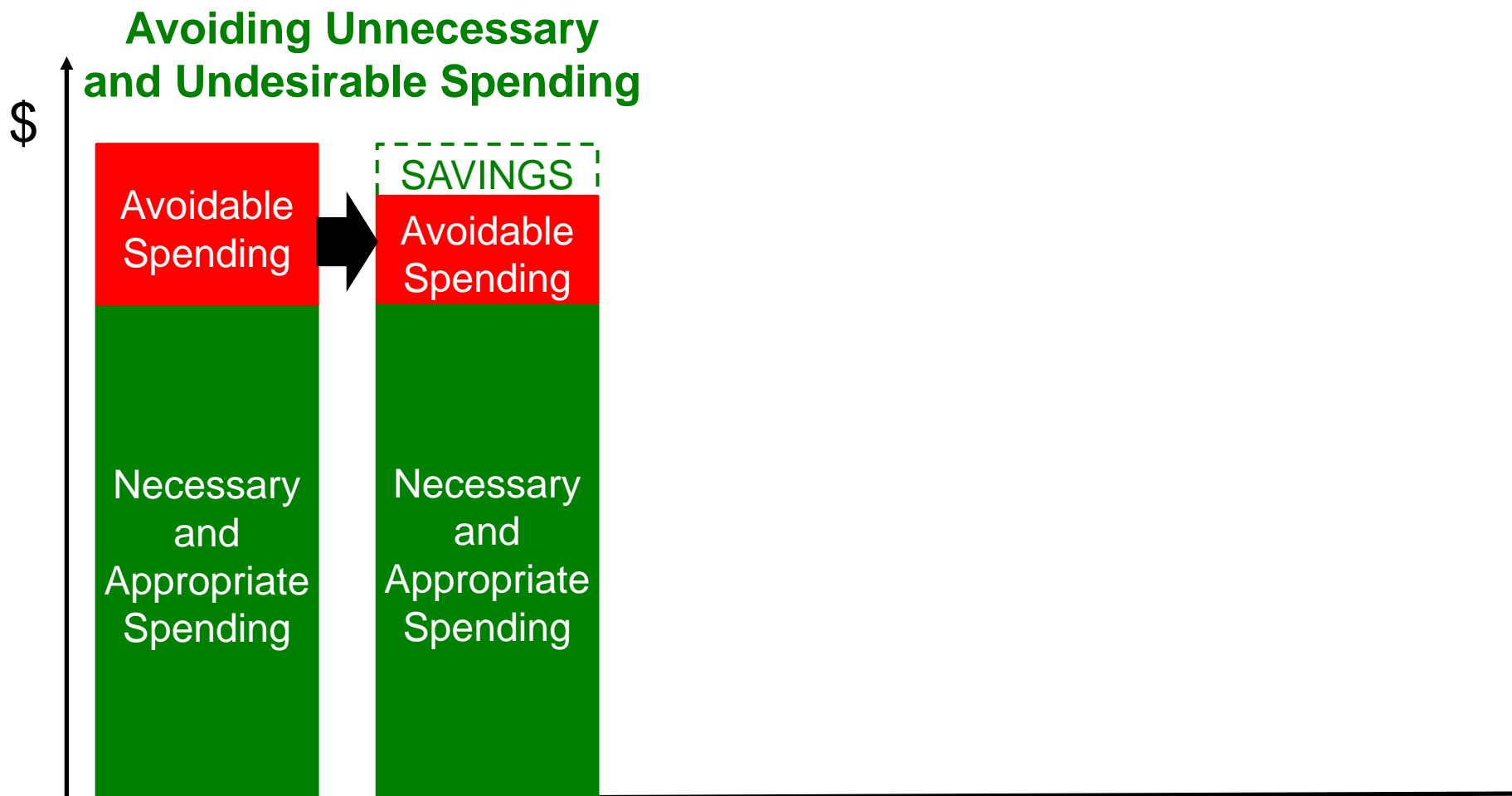
APPENDIX:
Problems with the CMS
Oncology Care Model



OCM: More \$ During Treatment + Shared Savings on Total Spending

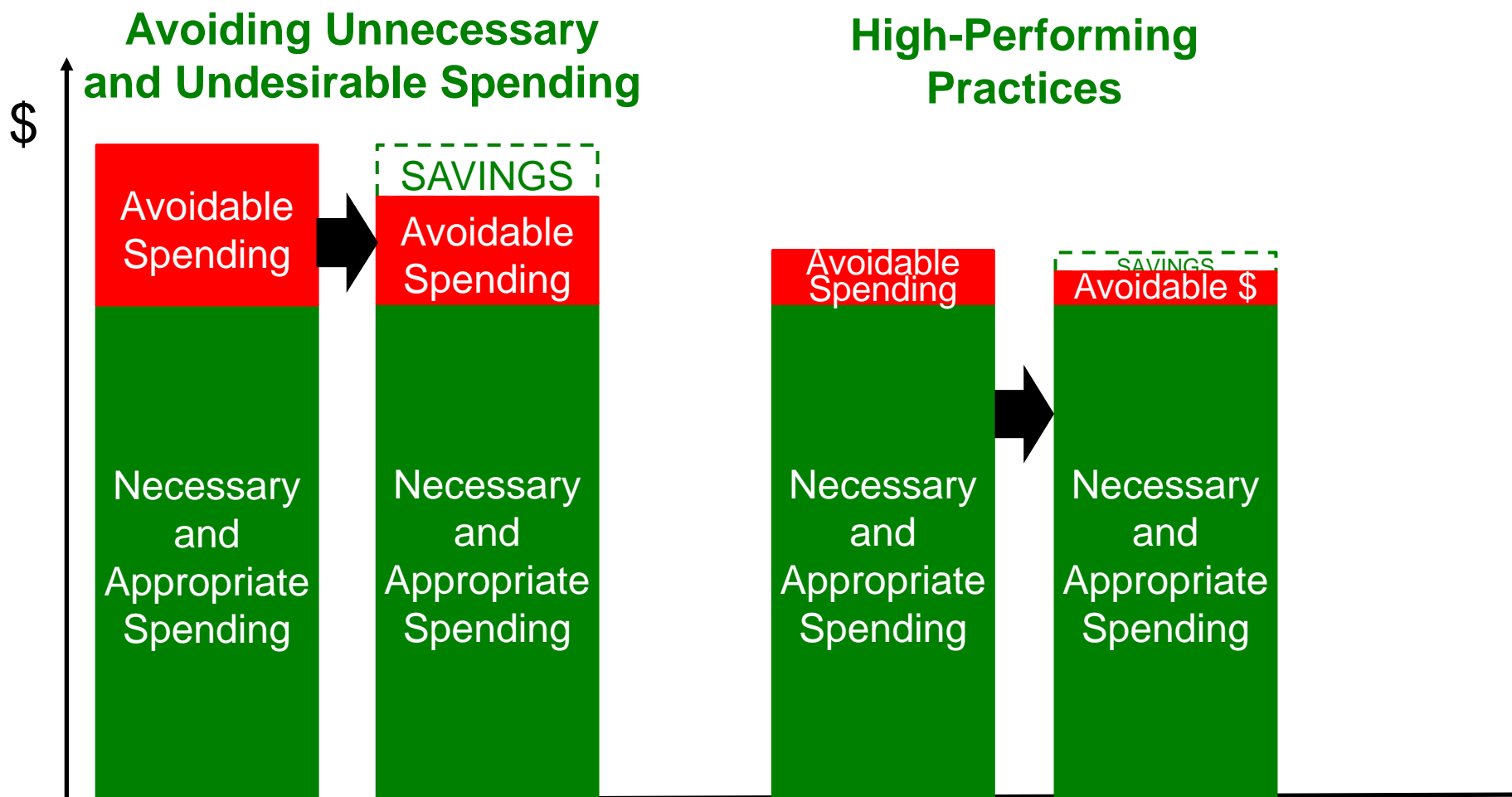


Will Savings Come Only From Avoidable Spending?



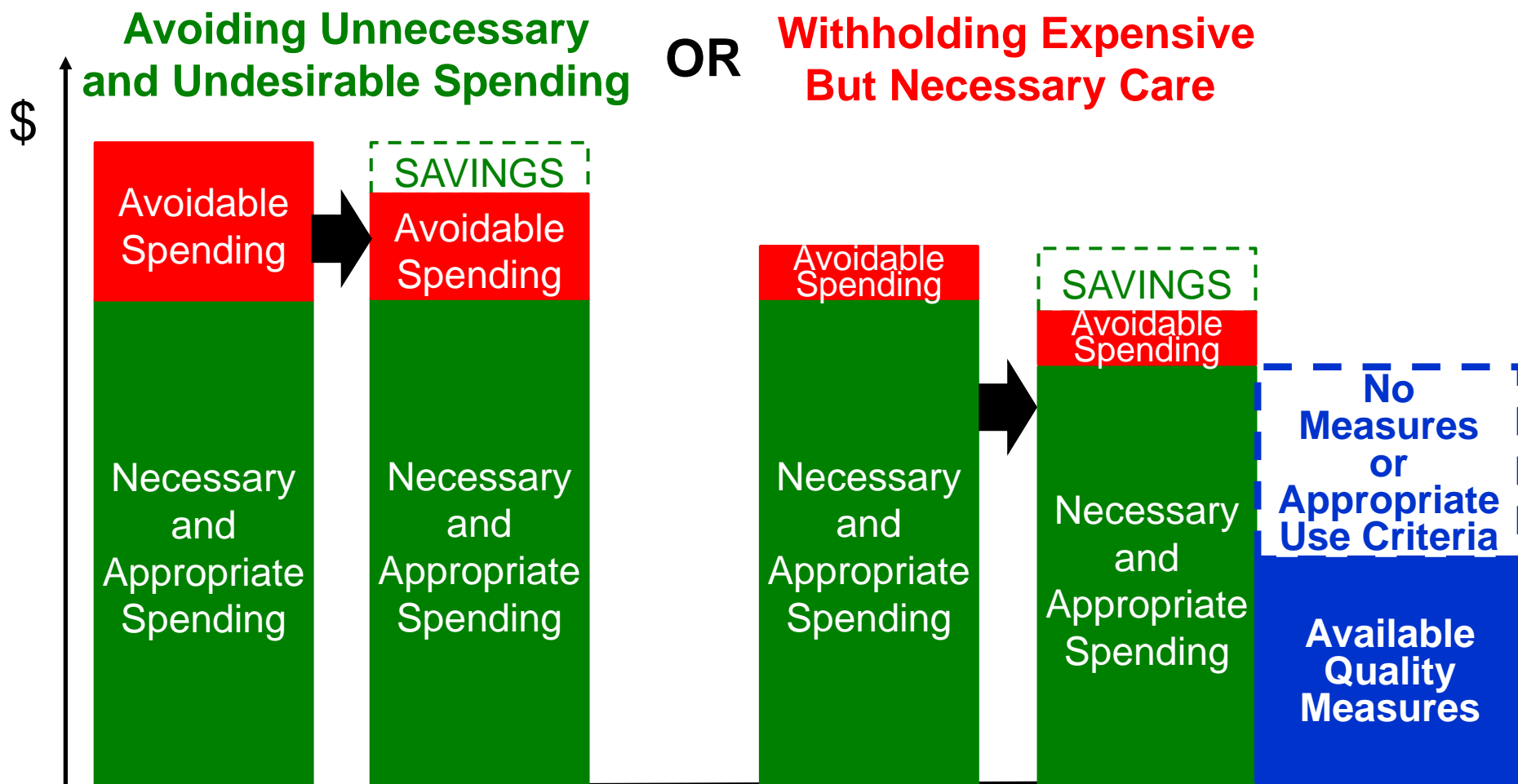


Fewer Savings Opportunities for Already High-Performing Practices



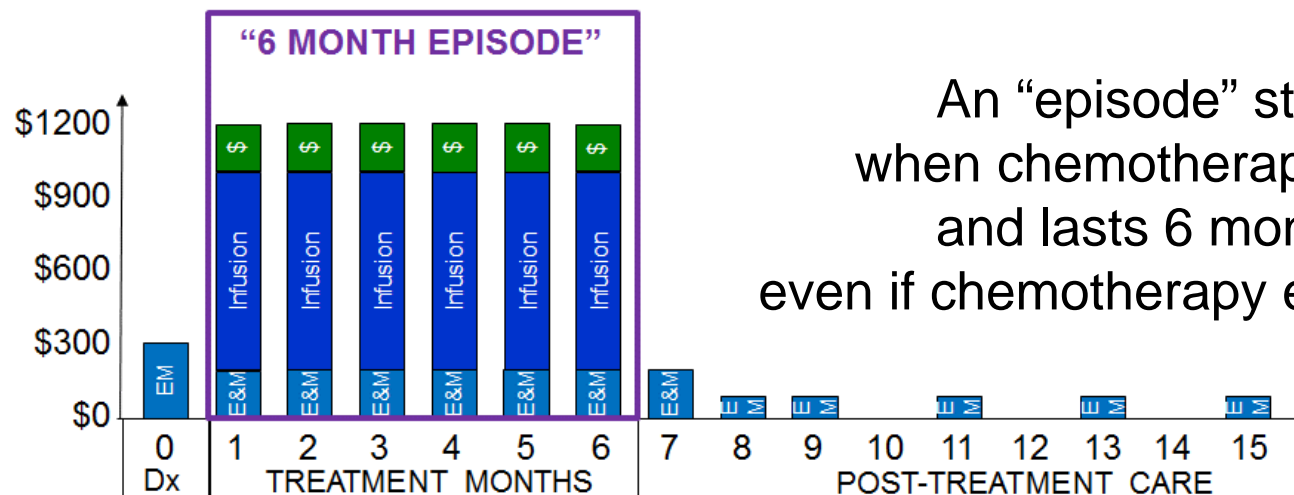


Quality Measures Can't Offset OCM Incentives to Stint on Care



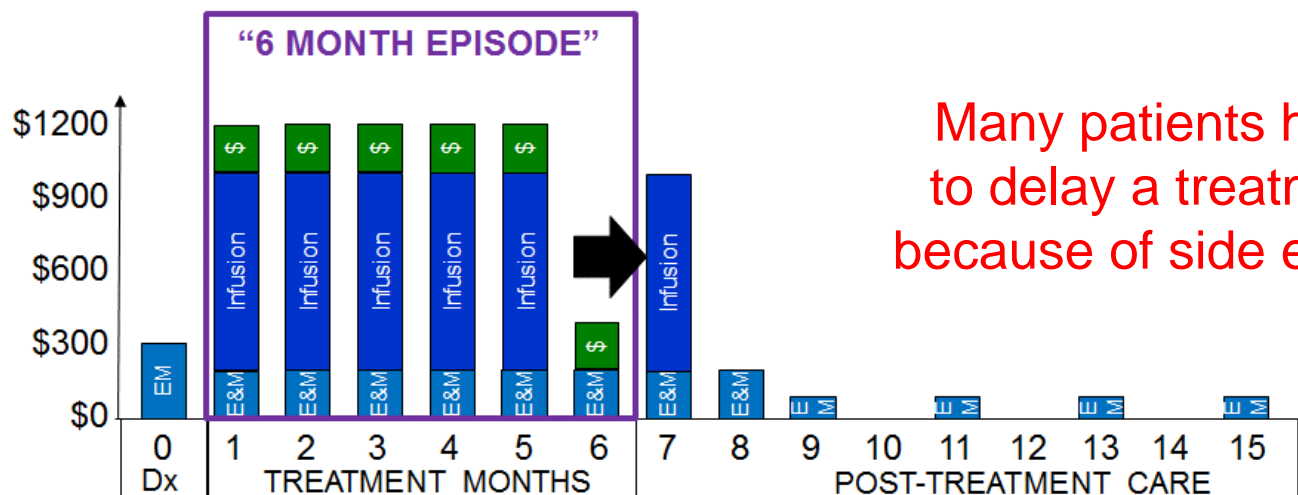
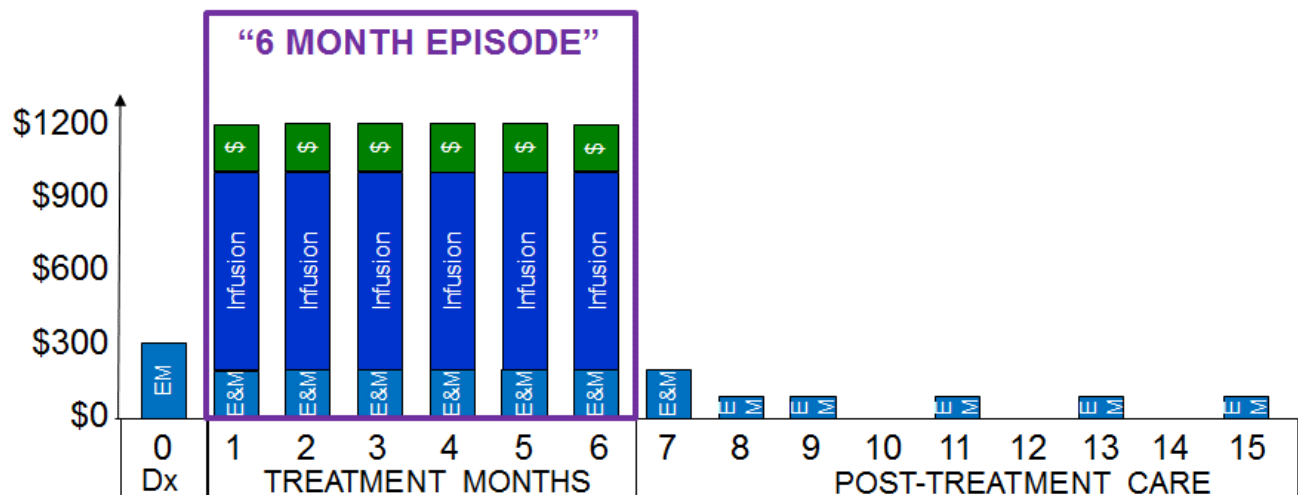


Extra Payments Are Made for *Fixed* 6 Month Episodes



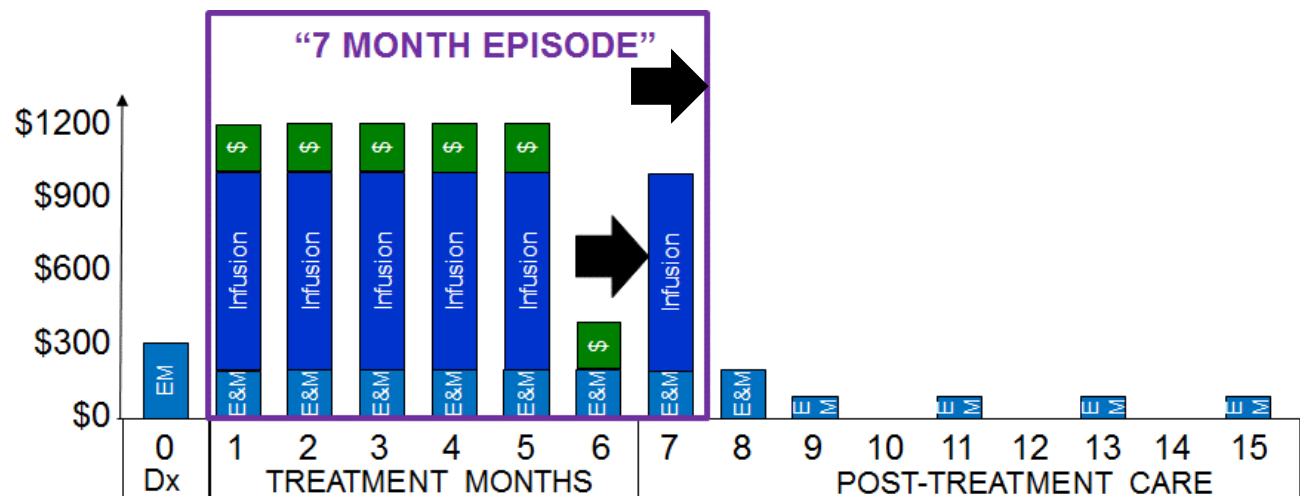
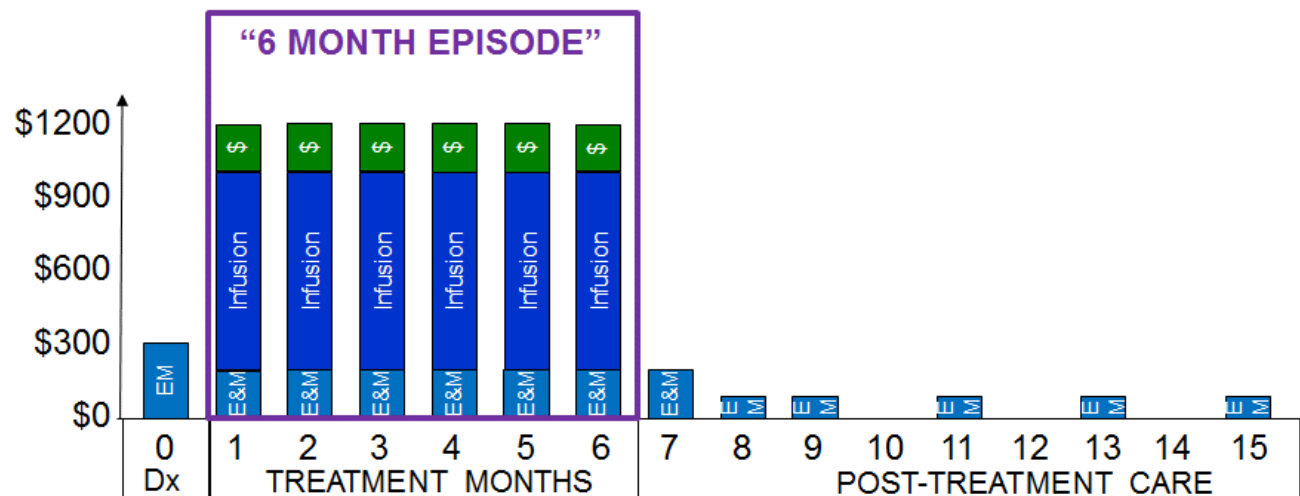
An "episode" starts when chemotherapy starts and lasts 6 months even if chemotherapy ends sooner

What Happens If One of the Patient's Treatments is Delayed?



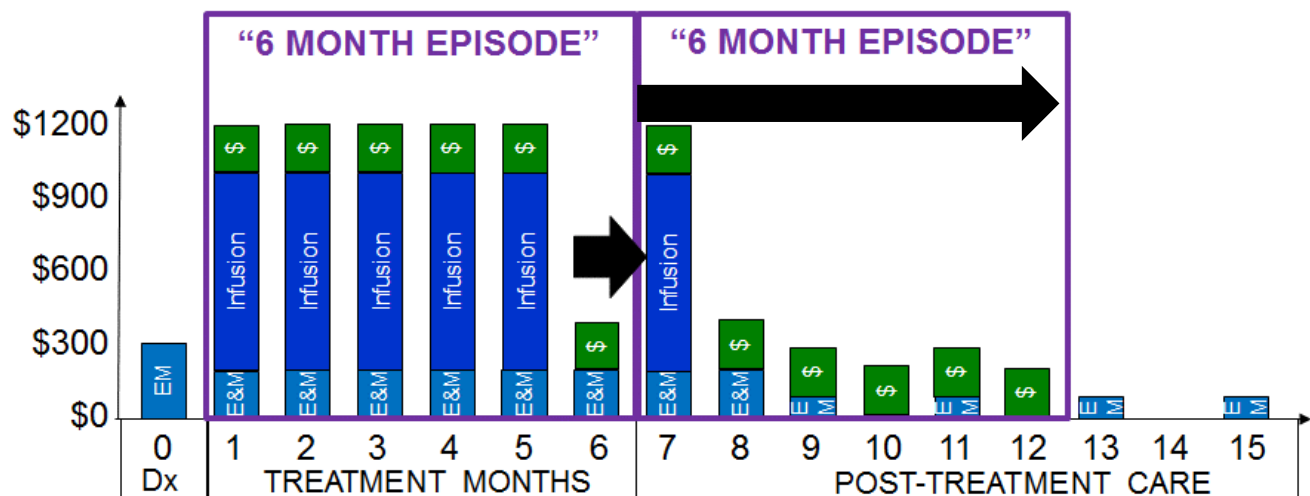
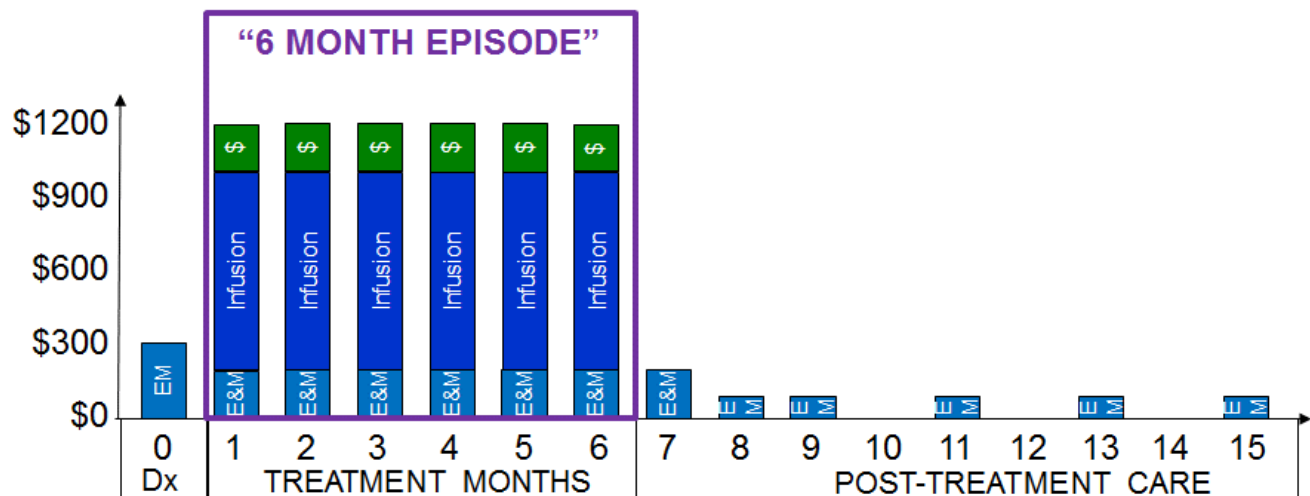


Logic Would Say That It's Now a Longer (7 Month) Episode



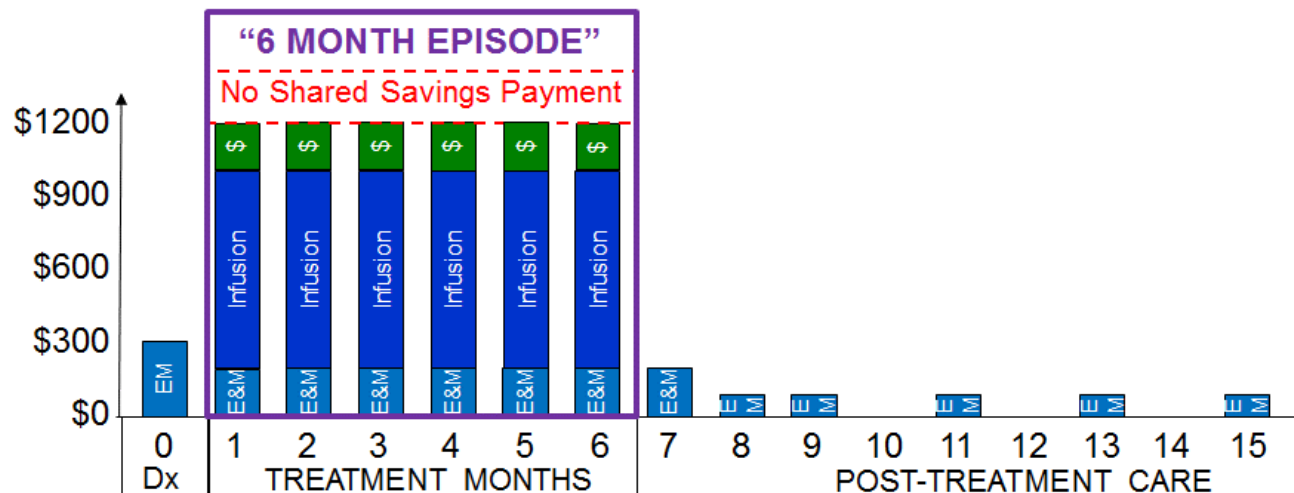


But CMMI Says It's a *New Episode* With \$960 More in Payments

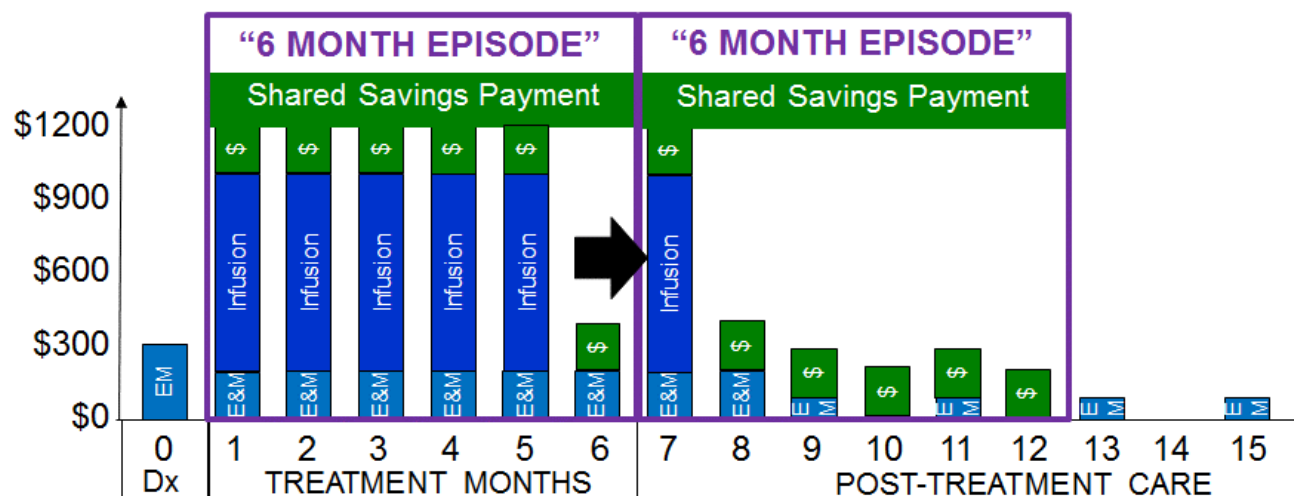




And Shared Savings Is More Likely With Same Spending in 2 Episodes



Penalty
for Helping
Patients Avoid
Side Effects?



Incentive to
Stretch Out
Treatment?



Problems with CMMI “Oncology Care Model”

- What's Good: \$160/month extra payment for practices
- What's Bad:
 - Could encourage delaying treatments in order to receive more PMPM payments & shared savings
 - Could encourage stinting on care to achieve shared savings
 - Oncology practice is accountable for all spending on their patients, even for health problems unrelated to cancer
 - Target spending level is based on historical spending for the practice's own patients, so it rewards practices that are currently overusing and managing patient care poorly
 - Methodology for adjusting spending targets to deal with new drugs, new evidence about effectiveness of treatments, etc. has not been defined.

August 7, 2018

Dear PRC:

Thank you for your time on the phone today and for your careful consideration of MASON.

I have decided to request that consideration of MASON by the full PTAC be delayed until the December meeting and that the PRC consider the following amendments as well as the document dated August 5, 2018 prior to issuing the final PRC report.

1. Please reconsider the 80% threshold of pathway compliance given the evidence supplied in the August 5 submission.
2. Change the quality withhold from 2% to 4 %.
3. Change the 2% add on to drugs to a flat fee of \$40 for shipping, handling and inspection costs as described in the August 5 submission.
4. Please reconsider the payment amounts as discussed under Criterion 3 in light of the data provided from COME HOME and ASCO as provided in the August 5 document and accompanying Powerpoint.
5. Please reconsider Criterion 4 in light of the additional explanation provided in the August 5 document.
6. Please reconsider Criterion 6 of evaluable goals in light of the documents provided on August 5 and the original submission.

Respectfully submitted,



Barbara L. McAneny MD

Innovative Oncology Business Solutions (IOBS), National Cancer Care Alliance (NCCA) and RS21 very much appreciate the thoughtful comments of the PRT report. This response will broadly address the PRT concerns, and in particular we endeavor to show:

- That the Oncology Payment Categories (OPCs) are not only possible but have been produced and can be modified in a timely manner to accommodate changes in care, and
- That the MASON model is built on a foundation supplied by COME HOME, Oncology Care Model (OCM), and the guidelines of the National Cancer Care Network (NCCN), and uses the capabilities of the current CMS claims paying system.

The treatment of cancer is complex and care quality and costs are best optimized by sophisticated solutions. In MASON, we attempt to manage the complexities by simplification (taking the drugs out) and by using data science to rapidly compute changing systems in an iterative fashion. Using a trial group of practices willing to share clinical data is the safest way to test and refine a new system prior to expanding it to all of oncology.

Overview, from the patient standpoint, including explanation of the Oncology Medical Home and patient safety:

The goals of a patient's initial consultation with an oncologist is a discussion of the disease and the staging process, and ensuring a mutual understanding of the disease and the patient's wishes. It's the job of the oncologist to explain to the patient what is possible to achieve, depending on the patient's disease stage and co-morbidities. It's the job of the patient and family to share their wishes and fears with the oncologist. The partnership of patient and doctor then agree on the staging plan, including appropriate tests and referrals. Treatment options based on the NCCN guidelines/pathways (always including the options of no treatment with surveillance, no treatment with palliative care, and clinical trials), are discussed and a course of therapy is decided on. In a fee for service (FFS) model, patient and family/caregiver education, development of the care plan, assembling a care team, and coordination of care with the team are not reimbursed and therefore sometimes are not well managed. The Patient Centered Oncology Payments (PCOP) processes developed by the American Society of Clinical Oncology (ASCO), and used with permission, do cover those costs, thus encouraging the activities.

The PCOP model consists of additional payments to cover the care coordination performed with the initial visit, the visits during treatment and other unreimbursed services which, when provided, increase quality and decrease cost. These payments are analogous to the MEOS payments of the Oncology Care Model and are included in the OPC.

After the plan is developed and the staging and other evaluations are completed, an OPC is assigned, and the Virtual Account is created. The OPC is the target price range. The Virtual Account is started with the OPC target price, and all the claims submitted for cancer care with the exception of the drugs are subtracted. The Virtual Account therefore keeps the practice

apprised of the spending as it occurs in near real time. The claims do not need to be adjudicated before posting to the Virtual Account, as adjudication only lowers claims. Appropriate staging processes avoid unnecessary or unsafe interventions and are therefore both cost effective and enhance patient safety.

All referrals are handled by the oncology practice per Oncology Medical Home processes. In COME HOME, patients told us that they don't have the energy to manage their care, so processes were built on the assumption that it takes all the energy a cancer patient has to just show up, and sometimes they need help with that.

Surgeons may refer patients to oncologists and oncologists may refer patients to surgeons. Surgical care is part of the NCCN guidelines and referral is incorporated into the pathways. Development of treatment plans by oncologists and surgeons is an integral part of the initial process.

The medical home processes are explained to the patient and the caregiving team, so that patients receive all appropriate care in the outpatient setting and not the ED or hospital. COME HOME showed that this results in significant savings. Ancillary services provided by the practice and the community are explained both verbally and with the use of online resources and handouts. We found in COME HOME that repetitive explanations are essential as a patient's care evolves, complications arise or the caregiver team changes. Patient telephone triage and ongoing education is paid for by the additional fees described in the PCOP model from ASCO, as this is not a covered service. This is analogous to the MEOS payments of OCM.

Symptom based triage played a crucial role in COME HOME and is the reason for the decreased ED usage and hospitalizations that resulted in significant savings.

Patient safety is enhanced by the triage process, with early intervention by clinicians who know the patients and their disease and therapies and have 24/7 access to the EMR and treatment plan, and by same day visits or telephonic intervention as indicated. Use of the triage pathways is a quality measure. Patients in COME HOME rapidly learned to call for the slightest symptom or problem, reassured by the fact that phones are answered by a person and not a recording, and that calls are either immediately taken by the triage nurses or returned within 2-4 hours. We can measure the time between call and call back. This is also a good quality measure and correlates with patient satisfaction.

Every staff member who interacts with the patient provides part of care coordination. The physician at the first consult speaks to the referring physician, coordinates the care of co-morbid conditions, arranges for surgical or radiation oncology visits as needed, orders any needed tests or procedures and then a follow up visit to complete the care plan. The patient care coordinators schedule all the tests, referrals and the return visit. Financial counselors are part of the process to help the patient navigate their insurance including prior authorization processes, manage co-pays and deductibles, access community resources or co-pay foundations, and manage social

problems. The financial counselors can also show the patients their Virtual Accounts. Nurses continue the education of the patient and care-giving team at the initiation of therapy and with each visit. The physician explains the drugs being used with their side effects, the pharmacist goes over the process again as the regimen is started, and the nurse does patient education a third time. In addition many practices have chemotherapy classes for new patients, which function as both education and a support group. Each of these processes are repeated multiple times as the patient's understanding grows, the caregiving team changes, or the patient's clinical situation changes.

Patient safety has many facets. The QOPI (Quality Oncology Practice Initiative) certification from ASCO is the best indicator of appropriate processes in the infusion suite. Practices must have USP 800 compliant pharmacies for safety in drug handling, and use Oncology trained nurses with Oncology Nursing Society Certification. Oncologists must be Board Certified or Board Eligible.

Patient safety for imaging and radiation oncology occurs by ACR certification of imaging and radiation therapy facilities. ASCs and hospitals must be accredited for surgical oncology services.

Patient safety and of state of the art care are ensured through the use of NCCN derived pathways. NCCN is the gold standard for evidence based care and is updated whenever a change in therapeutic recommendations occur. NCCN is willing to work with MASON to create pathways from the guidelines, certify that the pathways accurately reflect the guidelines and will work with EHR vendors and IOBS to produce compliance dashboards.

Overview from the administrative standpoint:

When the diagnosis and staging process is completed, performance status assessed, and Hierarchical Condition Categories (HCCs) are listed to account for pre-existing conditions, an OPC is assigned and a Virtual Account created. The OPC is the target range, and the Virtual Account records actual unadjudicated claims. (Adjudication makes claims go down, not up, so the Virtual Account will only be replenished after adjudication.) All the claims submitted from the date of the first oncology visit are in the Virtual account.

The oncologist is therefore held accountable (and is at risk) for the appropriate use of staging procedures.

NCCN guidelines include appropriate staging, surgical, and radiation processes, so the quality measures ensure that the patient is appropriately staged.

Having an OPC that reflects the actual cost of oncology care removes the concern of OCM participants that they are penalized for having sicker patients or patients who need newer, more expensive drugs.

4% of all E&M codes are withheld into a quality pool and will only be given to the practice if the pathway compliance is 80% or more.

Each practice will determine their tolerance for risk by purchasing the right amount of insurance in a captive company held by NCCA. The NCCA captive insurance company will hold reserves for moderate risk. NCCA will purchase a reinsurance policy paid for by all of the participating practices in proportion to their size and risk tolerance. Without this process, practices with adverse spending could go out of business, and patients would lose access to care.

Drugs are purchased currently through the buy and bill system and reimbursed by CMS at invoice pricing. The invoice reflects the bulk purchase of drugs, which reflects the Average Sales Price (ASP) of the quarter in which the drug was purchased, inclusive of rebates or discounts.

Physicians have no financial incentive to use drugs of higher cost, but will wish to avoid toxicity which results in more office visits or hospitalizations. Interventions for toxicity will add cost to the Virtual Account so physicians will be motivated to select the most effective, least toxic regimen. This obviates the concern that oncologists are motivated by drug margin, and takes into account that physicians have no control over the cost of drugs. The data science tools will show which regimens have more toxicity, data which is currently not available to treating physicians.

Having the drugs as a supply price also avoids the concern voiced by OCM participants that choosing the newer, better biologics, or accepting patients on expensive therapy for non-oncologic diseases, would disadvantage them financially.

If the proposed International Payment Index (IPI) system with a Competitive Acquisition Program (CAP) program is fully enacted, the CAP vendor will take the function of supplying the drugs and possibly decreasing costs. MASON would not be affected.

Inventory functions are paid by a \$40 flat fee per drug. This covers the cost of the shipping and handling of the drugs, which is not changed if CMS moves to the CAP program.

Pharmacy costs have risen with the development of USP 800 and with EHR processes. However, these fixed costs are quantifiable and can translate to a facility fee. The cost for a USP compliant pharmacy is the same in different areas of the country and across different practice settings. A facility fee that is transparent will avoid the need for cost shifting from drug margin. This will be scalable to all infusion centers. The facility fee is part of the OPC and the Virtual Account.

Infusion costs differ by different drugs because they have different requirements for equipment, tubing, monitoring, intervention for adverse reactions, nursing expertise, mixing costs and chair time. Therefore the infusion codes are still billed and will be included in the OPC and the Virtual Account.

The Virtual accounts will be monitored by the practice administrative staff to look for early deviance and alert the practice's physician leaders or individual physicians while therapy is underway, allowing for interventions to ensure patient safety and cost consciousness. Patients who are using resources more than expected can be identified and more aggressive case management processes can be instituted, thus increasing quality and saving money.

When the patient completes an OPC pathway, such as at the end of an episode consisting of surgery, adjuvant chemotherapy or radiation therapy, CMS is notified, and the patient is transitioned to a monitoring OPC. The remaining claims accrue to the Virtual Account, and when all the expected charges are paid, the final cost, i.e. the money used from the Virtual Account, is compared to the OPC. If the practice met both the quality metrics and created savings, the savings are shared. If the practice spent more than the OPC, the practice must pay back CMS using the reserves created by the captive insurance or by reinsurance if the amount was excessive.

The monitoring OPC is also defined by the optimal monitoring outlined by the NCCN guidelines and incorporated into the pathways. This is a much lower cost OPC since the expensive interventions are completed. A new Virtual Account is established. The PCOP payments first decrease, and then vanish as the patient recovers from the toxicity of treatment. We learned in COME HOME that for the first 3-6 months after treatment, patients are still accessing the triage system for residual toxicities.

If the patient relapses, the monitoring OPC ends, and the patient is assigned to a new OPC for metastatic disease. We have learned that various manifestations of stage 4 disease have different costs. For example, a patient with stage 4 colon cancer who has peritoneal metastases will likely have bowel obstructions requiring hospitalizations and surgery, whereas a patient whose metastatic disease is confined to the liver likely will not. Therefore the actual cost of care is different.

Under OCM, all stage 4 colon has a single target, so the ability of a practice to hit the target depends on how many patients present with peritoneal metastases. This is not something the practice can predict or manage.

If the patient goes on hospice, the patient is removed from the program.

Overview from CMS standpoint:

CMS will have access to the OPCs methodology, and the data and ability to verify its accuracy. OPCs, like DRGs, evolve over time, reflecting the changes inherent in health care. The Data Science Contractor will have the ability to continually ingest data from the practices of the pilot and instantaneously update the model as care changes.

The HCCs of patients with pre-existing conditions can be used to determine their baseline cost of health care, and HCC related claims can be separated from the oncology related claims.

The practices will be using NCCN guideline-based pathways and can submit compliance data to CMS quarterly. Internal monitoring will update nightly. CMS will easily be able to determine if each practice hits the quality target.

CMS receives claims and posts them to individual patients' accounts as the claims are received. Allowing these accounts to be viewed online completes the process of creating the Virtual Account.

CMS currently pays for drug claims as the ASP for the drug +4.3 %. This would be modified to pay the invoice price. Practices currently send data to CMS so a copy of the invoice for drugs purchased that quarter could be uploaded. Individual invoices would not be necessary under the current FFS system, as practices buy in bulk, not per individual patient.

The \$40 per drug handling fee could be a simple G code.

Facility fees are a common process for CMS. The cost accounting process to assess the expense of the infusion facility, familiar in other industries, would not take long, and would be far more accurate than the current system. This process could be used for all infusion centers, regardless of site of service, as the requirements for equipment and personnel are the same.

CMS paid MEOS payments under OCM. The PCOP payments of MASON are the same process.

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Reply to specific PRT comments:**Criterion 1.** Scope (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 criterion and deserves priority consideration

Thank you, we agree!

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: Does not meet criterion

Quality is delivering the right care to the right patient for the right indication. Cost savings occur when non-essential care is avoided and more effective care is delivered.

MASON will both ensure quality and deliver lowered costs by measuring practices against evidence based guidelines, allowing practices to learn about more effective regimens, and avoid unnecessary procedures and treatments. The ultimate goal will be to have a target price that accurately represents the cost of optimal care, and allows development of a bundled payment.

The NCCN is a consortium of academic institutions with experts in the specific tumor types providing guidelines that include diagnostic evaluations, chemotherapy, and surgical and radiation interventions. NCCN guidelines are used industry wide to guide care, and by payers to determine appropriate choices of therapy for reimbursement decisions. NCCN guidelines form the basis of all the available pathway products. NCCN has given us permission to state to PTAC that they are willing to work with MASON to make sure that the pathways meet their standards and can be generalized to all oncologists practicing in all settings.

Quality is currently determined by spot-checking measures, for example, the OCM measure of administration of adjuvant chemotherapy within 8 months of surgery for stage 3 colon cancer. This measures whether or not the oncologist understands what needs to occur for one tumor type in one setting, but is not an indicator of quality of care in other tumor types or in general. Compliance with pathways can be for all tumor types and will allow the oncologist to be measured overall, and for specific tumor types and clinical settings. The software for pathway compliance can allow oncologists and practice leaders to drill down to patient level information to ensure that the care being offered is appropriate.

Both omissions and extra testing would be measured. Documented deviations from treatment protocols would be measured against acceptable exceptions, and if the reason was legitimate (patient preference, toxicity, etc.), the physician would be considered to be on pathway and not penalized.

Currently drug costs are measured in one silo, office visits in another silo, and ED or hospital usage in a third. The OPC will include the total costs of oncology care except for the drugs. Therefore we will be able to generate information about the downstream effects on patients for a given choice of regimen. If one regimen requires additional expenses to manage the toxicity, that will become apparent by a higher OPC. This information will become invaluable for oncologists who could then select regimens with equivalent outcomes with less toxicity and therefore less cost of care. MASON will include this information, which can provide guidance to all practices, whether participating in the pilot project or not. It has obvious implications for value based pricing for pharmaceuticals as well.

The literature has suggested that as much as 30% of the cost of care is due to unnecessary testing and treatments. By following NCCN guidelines, modified into pathways embedded in the EHR, significant savings would be accomplished.

Precision medicine uses genomic testing to predict therapies likely to work as well as those that would be ineffective. Precision genomic testing is part of the NCCN guidelines and generates savings by avoiding therapies that won't work and focusing on those that will. Obviously this has value to the patient who enjoys better outcomes as well as reducing costs.

The first step in understanding opportunities to generate additional cost savings is to create transparency about the actual baseline costs. The current payment system is such a hodgepodge of cost shifting that no one really knows the actual costs of providing care. A major goal of MASON is to create transparent costs. Currently drugs margins are used to cover the shortfall in drug administration and pharmacy infrastructure. By pulling out the drugs and paying at invoice price, by paying a facility fee that covers the fixed costs of having an infusion suite that meets quality and safety standards, and by having the infusion codes reflect the actual nursing time and supplies, accurate costs of care can be generalized across sites of service beyond the practices of NCCA.

On the feasibility of creating and maintaining OPCs, RS21 has been able to develop multiple OPCs from a set of clinical data that has been appropriately anonymized. This process involved cleaning the data, identifying clusters from that data, and creating probability distributions describing the likelihood of costs of treatment. OPCs were able to be created from the provided data in order to prove that the necessary calculations could occur within a reasonable amount of time to make the MASON model feasible. Examples of these initial results can be seen in Figures 1 and 2 below.

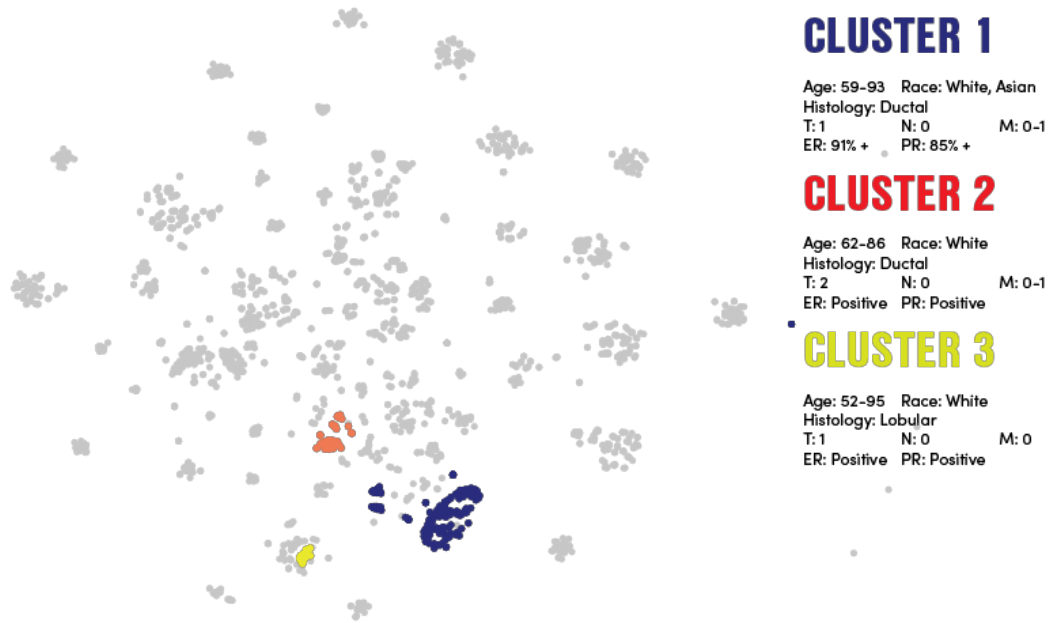


Figure 1. A Stochastic Neighbor Embedding graph that has reduced the number of dimensions in the clinical data to represent similarity between episodes. Three OCMs have been highlighted that correspond to the cost distributions in Figure 2.

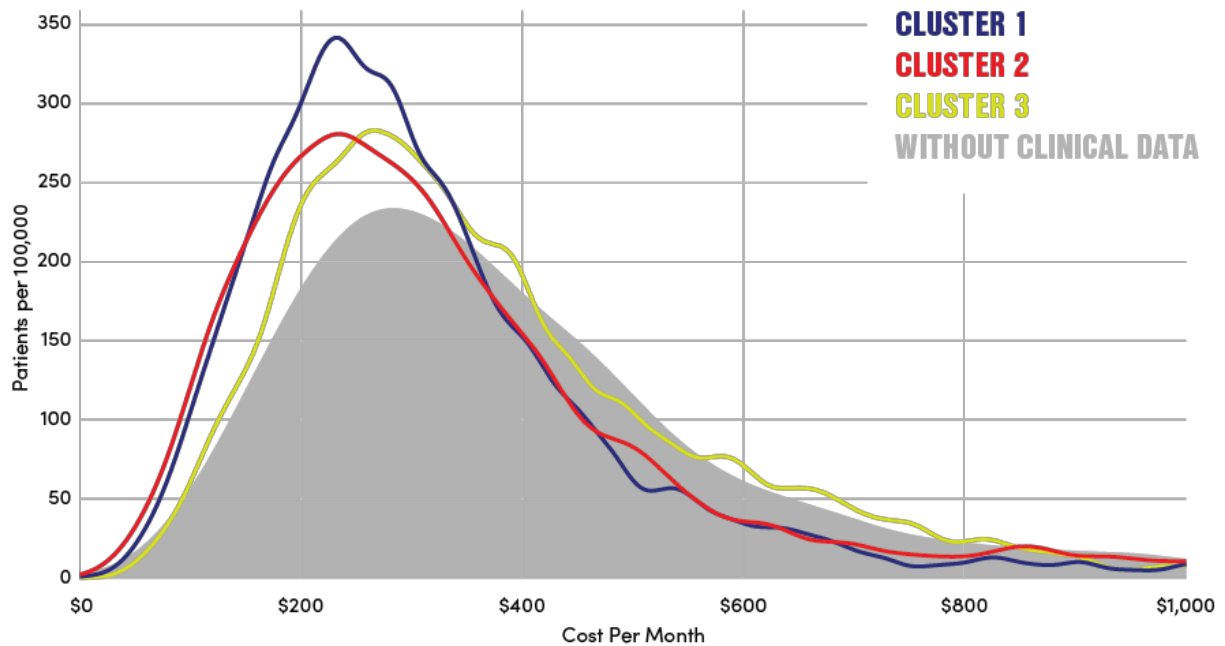


Figure 2. Cost distributions for the three OCMs highlighted in Figure 1, as well as the distribution of costs without clinical data. These cost distributions do not factor in J code claims.

The cleaning and informatics involved in successfully fusing data sources together, a seemingly daunting task, is easily automated for all data sources that have well-defined or quantitative data types. For unstructured notations that accompany the clinical data, a host of solutions exist in both the academic and commercially available managed-services spaces. With the initial set of data, RS21 was able to pull a number of variables, such as hormone and protein indicators, from these notes through natural language processing techniques that are computationally efficient. This process is finely tuned and easily replicated.

Once the suite of data surrounding episodes has been cleaned and joined, the task of creating clusters is somewhat trivial. The density-based spatial clustering algorithm used to create the clusters normally has an exponential computational complexity, meaning that the run-time of the algorithm exponentially increases as the number of items in the set linearly increases. This was mitigated through pre-indexing the input episode data, reducing the computational complexity to a logarithmic pattern as illustrated below in Figure 3. The initial clustering process on the provided data was *completed in under a second*.

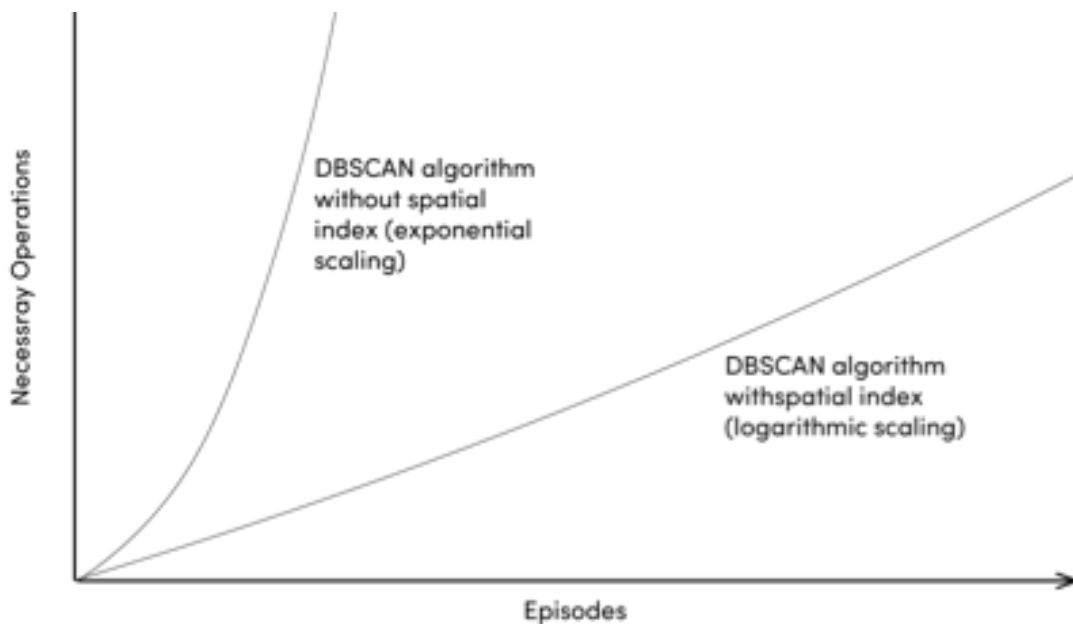


Figure 3. Graph of necessary computations to execute the DBSCAN algorithm with and without a spatial index. This illustrates that with an index, the method will scale appropriately to handle many episodes.

The most time intensive process for the proof-of-concept study was the creation of cost curves describing the likelihood of costs of treatment for episodes within a cluster. This process is a common one in the field of software engineering and data analysis, for which several services and software suites have been developed such as Apache Hadoop distributed processing clusters. These types of applications would take the task of iterating through all of the episodes in a

cluster, retrieving all of the claims for those episodes, and then summarizing the cost of those claims by splitting the workload up by episodes and having a number of systems work on them in parallel. Parallel processing greatly reduces the time necessary to create the final cost distributions, as illustrated in Figure 4 below. RS21 has extensive experience working with these technologies to reduce processing time. For example, RS21 recently reduced the time a hurricane simulation software took to summarize over seven terabytes of data from 15-30 minutes to a matter of seconds.

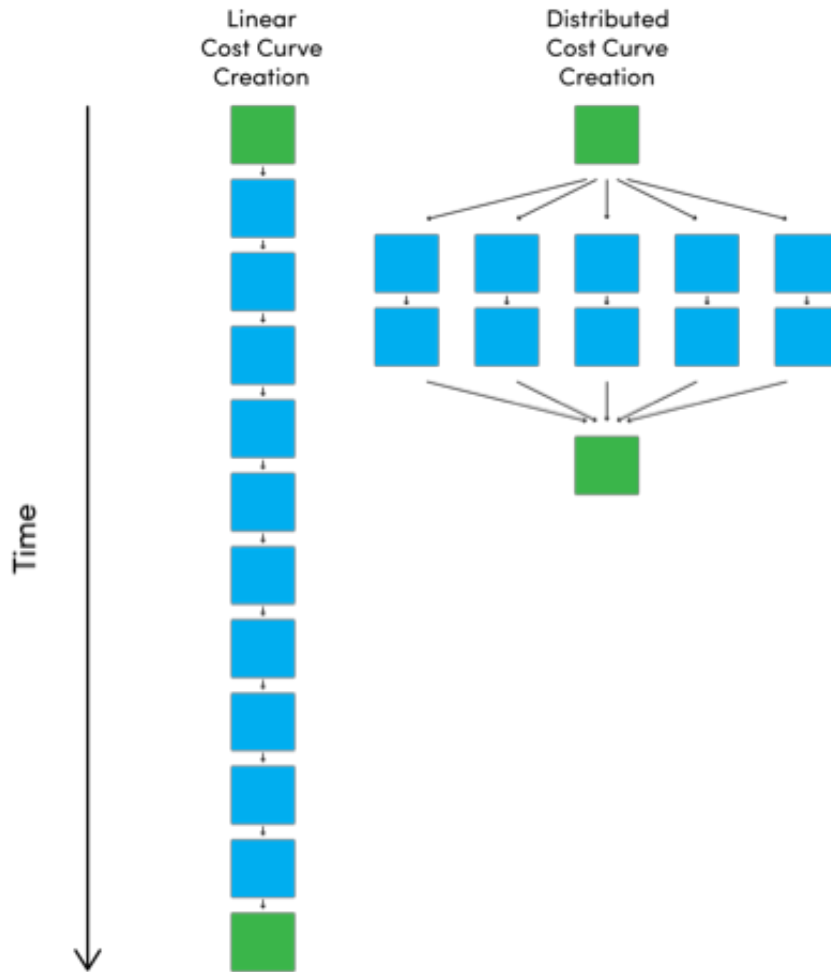


Figure 4: Diagram of linear vs distributed cost curve creation process. Green blocks represent processing that needs to be done in context of the entire set, where blue blocks represent episode-specific computations that can be parallelized.

We therefore request reconsideration of Criterion 2, and will be happy to discuss this further.

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: Does not meet criterion

Under the current system, the Oncology Care Model (OCM), practices are paid fee for service claims, MEOS payments for care management, and have no ability to evaluate the total costs of care as the claims are not seen in real time. The current system has not been able to create an accurate target for cost of care, making it difficult for practices to accept risk and become a full APM.

MASON includes payment by CMS of fee-for-service claims, but unlike current Medicare or OCM, all claims would be visible to the practice, including hospital claims, surgical care, primary care and the entire care team. The Virtual Account provides this information real time, or at least within a few weeks.

The ASCO Patient Centered Oncology Payments (PCOP) are analogous to the MEOS payments, and pay for the development of the treatment plan and the care coordination functions of the Oncology Medical Home. New Mexico Oncology Hematology Consultants Ltd currently has 2 commercial payer contracts using the PCOP methodology and both payers are pleased with the savings being generated. Without payment for care coordination, which mostly consists of people working with patients and families and the other members of the care team, these functions are not sustainable. The care coordination by nurse driven triage pathways generated the savings from the COME HOME CMMI award.

The PCOP payments are more specific than the MEOS payments, and start with the beginning of the oncology doctor-patient relationship rather than with the prescribing of chemotherapy. They also vary in amount, reflecting the intensity of the services provided during the patient's cancer episode.

Facility fees that meet quality and patient safety criteria are very useful in managing the fixed costs of infrastructure. They exist in HOPPS but not in the Physician Fee Schedule or in the OCM. Across other industries, cost accounting determines the fixed overhead very accurately. Because of the current system of cost shifting, most practices and payers do not know if the infrastructure cost is being overpaid or underpaid. No one understands the additional costs of regulatory requirements, to see if there is value. We propose to use the NCCA practices to determine the costs of having an infusion center that meets criteria. This cannot be done under the current payment system.

The NCCA practices operate under the PFS and are therefore very lean. (Practices that have not streamlined their processes have not survived and get acquired by hospitals.) The NCCA practices have QOPI and Oncology Medical Home certification for safe infusion suites that meet all the regulatory requirements. The costs may underestimate the costs in hospital departments that have more overhead from other functions. However, for a benchmark, the NCCA practices will be able to produce accurate data. When MASON is generalized to oncology practices, it will encourage practices to become equally lean.

HCCs represent some but not all of the factors leading to co-morbidities and changes in costs. However, when the HCCs of a given patient are known, the claims data prior to the cancer episode will reflect the payments for managing the HCCs. This helps determine which costs that occur during the cancer episode are related to the cancer or reflect the baseline costs of the patient's pre-existing conditions. Those codes can be removed by the data science processes to give an accurate target for cancer costs, and will avoid penalizing oncologists for taking care of sicker patients. The current system of the OCM has been unable to separate the oncology costs from the costs of the patient's co-morbid conditions. The MASON OPC will accomplish this.

We do expect that other factors will emerge, as occurred with COME HOME. We learned in COME HOME the importance of having a caregiver, and having transportation and shelter security. Other social determinants of health will emerge from the data processes as well. This is very different from the usual methods of payment, and under MASON, practices may elect to provide transportation, or spend additional resources on patients without caregivers.

The OPCs will be demonstrated in the on site visit on December 10th. They are a new construct, analogous to DRGs. The modifications over time of OPCs will take minimal time as the data is continually ingested, and computational times are measured in seconds.

This is a key part of MASON, and addresses the problems practices are having with OCM. Accurate target pricing is required if practices are to take risk for costs of care, and if we are ever to get to a bundled price.

The PRT was concerned that this would be a slow process, but as we have illustrated in the response to Criterion 2, the proof-of-concept OCMs that have been developed prove that the technique is efficient and can scale to create OCMs from large numbers of episodes. Once the OPCs are shown to be trusted, it would be reasonable to expand the pilot to a generalized model. Oncologists are unwilling to go at risk for OCM, just as many ACOs may drop out of the program if forced into a two-sided risk model they don't trust.

During the development phase, just as with any new product, continuing dialogue between the stakeholders will strengthen the product.

We therefore request reconsideration of this criterion and are happy to discuss it with you.

Criterion 4. Value over Volume.

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

PRT Qualitative Rating: Meets criterion

We agree that MASON meets these criteria, but want to explain better how pathways compliance works. If the physician changes the regimen or selects a regimen that is not preferred, there is a drop down box in the EHR that gives acceptable reasons. The software can pull the compliance data fields and then modify them by the reason codes given. The physician is only not in compliance if there is no reason code. For example, in the pathways, there is a protocol for staging which occasionally includes MRI. If the patient is allergic to gadolinium, or is claustrophobic and cannot tolerate the MRI, that can be explained and the CT can be substituted without marking the physician off-pathway. If the physician orders an inappropriate test, he/she would be off-pathway. Most commercially available pathway systems can manage this. The ones that cannot are too inflexible for clinical care.

Criterion 5. Flexibility.

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

PRT Qualitative Rating: Meets criterion

The system of allowing pathway compliance to be 80% allows for the flexibility. If an event occurs that requires a change in therapy, such as early relapse, the first episode is ended. If an episode ends early, no shared savings or risk payments would occur. At relapse the patient would be assigned to a metastatic disease OPC, which would start with the time of documented relapse and end with either progression, death, transfer to hospice or change in regimen.

Criterion 6. Ability to Be Evaluated.

Have evaluable goals for quality of care, cost, and any other goals of the PFFPM.

PRT Qualitative Rating: Meets criterion

Evaluation can be done by matching groups both in and out of the OCM model, as was done for COME HOME, using a difference in differences approach. Both measures have value: the most value to the model is seen when the outcomes of efficacy quality and cost of the intervention are compared to the rest of the market practicing as business as usual. However, given the amount of data available in the OPC and the closer match of practices in NCCA to OPC practices, it will be possible to measure the specific interventions of MASON as compared to the Oncology Medical Home processes and care coordination interventions common to OCM practices.

Other metrics will include pathway compliance, which will reveal a wealth of data on practices, the QOPI certification and Oncology Medical Home certification, and the ability to generate savings or hit the target range of the OPCs. Patient satisfaction is very high with the Oncology Medical Home practices, generally in the mid 90's, so metrics such as same day visits used when indicated, satisfaction with the answers given through the triage pathways, and other measures, will be useful.

Numbers of admissions and readmissions are easily measured and will never be zero. The better measure is avoidable admissions and readmissions.

A lower number of patients dying in the hospital is a good measure. Again, some patients will die in the hospital but with good palliative care and hospice, this can approach lower levels.

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 criterion

Using the HCCs to establish a baseline cost of care for a given patient, and measuring the cost of care for the cancer above the baseline level, is designed to eliminate the PRT's concern about having ongoing care of the patient's other medical problems performed by other physicians such as primary care physicians. This is better than in OCM, where the total cost of all care is included, acting as a disincentive to accept patients with significant other problems into the practice.

We also feel that having the data on current spending through the Virtual Account will increase rather than decrease care coordination, by avoiding duplicative procedures. Managing comorbidities early decreases total cost of care, and would be encouraged by the model.

The concern about eliminating high spending clinicians mostly would affect surgical specialists where a higher price can be commanded under commercial plans. This is the case when the surgeon works at an expensive academic institution, but is the best surgeon for the patient's specific problem. Fortunately this is rare but would cause the target to be missed. If a patient is transferring care to that institution, then the OPC would be closed, as it is not good to penalize a physician for referring the patient for the best care. If the patient is referred out for a clinical trial to another institution, the OPC would also be ended as the treating oncologist would change.

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: Meets criterion

The COME HOME Oncology Medical Home model is built around patient choice, and MASON is built on the foundation of the Oncology Medical Home. The PCOP payments cover the costs of patient education, which is the foundation of patient choice. Patients on their first visit with an oncologist are too emotional to make decisions. It takes several sessions of patient education, ideally with different members of the care team, for patients to really understand what is possible, what the modalities of treatment are, what precision medicine means, and their prognosis. The PCOP payments fund the extra time that the physician takes with patients and their families, the time the nurse educators take, the “chemo classes” and support groups that help patients make decisions.

In COME HOME we found that very few patients elected chemotherapy at the end of life—when the end of life was predictable. We felt this was partly due to the extensive ongoing education and involvement of caregivers, and partly due to the trust that was established with the care team.

End of life discussions are not always done in one session, but are done as part of ongoing decision making with the patient at every relapse or encounter for toxicity.

The MASON OPCs are the model for payment, and while not designed for patient decision making, would assist in the patient decision making when patients choose to see the Virtual Account.

As we learn the toxicities of various regimens, e.g. the likelihood of a hospitalization or office visits for symptoms, patients will be able to become better at making their choices.

Switching OPCs is not cumbersome but is similar to the DRG process of inpatient care. The original OPC will be assigned after staging is complete. Since the factors that assign an OPC are in the data logic, the entry of the data into the EHR and transferred to the OPC software will result in the assignment of the OPC. At the proposed end of a regimen, the patient will be assigned to a surveillance OPC. At the documentation of relapse, the next OPC will be assigned by the same data entry process.

Patients would exit the model if they transferred their care to a different practice, enrolled in hospice, or died.

It is unlikely that physicians will refuse to see patients with more difficult conditions under MASON, as the target price (OPC) will reflect the clinical situation. This is not the case with

OCM, where if the patient has significant illnesses or is on any biologic, the practice can predict it will not meet the target. This is exactly one of the items MASON looks to correct from the OCM. In addition, physicians hate giving up their patients.

If we find that a given physician or practice is opening and closing OPCs more than expected, the data reports will alert the model administrators.

Criterion 9. Patient Safety.

Aim to maintain or improve standards of patient safety.

PRT Qualitative Rating: Meets criterion

As we increase the use of pathways patient safety should improve. The toxicity of treatment plans that are unlikely to be effective contributes to patient harm, and the predictive models that develop from the OPCs will be helpful to oncologists in the development of the treatment plans.

Criterion 10. Health Information Technology.

Encourage use of health information technology to inform care.

PRT Qualitative Rating: Meets criterion

Using an EHR is just the beginning of the MASON process. Data science (augmented intelligence) is the machine learning process that helps manage rapidly changing systems with multiple independent and dependent variables. The combination of claims data sets with clinical data sets is essential to create a new model.

(Continued on next page)

Summary

We believe this is an unequalled opportunity to use a willing set of physicians who have agreed to participate and generate good quality data in the process of caring for patients, with data scientists using claims and clinical data that can hopefully build on the foundation of COME HOME and OCM to advance oncology practices along the continuum to value based care. We will incorporate decision support for physicians by the pathway process.

Oncologists are busy with patient care, are suffering from “model fatigue”, and need to be shown that a model has merit before they reconfigure their practices to implement anything. However, physicians do want an APM, and cannot handle the required risk in OCM.

The role of the MASON pilot project is to perfect the model, look for needed mid-course corrections and demonstrate to peers that MASON is a superior model. Commercial payers are looking for predictability of cancer costs and eventually for bundles. When MASON is documented to work, oncologists will more willingly make the transformation.

Thank you again for your thoughtful and detailed comments, and your consideration.

Barbara L. McAneny MD
Kameron Baumgardner
December 3, 2018

MAKING ACCOUNTABLE SUSTAINABLE ONCOLOGY NETWORKS

Monday, December 10th
12:30 PM EST

Barbara L. McAneny, MD, MACP, FASCO
Kameron Baumgardner, RS21 CTO

THE OCM VS MASON OPCs



TARGETS VS COSTS

	Patient 1	Patient 2
Baseline Price	\$22,598.69	\$22,598.69
Actual Expense	\$9,688.51	\$49,278
Age	80	82
Gender	Male	Male
Episode Duration	10/1/2014 – 3/31/2015	10/6/2014 – 4/5/2015
Home Zip Code	45365	45318

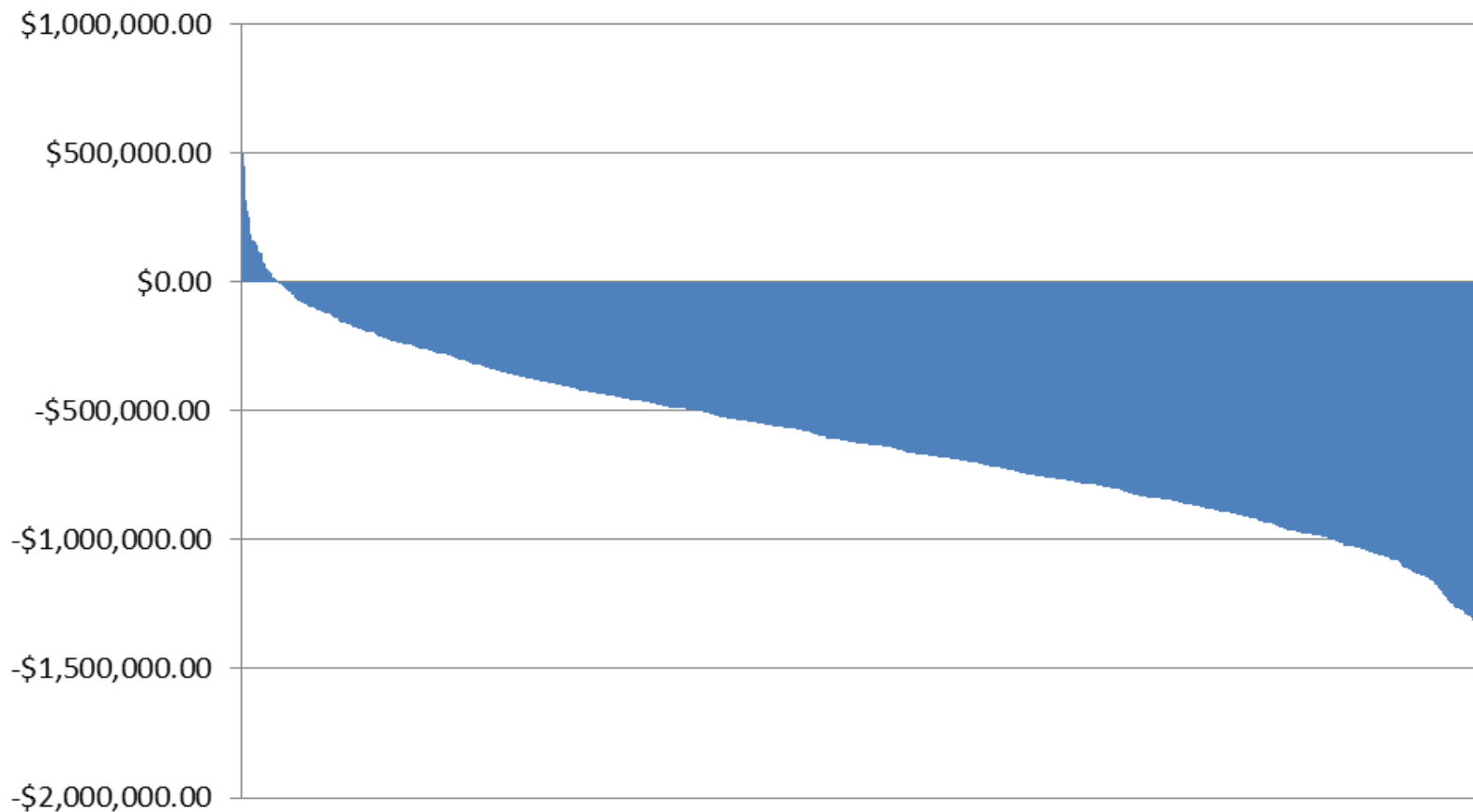
- For example, these two patients with pancreatic cancer show many similarities in the data that OCM uses.
 - Same cancer type
 - Same HCC group
 - Similar Age
 - Same Gender
 - Neither had surgery or radiation
 - Neither were involved in a clinical trial
- Other factors not in the OCM dataset determine the actual cost of care.

TARGETS VS COSTS



- By looking at 16,000 historical episodes, we can determine that the linear regression model used by the OCM is not appropriate.
 - OCM predicted vs actual values for historical episodes indicates that residual amounts are not uniformly distributed around the OCM target (red line).
 - R-squared value of 0.334
 - The lack of clinical data and other factors in the model prevents OCM from setting sustainable targets.

DOWNSIDE RISK IN OCM



Simulating 1,000
OCM
Performance
Periods based on
the historical
episodes reveals
that only 37 of
1,000 (3.7%)
Performance
Periods are likely
to see a shared
savings payment.

PROOF OF CONCEPT OPCs

Initial Results

OUR INITIAL ANALYSIS

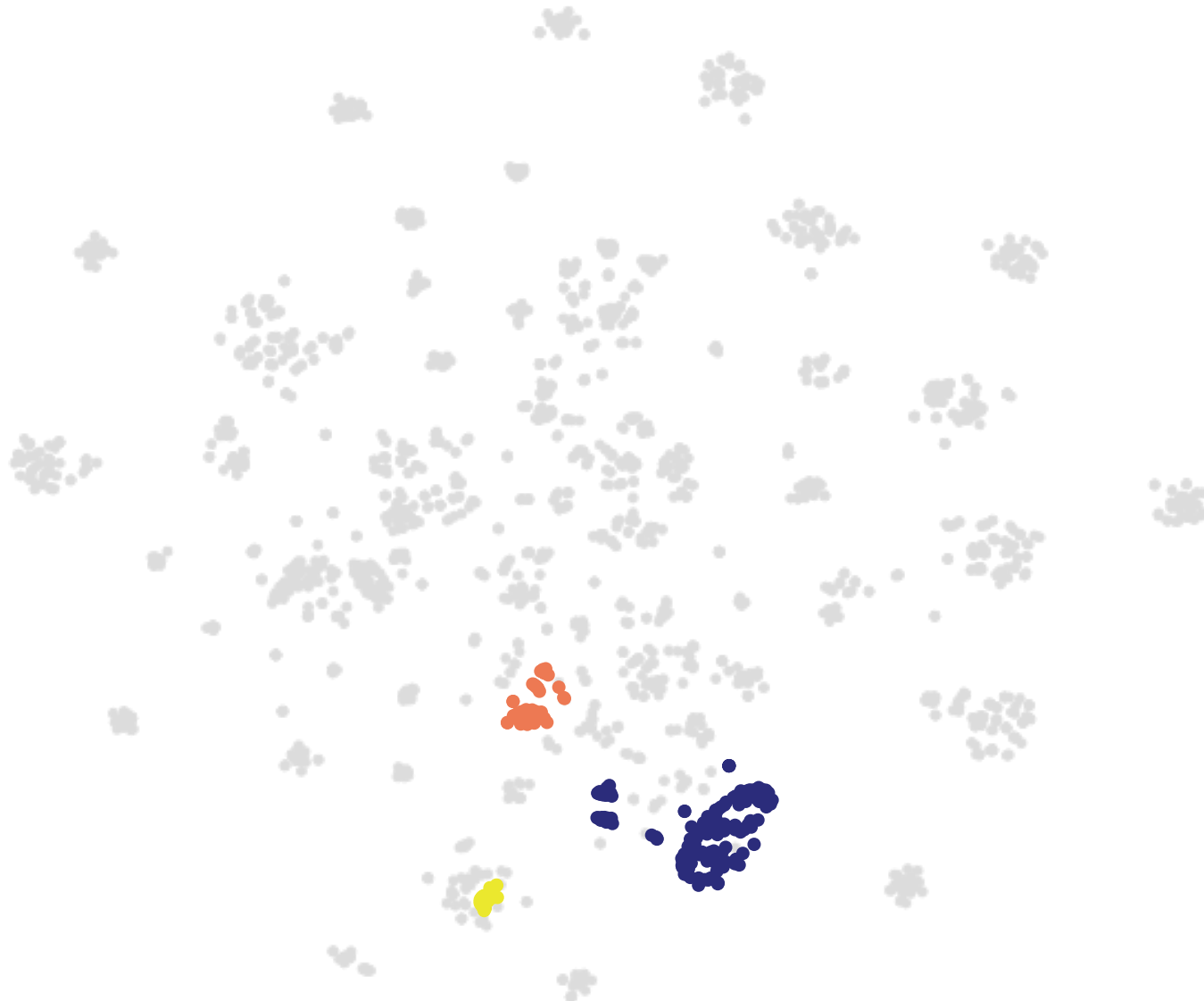
DATA

- We looked at 2,517 total episodes (693 breast cancer episodes) from the provided blinded data set and were able to pull:
 - Demographics (Age, Race, etc...)
 - Risk Scores
 - T, N & M
 - Histology
 - ER, PR, and HER2
- We analyzed these episodes to identify Oncological Payment Clusters (OPCs), and then created 5,000 synthetic episodes per OPC.

METHODS

- Clusters were created using a Density-Based Spatial Clustering (DBSCAN) on the set of blinded episodes that we had spatially indexed.
- Cost distributions for OPCs were created from the simulated episodes by:
 - Identifying the length of the episode by the difference between the dates of diagnosis and latest treatments.
 - Gathering Oncologically-relevant claims together to get a total episode cost.
 - Dividing total cost by the episode length to examine the distributions of cost per month for each OPC.

T-DISTRIBUTED STOCHASTIC NEIGHBOR EMBEDDING CLUSTER CHART



CLUSTER 1

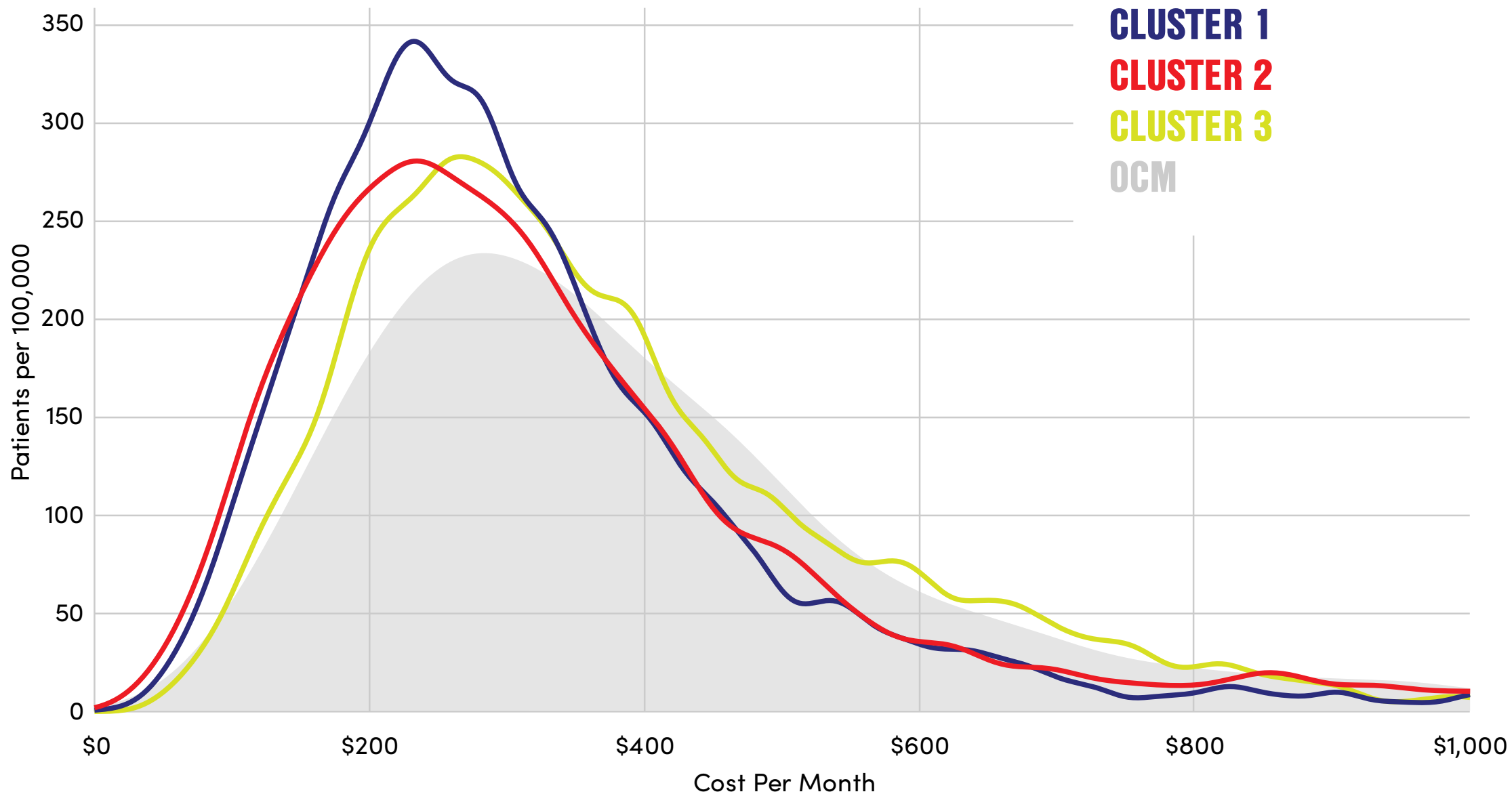
Age: 59-93 Race: White, Asian
 Histology: Ductal
 T: 1 N: 0 M: 0-1
 ER: 91% + PR: 85% +

CLUSTER 2

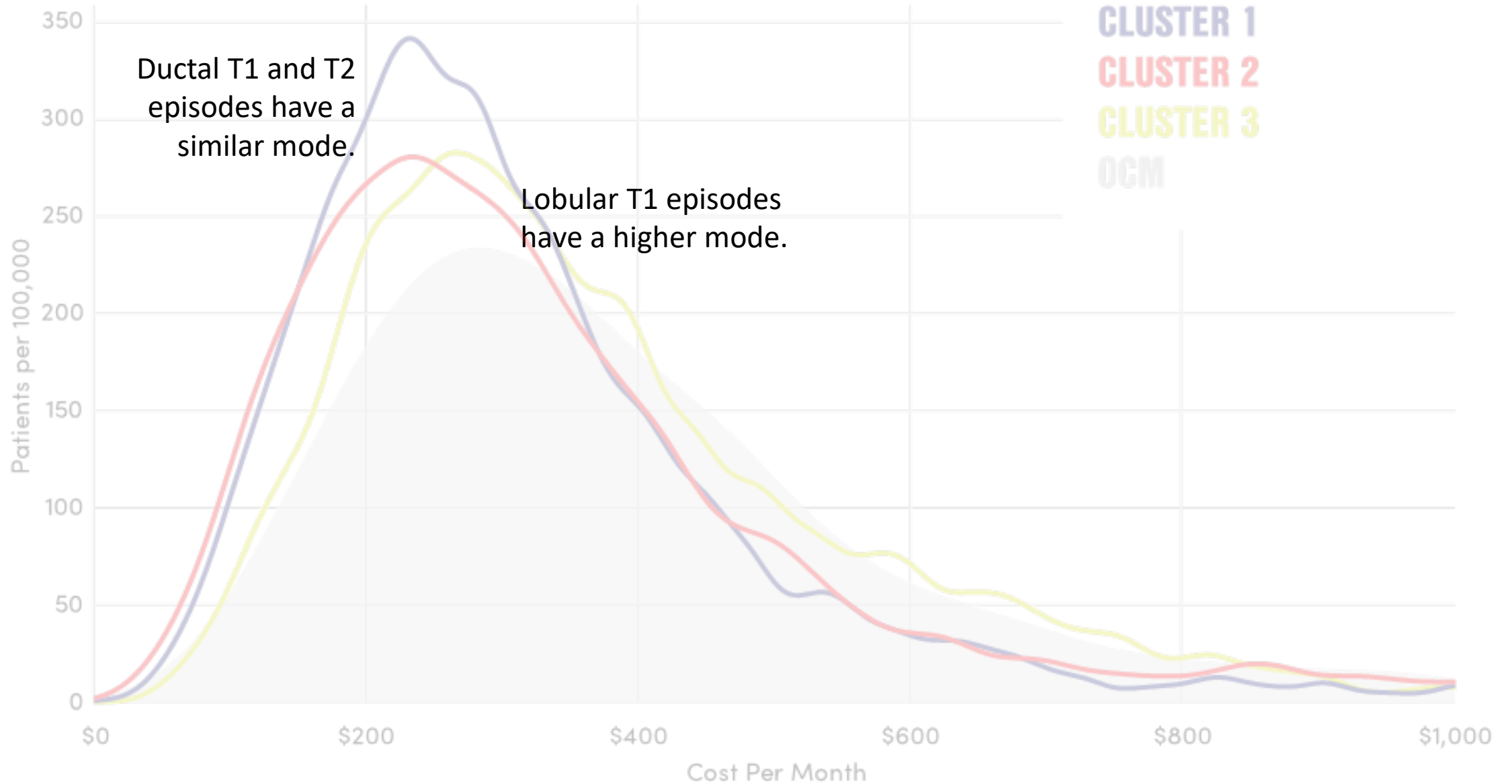
Age: 62-86 Race: White
 Histology: Ductal
 T: 2 N: 0 M: 0-1
 ER: 100% PR: 100%

CLUSTER 3

Age: 52-95 Race: White
 Histology: Lobular
 T: 1 N: 0 M: 0
 ER: 100% PR: 100%



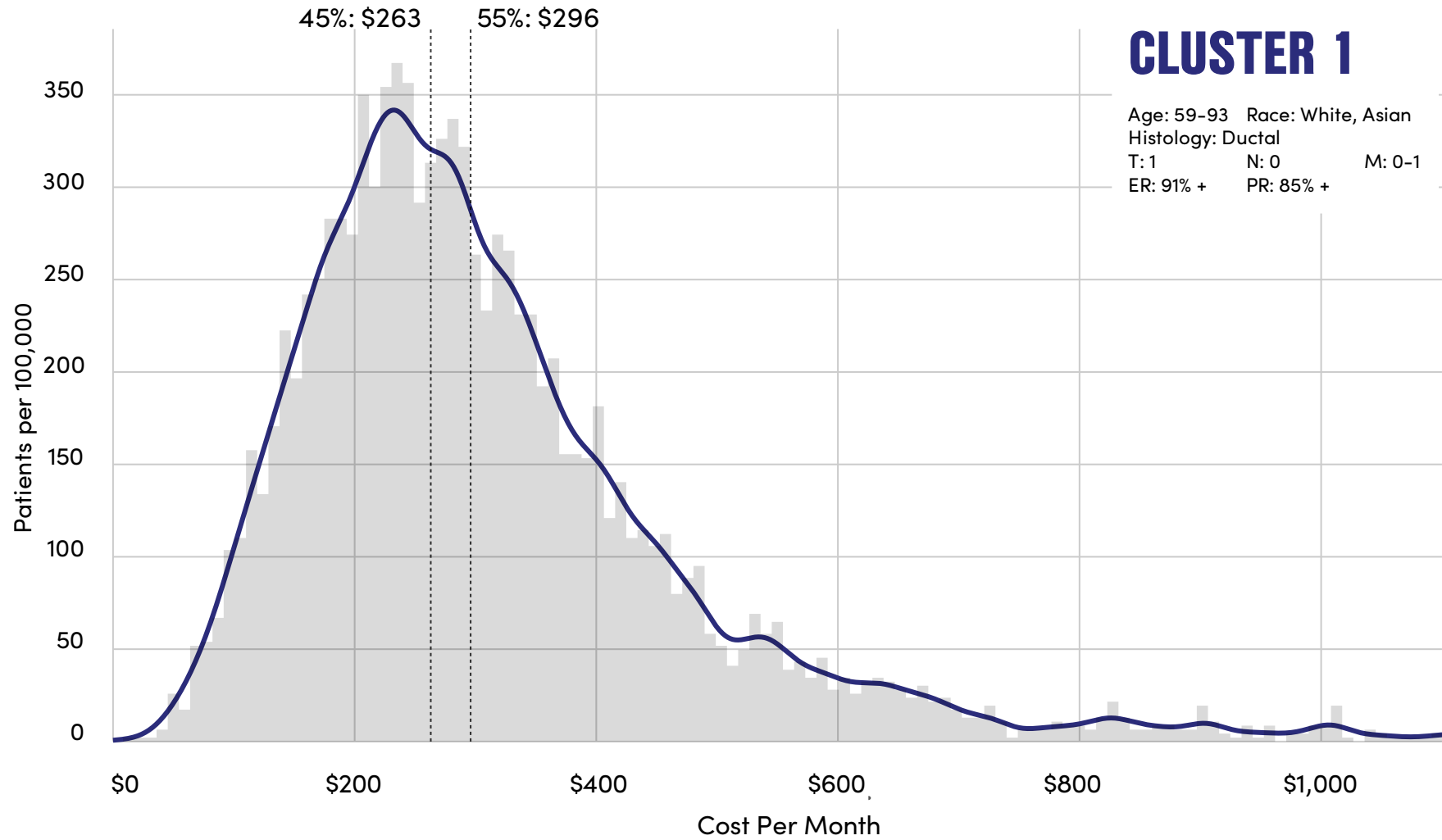
CLUSTER 1
CLUSTER 2
CLUSTER 3
OCM

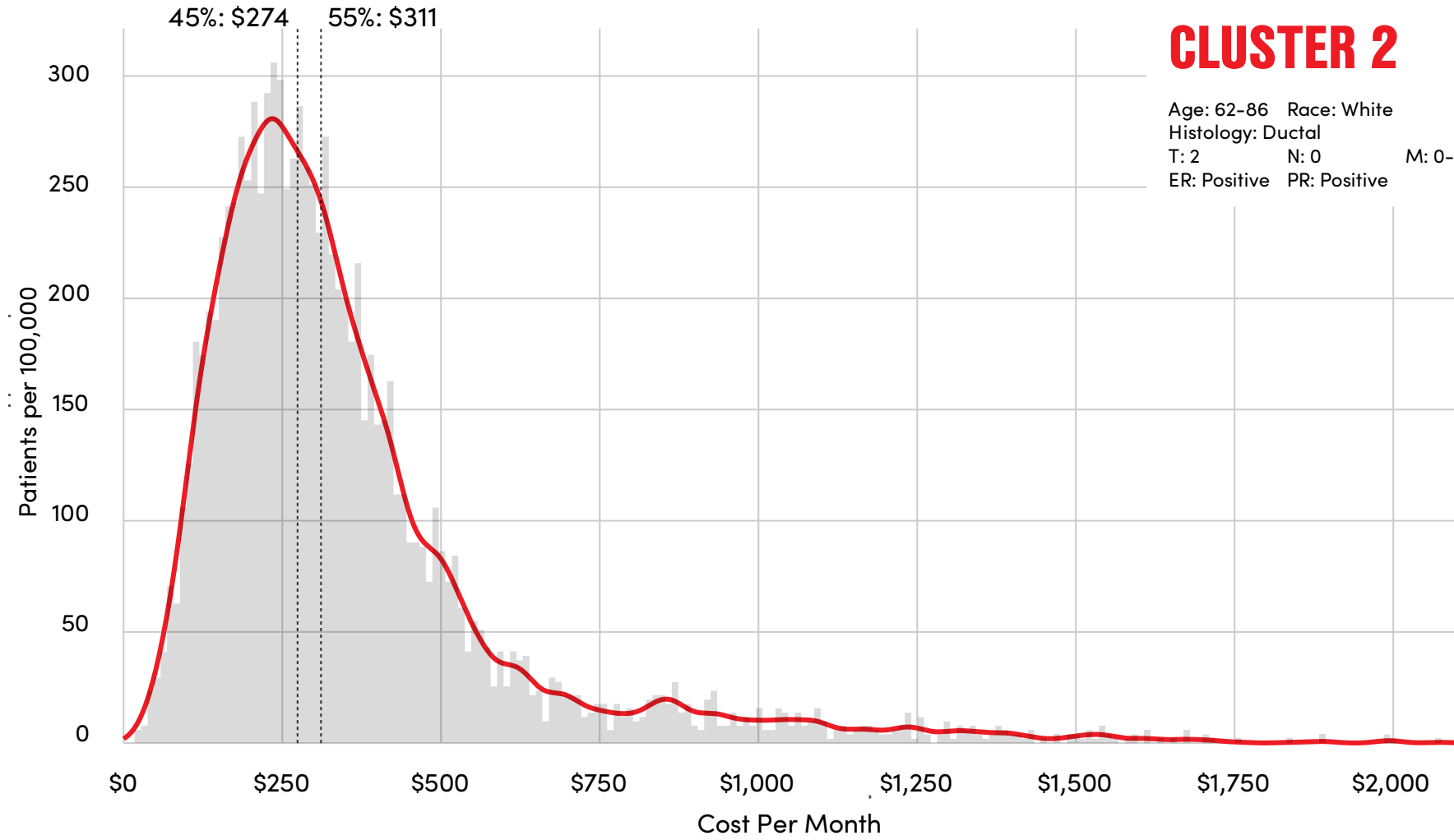


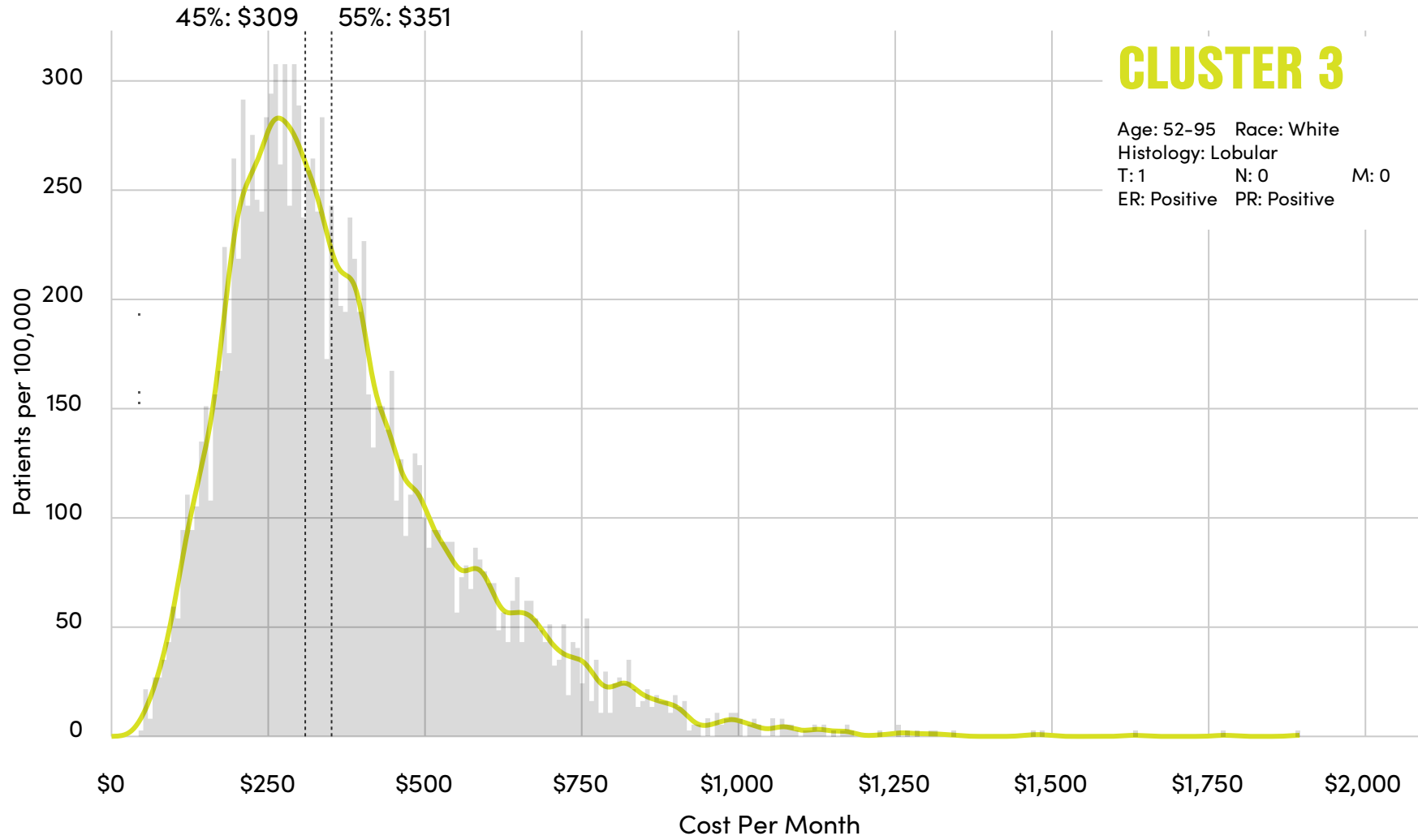
Ductal T1 and T2 episodes have a similar mode.

Lobular T1 episodes have a higher mode.

CLUSTER 1
CLUSTER 2
CLUSTER 3
OGM







WHAT'S NEXT

ANALYSIS

- Analyzing larger sets of data may remove some 'noise' from the results.
- RS21 will perform other statistical analysis on the probability distributions (e.g. chi-squared tests, etc.) to further flesh out differences between OPCs or identify anomalies.

DATA

- Integrating more types of variables (e.g. genomic indicators) will create more discrete OPCs.
- Integrate intent-of-care, which is not currently factored into the demonstration OPCs.

PROOF OF CONCEPT OPCs

*Computational
Feasibility*

THE TWO PRIMARY TASKS

CLUSTERING

Grouping episodes together based on demographics and clinical data to create OPCs.

We have already sped this process up by implementing a 'spatial index' on the episode data.

COST-CURVE CREATION

Analyzing the claims of episodes within OPCs to understand expected costs.

Cost curves can be created faster by parallelizing the analysis, a common solution to analyzing big data.

POTENTIAL CHALLENGES

CLUSTERING

DBSCAN clustering methods need to search through each item in the set every time it 'places' an episode, meaning that computing time exponentially grows with increasing data sizes.

COST-CURVE CREATION

In order to understand costs, each claim for every episode must be retrieved and analyzed, which can become time-consuming.

SOLUTIONS

CLUSTERING

RS21 has already implemented a 'spatial index' on the episodes provided, which resulted in the creation of clusters in seconds instead of hours. Spatial indexing creates a 'lookup table' for neighborhoods of episodes, preventing the algorithm from needing to look through all episodes to locate clusters.

COST-CURVE CREATION

Summarizing large quantities of data is a common problem which has well-known and supported solutions such as Apache Hadoop and other distributed data processing tools. These work by having multiple servers work in parallel, feeding summaries of the episodes to a 'master' server which would produce the final cost curves from those summaries.

PROOF OF CONCEPT OPCs

*Separating cancer
related costs and non-
cancer related costs*

CANCER VS NON-CANCER COSTS

EPISODE SIMULATION

The current cost curves have been created by simulating 5,000 episodes per OPC. These simulated episodes are created by sampling an episode length and number of claims, then sampling the same number of claim codes from all episodes in the OPC to create cost curves.

This process selects more common codes for the OPC and minimizes codes that are uncommon.

These selected codes are representative of the claims that are related to treatment.

OUTLIER DETECTION AND FILTERING

MACHINE LEARNING

There are more advanced techniques to perform outlier detection to identify claims that are relevant to OPC cost of care.

These may include clustering techniques, isolation forests, and other statistical methods.

Additional data will assist in identifying patterns of claims pre- and post-diagnosis, or between cancer-free demographic segments and OPC claims.

**THANK
YOU**

ABOUT RS21

RS21 is a world-class software development, data analysis, and creative design consultancy that solves the world's most complex challenges through machine learning and data visualization. We work to help cancer researchers look across datasets, communities recover from natural disasters, and healthcare organizations address the social determinants of health.

OUR LEADERSHIP



**CHARLES RATH,
PRESIDENT & CEO**

Charles R. Rath is the President & CEO of RS21, one of the fastest growing companies in America created to help businesses and communities prepare for a dynamic and changing world.

Charles was recently identified as a 40 under 40 Vanguard by Next City for innovations in urban resilience. He speaks globally on the future of technology, with a particular focus on next generation applications for data, analytics, and visualizations. Charles holds a Master's Degree in Public Policy from American University in Washington, DC and a Bachelors from the University of Missouri.

PHYSICIAN-FOCUSED PAYMENT MODEL
TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL WITH
INNOVATIVE ONCOLOGY BUSINESS SOLUTIONS, INC. (IOBS)
ON
MAKING ACCOUNTABLE SUSTAINABLE ONCOLOGY NETWORKS
(MASON)

Thursday, June 21, 2018

12:30 p.m.

PRESENT:

GRACE E. TERRELL, MD, PTAC Committee Member
ROBERT BERENSON, MD, PTAC Committee Member
BRUCE STEINWALD, PTAC Committee Member

ANN PAGE, Assistant Secretary for Planning and
Evaluation (ASPE)
JULIA DRIESSEN, PhD, ASPE

BARBARA L. McANENY, MD, MACP, FASCO, IOBS

P R O C E E D I N G S

[12:31 p.m.]

1
2
3 MS. PAGE: I'll just say, Dr. McAneny, we
4 do this for all calls with submitters. This call
5 is being transcribed, and we do that for a couple
6 reasons. A, it helps our memory, so we don't have
7 to try to remember what was said. We actually have
8 a transcription, but then when the PRT's report is
9 posted on the PTAC website, the transcription is
10 too. And that's because we consider it sort of an
11 event. Then it's part of the proposal.

12 DR. McANENY: Okay, okay.

13 DR. TERRELL: Sure. So thank you, and,
14 Barbara, basically, thank you for submitting the
15 MASON proposal. What we have done as the PRT --
16 you probably know all this, but there's a
17 Preliminary Review Team of three. In this case,
18 I'm the one leading that.

19 We have typically -- and this is what
20 we've done in this case. We receive the proposal.
21 We get information. Say if it's a -- you know, if
22 the application and all that has been completed,
23 acceptably by the ASPE team, and then we have some
24 time where we are on the phone together, we're not

1 deliberating, but we're just sort of going through
2 what we need to ask and understand what we're
3 confused about.

4 We did that with a couple of meetings in
5 the case of this one, formulated some questions,
6 which we sent to you, and received those answers
7 back.

8 And also, we end up with research that we
9 ask for sometimes, or we will talk to -- if there's
10 aspects that we think is relevant from other
11 federal programs, that we'll get information from
12 that. And we did in this case. We had a
13 conference call that involved CMS and OACT and did
14 that back on the 11th.

15 So this is now a time when we can have a
16 chance to talk to you with things that have come
17 up. Sometimes after this, there will be further
18 questions. I'm trying to think if there's been a
19 time when we've actually had two. I think I was on
20 one PRT where we spoke to the submitter twice, but
21 oftentimes, after having an opportunity like this,
22 we don't do that. But we may end up sending you
23 some more questions just to answer by email.

24 So, with that, we've had a little bit of

1 conversation about some of the things that we're
2 wanting to get some more elaboration about, and so
3 I'm just going to go through the ones that we had
4 sort of thought about ahead of time. And as we go
5 through these, I would use my time just to say
6 those, and then Bruce and Bob may ask -- or me, for
7 that matter -- further clarification or other
8 things that come up as we're talking.

9 Does that all sound okay with you?

10 DR. McANENY: That sounds fine with me. I
11 didn't know this would be a formal transcript, so I
12 didn't prepare written comments.

13 DR. TERRELL: Okay.

14 DR. McANENY: So, hopefully, I will not
15 be too informal or ungrammatical.

16 DR. TERRELL: Okay. Well, I'll try to be
17 good too.

18 So, anyway -- so my first thing to say is
19 because the proposed model was reliance on some of
20 the oncology payment categories, or OPCs, we wanted
21 to discuss in more detail some of the definitions
22 of the varying episodes and treatment regimens that
23 will be established, including the evidence that
24 will be used to construct the episodes and any part

1 of that that will be proprietary.

2 So could you talk a little bit about how
3 you're going to define these episodes and treatment
4 regimens, how you're going to establish that?

5 DR. McANENY: Yes, I'd be happy to.

6 So the first thing I want to say, however,
7 is that I look at this as a much needed refinement
8 for the oncology care model, which constructed its
9 episodes based on time.

10 So that has created multiple problems, as
11 I outlined in many of my answers, in that the time
12 for various regimens vary considerably, and time
13 becomes an artificial construct when you're looking
14 at oncology regimens.

15 So the way we would define this regimen is
16 it will be documented in the pathway descriptions.
17 So in the medical literature, which is definitely
18 open source, there are literature-based
19 chemotherapy treatment regimens.

20 So, for example, of breast cancer, it can
21 vary from Adriamycin, Cytosan, times four doses,
22 which -- every three weeks or sometimes every two
23 weeks, which means that the regimen lasts
24 approximately three months.

1 Then there are some where the patient gets
2 Adria-Cytoxan followed by a taxane and Herceptin,
3 and that particular regimen goes on for a year. So
4 trying to fit either of those into a six-month
5 arbitrary interval doesn't really work.

6 So we chose to look at time as just being
7 one more of the variables that would be needed to
8 construct each category, recognizing that a patient
9 will fall into more than one category.

10 So in the breast cancer example I just
11 gave, if you have the person who's getting what we
12 refer to as ACx4, which is a very literature-
13 defined regimen, it is also -- at the end of that
14 regimen adjuvant chemotherapy, they will then -- if
15 they elected lumpectomy with radiation, they would
16 then go on and get radiation. If they did not,
17 they would just go on to either hormonal therapy or
18 surveillance, depending specific criteria of the
19 cancer itself, whether it is sensitive to hormones
20 or not.

21 And so the next episode would be also of
22 varying length if the patient is on simply
23 surveillance. They have completed all their
24 chemotherapy and we're just watching them, then

1 that surveillance episode can be years long, and
2 then an arbitrary six-month payment period makes
3 sense.

4 If the patient then is on radiation
5 therapy, they would need to have the radiation
6 completed and then go on to a surveillance episode,
7 and if the woman is unfortunate enough to relapse,
8 surveillance episode ends, and she would go back to
9 an OPC for metastatic disease.

10 So the regimens are defined by the medical
11 literature and are well established through the
12 NCCN guidelines. The regimens as described in the
13 NCCN guidelines and which we use for the COME HOME
14 pathway guidelines also include the appropriate
15 imaging, the appropriate genomics, you know, when
16 needed, and the -- for example, in
17 Adriamycin/Cytosan, followed by taxane/Herceptin,
18 it would also include an echocardiogram every three
19 months, and that's pretty much the standard of
20 care.

21 DR. TERRELL: Yeah, yeah.

22 DR. McANENY: Those are not proprietary.

23 So what we did is we would take that
24 oncology payment category to make it as precise as

1 possible for a specific patient with specific
2 clinical characteristics and define it by the
3 regimen that was chosen, and the OPC would then
4 include everything but the drugs. It would include
5 the cardiac echo in my previous example. It would
6 include office visits. It would include surgery,
7 radiation therapy, visits for the primary care
8 doctor. It would include everything else that
9 would be determined to be the standard of care for
10 that.

11 And we do this in two ways. We start out
12 with the regimen, as selected as the standard of
13 care in the pathways, and include all of that. We
14 double-check it by a statistical method, where we
15 can take patients with those categories, those
16 clinical characteristics, and see whether or not
17 the codes are done in common for that particular
18 person.

19 So, for example, the cardiac echo codes
20 would be there probably four times for the person
21 who is getting a year of Herceptin because we do
22 those every three months. So we would expect to
23 see three of those codes within that, so that gives
24 us a double check that says, "Yes, this is part of

1 the standard of care." So it's an iterative
2 process going from the clinical characteristics to
3 the claims data and back and forth to really fine-
4 tune those episodes.

5 I would also add that this is not going to
6 be something where we can create it once and then
7 we're done because practice changes. They may
8 decide, you know, in 2021 that AC is no longer the
9 best regimen for breast cancer; it should switch to
10 something else. And that would have a different
11 set of timeline and of processes to go with that.

12 MR. STEINWALD: May I ask a question, Dr.
13 McAneny?

14 DR. McANENY: Sure.

15 MR. STEINWALD: This is Bruce Steinwald.
16 I am a member of the PRT.

17 Did you consider alternatives to the
18 approach that you posed in your proposal? And by
19 that, I mean as opposed to starting from scratch.

20 You may know that we reviewed a proposal
21 from Hackensack with the Cota system, which looks
22 and sounds like it's similar to yours, and we also
23 wondered if there were other -- other systems in
24 place or in development that might have

1 accomplished the same aim as your OPCs and without
2 requiring you to basically start from square one.

3 DR. McANENY: Well, I actually looked at
4 the Cota system as being more starting from square
5 one because it had a very complicated coding system
6 that I found difficult to actually follow and
7 figure out how to implement.

8 I tried to base the idea of an oncology
9 payment category on something that Medicare is very
10 familiar with, the idea of a DRG or an APC, so that
11 it sets up as a specific kind of category for that.

12 I'm not familiar with any others, other
13 than the Cota process, which was just for breast
14 cancer, and therefore, I felt more limited. And I
15 thought that would take a lot more restructuring of
16 the way practice occurs than to just look at what
17 we standardly do now and work with the claims
18 process.

19 MR. STEINWALD: And other than that
20 system, you didn't -- you weren't aware of any
21 others that were in development that might also be
22 of benefit to you?

23 DR. McANENY: Well, I was on the team that
24 helped work with the ASCO PCOP model, and

1 originally with COME HOME. I was requested at the
2 beginning of that RFP to make it be self-
3 sustainable in year three. At that point in time,
4 when I started out with COME HOME, I thought, well,
5 the drug should be in the -- in the bundles because
6 that way, you know, it should -- everybody should
7 be using pretty much the same drugs, and it should
8 all be a wash. But my experience with the Oncology
9 Care Model has convinced me that that was in error
10 and should not be part of it.

11 For the ASCO PCOP model, again, it does
12 not include the drugs. It basically looks at the
13 fact that a lot of the things that we do are not
14 well reflected in the fee-for-service payment
15 system. There's a -- as you guys are well aware,
16 there's a marked disconnect between what we get
17 paid for and what we actually would like to be able
18 to do for patients.

19 So those are the only two I'm aware of for
20 -- that are specific bundle-creating processes for
21 oncology.

22 MR. STEINWALD: Okay. Thank you.

23 DR. BERENSON: So let me jump in. This is
24 Bob Berenson, and I am still confused about one

1 thing in developing the OPC spending targets.

2 I understand -- I have an echo. Does
3 anybody else have my echo?

4 DR. McANENY: Nope. You sound good to me,
5 and I doubt you're ever confused about anything,
6 Bob.

7 DR. BERENSON: Well, I am.

8 I have a slight echo, so I will deal with
9 it, as long as everybody else is happy.

10 DR. TERRELL: There's no echo here.

11 DR. BERENSON: What you have laid out is
12 sort of a normative -- sort of normative
13 requirements. You know, the drug costs so-and-so,
14 and here is how you give it. Here is how many
15 doses you give, four echos a year. These are sort
16 of activities that should take place -- drugs
17 prescribed, surveillance, testing, et cetera, a
18 number of visits perhaps.

19 But then, empirically, patients inevitably
20 get hospitalized, et cetera. Well, hospitalization
21 would be a major part of it. So I don't
22 understand. Explain to me the difference or how
23 both the actual spending for a cohort of patients
24 who go into a protocol is determined and how much

1 of it is based on the sort of normative, which you
2 can get from the literature, these normative
3 standards that should be done for good care for
4 those patients. Do you understand what I'm getting
5 at?

6 DR. McANENY: I think I do. So let me try
7 to answer that.

8 We started out, as we looked at this, with
9 looking at claims data, and we found that there
10 were some clusters of claims data, to continue with
11 the breast cancer example, and this has been one of
12 the problems that the OCM has had in that they try
13 to average it all together and hope that the
14 actuarial quantity of patients and quality of
15 patients that show up in each practice will sort of
16 lead toward that, that average, which is an
17 assumption that we have significant problems with,
18 since we have the law of small numbers to contend
19 with.

20 But we noticed in the -- in the claims
21 data we had for our 7,000 COME HOME patients that
22 there would be clusters, and in those clusters of
23 claims data, we would see the hospitalizations.
24 We'd see the surgical cost. We'd see the radiation

1 cost. We'd see the total cost of care since we had
2 all the Medicare claims for those patients.

3 So, as we look at those various clusters,
4 then what we realized was that there are also some
5 clinical characteristics that fit with those
6 clusters. That people with HER-positive disease
7 are going to be significantly higher than people
8 who don't. That people who have peritoneal
9 metastasis with colon cancer are going to have more
10 hospitalizations for bowel obstruction symptoms,
11 which we cannot manage in the outpatient arena, and
12 those patients will have more hospitalizations than
13 someone whose stage 4 colon cancer is manifested by
14 liver metastasis only, where they mostly are an
15 outpatient and rarely are in the hospital. So we
16 would account for the hospitalizations that way.

17 And because this process has to go back
18 and forth between the claims data and the clinical
19 data, we try to look at the claims data, measure
20 what we can pull out clinically, and then flip it
21 to use that as a predictive situation. So if I can
22 look in my EMR and see this patient has stage 4
23 colon, but I can also put in a field that says they
24 have peritoneal metastasis, the OPC for that

1 particular patient would be different than the OPC
2 of a patient with just liver mets because there
3 would be more hospitalization.

4 DR. BERENSON: So that's empirical.
5 That's empirically determined.

6 DR. McANENY: Yes. Yes.

7 And as one of the things that we need to
8 be able to do to develop these categories -- so let
9 me back up a little bit.

10 The goal of creating an OPC was to give
11 each practice, each doctor taking care of an
12 individual patient, a more realistic optimal target
13 to aim for in terms of the cost of care of a well-
14 managed patient, rather than hoping that as a group
15 of patients in my practice that I got very few with
16 peritoneal mets a whole bunch who just had their
17 liver involved, you know, because then I would come
18 out ahead.

19 So that we were trying to create something
20 that gives you a real target for optimal therapy
21 and then be able to manage to that rather than
22 trying to manage actuarial risk.

23 And that this will take time to develop
24 because you have to have a certain volume of

1 patients that fall into each one. So the OPCs
2 would be developed faster for patients who have
3 colon cancer, breast cancer, and lung cancer, the
4 three most common sites, than somebody who comes in
5 with a thyroid cancer where it may take years to
6 get -- or a couple years, probably, to get a
7 statistical group.

8 So that's why when the RFI came back in
9 last November saying that Medicare wanted to look
10 at some pilot projects, we talked to this group of
11 NCCA practices, all of whom are willing to
12 participate, and thought, okay, all but like one of
13 these are on the same EMR. We can pull the
14 clinical data. They have agreed to use the
15 pathways, and we can extract pathway compliance
16 from them.

17 So we know the clinical characteristics of
18 the patient. We know what regimen they're on. We
19 know how often various codes ought to be submitted
20 for the appropriate therapies in this, and we know
21 from the previous claims data what the target OPC
22 payment should be.

23 But that will get modified over time. As
24 we -- as we get more and more patients, we should

1 be able to narrow that down.

2 DR. BERENSON: So I think I mostly
3 understand that, but you gave the example earlier
4 about treatment of breast cancer. There might be a
5 new drug that comes along and it will change it.
6 So if we're starting de novo with a new drug where
7 we need to collect data on hospitalization rates,
8 et cetera, what kind of "n" do you need? How long
9 would it take before we actually can develop an OPC
10 for that treatment?

11 DR. McANENY: Well, that was one of the
12 reasons that I did not include the drugs and I
13 decided that I was previously wrong to think that
14 that would all be a wash.

15 DR. BERENSON: Okay.

16 DR. McANENY: And that that's the thing
17 that the OCM is struggling with, to decide who's an
18 early adopter and who's a late adopter, et cetera,
19 because there's a new drug coming out every week.

20 So what we have found with the pathways is
21 that meeting after ASCO to see if there's anything
22 that changes therapy and being able to have a
23 quarterly pathway update process so that we stay
24 current. We found that that works pretty well.

1 There are very few things that are faster than
2 that, but we have the ability to call a pathway,
3 call if some new wonder drug occurs.

4 And, as we put those in that process, one
5 of the things we're hoping to be able to do is to
6 say, okay, we add a new drug regimen to this. We
7 also have the triage pathways that were the heart
8 of COME HOME. So, as we start a new regimen, we
9 can measure over the following several months while
10 that regimen is in action, how many times people
11 are activating the triage pathways needing
12 interventions that occur in the office or
13 interventions that occur in the hospital and
14 collect that data, which would allow us then to
15 create an OPC for that, that included that new drug
16 and its new side effects.

17 DR. TERRELL: I'm going to move us a long
18 a little bit.

19 Before we get off this question, though --
20 and I think it's relevant to what we're all -- the
21 discussion we've just had -- is related to any
22 proprietary components of how this will be
23 developed.

24 So you may have noticed that in the

1 responses to PTAC that the Secretary has basically
2 made some comments that anything that was
3 proprietary in nature, they were likely not going
4 to -- you know, weren't going to implement or use.

5 So there's been a lot of work done
6 already. You've done a lot of it in cooperation
7 with CMS as it relates to the previous
8 demonstrations, but are there components of this in
9 terms of how you're going to develop it, these OPCs
10 that would be considered, quote, "proprietary"?

11 DR. McANENY: Well, the short answer would
12 be no.

13 DR. TERRELL: Okay.

14 DR. McANENY: I have a -- I really am
15 frustrated with the whole pathway industry because
16 pathways are derived from the medical literature,
17 and I strongly believe that those should be open
18 source and they should be modifiable.

19 So when we created the pathways for the
20 drugs and the drug usage of the diagnostic and
21 therapeutic pathways, we created those through COME
22 HOME. I have now sort of given those to this
23 National Cancer Care Alliance group to just update,
24 but they are on the website. If you look at the

1 NCCA --

2 DR. TERRELL: Yes.

3 DR. McANENY: -- website, they are there.
4 They're completely open, just like NCCN is.

5 DR. TERRELL: Okay.

6 DR. McANENY: My triage pathways that I
7 personally developed that help guide people to the
8 right site of care are currently proprietary, but I
9 would roll those out as part of this and make them
10 not proprietary if that were necessary.

11 There are other options for that. People
12 can use whatever system of triaging patients to the
13 right source -- site of care that they wish. So it
14 would not be mandatory to use any proprietary
15 pathway processes.

16 DR. TERRELL: Okay.

17 DR. McANENY: As we generate an OPC, you
18 know, we envision that becomes, more or less, the
19 property of CMS. You know, that it's sort of like
20 the RUC works with CMS as well.

21 DR. TERRELL: Okay. Very helpful. Thank you.

22 So, as this is just a comment back based on -- as
23 opposed to a question based upon, you know, the meetings
24 that we had where we had a chance to talk to the folks at

1 CMS and OACT, and one of the things that they stated about
2 the six-month period that they use for their current OCM
3 model is that they felt like most of the chemo regimens
4 were within that six-month window, anyway, if I'm recalling
5 what they said correctly, when they looked at it. And they
6 had a need for simplicity.

7 So one of the things that's been very specific to
8 your points here is that many of them are not, and they're
9 longer. Do you have any data that would basically give a
10 percentage of how many -- of how much would typically, in
11 terms of chemotherapy period and whatnot, be longer than
12 six months in terms of standard types of cancers that
13 you're proposing?

14 DR. McANENY: I would -- I haven't compiled as a
15 percentage --

16 DR. TERRELL: Yes.

17 DR. McANENY: -- of how much is six months versus
18 how much is not, but I can tell you that a lot of what we
19 treat is metastatic disease --

20 DR. TERRELL: Yes.

21 DR. McANENY: -- which goes on for forever or as
22 long as the patient has reasonable performance status and
23 wishes therapy.

24 DR. TERRELL: Yes.

1 DR. McANENY: So all the metastatic regimens are
2 much longer than that. All the breast cancer that get
3 hormonal therapy are five years to ten years.

4 I think that a distinct minority of chemotherapy
5 regimens are completed in six months.

6 DR. TERRELL: Okay. Thank you. That's helpful.
7 So --

8 DR. McANENY: So I think that actually, rather
9 than simplifying it, what we're finding in OCM is that that
10 added some confusion because what happens when there is a
11 delay or the regimen is eight months long or patients are -
12 - have an intercurrent pneumonia that delays therapy, and
13 they're now an eight-month, nine-month regimen. Is that
14 two episodes? Is that one?

15 And with the arbitrary end of an episode not
16 correlating with the calendar episodes for the quality
17 data, any patients that I meet in December who elect to
18 delay their staging until after Christmas are not
19 completely staged until January, so their regimen starts in
20 January. They're not staged, so I get bad quality numbers
21 because I'm not staging my patients that are registered to
22 me in December. I mean, it's a very strange process.

23 DR. TERRELL: Okay. Thank you.

24 So let's move on to the justification of 2

1 percent over invoice reimbursement for the drugs. Tell me
2 how you derive that as being the right way to assess this
3 and the right number.

4 DR. McANENY: So two things on that. One is that
5 I was trying very hard for transparency because I know
6 there are two assumptions out there. One is that
7 oncologists will select drugs based on profit, and the
8 second is that we actually make money on Medicare
9 chemotherapy. Unfortunately, the second one is not true,
10 unfortunately for me, and most oncologists have no clue
11 what anything costs.

12 So for the vast majority of oncologists, I doubt
13 that they are making that. So I disagree with those two
14 assumptions.

15 However, Medicare pays pretty quickly. They pay
16 within 14 days. What happens -- and my theory here is that
17 I want to create a system that will work not just for
18 Medicare and governmental payers, but will allow us to do
19 bundling and value based-type care for all patients,
20 commercial patients as well.

21 DR. TERRELL: Mm-hmm.

22 DR. McANENY: Unfortunately, commercial payers
23 love to string out the payment for the expensive oncology
24 drugs. So part of the 2 percent is the time cost or the

1 time value of money.

2 So I buy a drug, and if it's 5FU and it cost me
3 two bucks, I don't really care if they take 60 days to 90
4 days to pay me, which is not unusual.

5 DR. TERRELL: Mm-hmm.

6 DR. McANENY: They'll usually pay the E&M codes
7 pretty quickly, and then they'll stall and want more data
8 and, you know, all this stuff for the drug cost.

9 And so we find that an average time that we're
10 being paid back for the medications that we are buying and
11 billing is between 60 and 90 days.

12 Now, I have to purchase these drugs, and I have
13 to pay the vendor for them either immediately, which is
14 what they want, or I can sometimes -- the best terms you
15 can get for that is 30 days, which means that oncology
16 practices are being the bank for payers.

17 DR. TERRELL: Oh, I'm very intimately aware of
18 this issue. When I was the CEO of a multispecialty group,
19 we had a high volume, oncology private practice as part of
20 it, and we had to manage those costs very, very carefully
21 for all the reasons that you've outlined.

22 But let me -- let me get -- so the 2 percent -- I
23 just want to make sure -- was part of the time cost of the
24 bank.

1 DR. McANENY: Right.

2 DR. TERRELL: But that also includes estimations
3 for commercial payers, because that may be an issue with
4 respect to what you're -- what a Medicare program would
5 find acceptable.

6 DR. McANENY: Right.

7 DR. TERRELL: So that needs to be thought through
8 there.

9 DR. McANENY: Well, there's -- and I understand
10 that, and I know -- and I was aware that Medicare would
11 probably not like the percentage because they are concerned
12 that that means we like the more expensive drugs.

13 But the reason I bring that up is that the more
14 expensive drugs are the ones that put my practice at higher
15 risk --

16 DR. TERRELL: Mm-hmm.

17 DR. McANENY: -- of not being able to manage the
18 cash flow. The --

19 DR. TERRELL: But you're saying that's mostly for
20 the commercial payers?

21 DR. McANENY: But not all.

22 DR. TERRELL: Okay.

23 DR. McANENY: If we get denied on Medicare, I
24 have claims that are going all the way to the ALJ, which is

1 out two years.

2 DR. TERRELL: Okay.

3 DR. McANENY: So it's not simply that. If you
4 have a denial with the commercial payers, you usually will
5 either get completely denied, which is rare, or paid at
6 about 90 days. But for Medicare, there's a subset, and I
7 don't have good data on this everywhere, I will freely
8 admit, on how often people end up writing off Medicare
9 patients.

10 The other thing is that we get a significant
11 amount of bad debt from the patients who have inadequate
12 Medigaps.

13 DR. TERRELL: Yep.

14 DR. McANENY: And I notice that Medicare tends to
15 look at fee-for-service Medicare as being different from
16 Medicare Advantage, but we have significant amounts of
17 patient parts from those who are on Medicare Advantage
18 plans, and we have significant quantities of delay in
19 paying the Medicare Advantage balance.

20 DR. TERRELL: Okay.

21 DR. McANENY: A lot of that is the time cost of
22 money.

23 If I were to average it out and just have it as a
24 fixed add-on that was drug irrelevant, I calculated that as

1 being about \$20-per-infusion event to cover that.

2 The other expenses that I couldn't fit into the
3 infusion center fixed-cost facility fee, which covers the
4 USP 800-compliant pharmacies and double gloves, the
5 protective equipment, all the stuff that are used for every
6 single patient, part of the issue particularly with the
7 biologics and the more expensive drugs, which is really a
8 problem for many oncology practices, is the specific
9 handling requirements for that, all the shipping cost in
10 terms of -- if I say, "Whoops. This vial is cloudy, or the
11 seal is cracked. I'm not going to infuse this into a
12 patient, and I need to send it back," there are a lot of
13 those kind of carrying costs that are there just as part of
14 a pharmacy.

15 And part of the underlying issue -- and this is
16 something that you'll have to -- so I'm asking for
17 technical advice here, now that you're allowed to give that
18 -- is that, you know, I have two things to sell as a
19 business. One is a block of my time and expertise, and the
20 second one is the infusion drugs. And you can't buy the
21 apple and sell the apple for exactly the same amount of
22 money or you're not in business for very long.

23 Two percent is an amount that would cover the
24 cost of doing that. It does not leave much of a margin, if

1 any, but it means that I would no longer be losing money on
2 Medicare patients.

3 DR. TERRELL: Okay.

4 DR. McANENY: Now, this technical advice, would
5 this be more likely to be accepted by Medicare if I got
6 away from the percentage because of their concern that I
7 would be selecting expensive drugs, even though when you --
8 I will point out that one of the things I submitted in my
9 original PTAC proposal was a survey we did within the
10 National Cancer Care Alliance, where we got the actual
11 costs of drugs that people were acquiring them for and
12 compared those to ASP, which -- an ASP+6 for -- or 4.3 with
13 the sequester for Medicare reimbursement, and there was
14 significant quantities of red ink on that page. And I
15 don't know whether you guys appreciated that or not.

16 DR. TERRELL: I don't know that -- number one, we
17 can't exactly give technical advice. We can give initial
18 feedback, is sort of the way that the clarification --

19 DR. McANENY: Okay.

20 DR. TERRELL: -- in the law came, and even if we
21 could, I don't know that we can guess Medicare's policy
22 thought process.

23 So the way that you've asked that right now, I'm
24 not sure that we can be terribly helpful, but we will take

1 that offline. And if there seems to be something that we
2 can provide that we believe we can that would be useful and
3 meaningful, we will do so.

4 But I'm going to move on from that, if that's
5 okay with everybody else.

6 DR. McANENY: Okay.

7 DR. TERRELL: Are there any questions related to
8 this before we go to the concept of virtual accounts?

9 MR. STEINWALD: No.

10 DR. TERRELL: Okay. All right. So just walk us
11 through the whole virtual account. We -- you know, as
12 you're seeing it. You know, what makes it up? How do you
13 construct them? Just give us some clarification, and then
14 I think what's going to happen as you do that is that we're
15 going to have some more clarifying questions.

16 DR. McANENY: Okay. So let's assume that the OPC
17 for a given patient, for ease of numbers, is \$100,000.
18 That includes their hospital rate. You know, they'll be in
19 the hospital for original surgery. It includes radiation.
20 It includes E&M visits for all of the physicians involved.
21 It includes pathology. It includes infusion cost. It
22 includes everything that we rolled into the OPC. So let's
23 assume that that is \$100,000.

24 So then in the virtual account, no money changes

1 hands, but we can see in that account, which is just a
2 computerized visual of this, that Barbara McAneny has
3 \$100,000 in her account, and then the hospital bills come
4 in, and they're subtracted from that. My office bills come
5 in and they're subtracted. Everything is subtracted that
6 we listed out there, including the meals, like payment for
7 all of the care management, patient education, phone
8 triage, processes that currently don't have an E&M code.
9 So that is listed in there.

10 The first thing I do, I look at that virtual
11 count, and through funds of the practice, not from that
12 because I haven't gotten any money from that yet, is I put
13 -- I assume that some percent of that goes into the quality
14 pool that I know I'm not going to be able to achieve unless
15 I get the -- unless I meet my quality thing. So -- now I'm
16 blanking on the number that I put in on that. I think it
17 was 4 percent.

18 DR. BERENSON: Two.

19 DR. McANENY: Two. Two percent. So that 2
20 percent goes into that. So I know that only \$98,000 is
21 really available to me unless I meet the quality bonus.

22 Then I would also have purchased, just out of the
23 practice's funds, reinsurance, so that if a patient -- if a
24 given patient is -- if I set my limit at -- I can't afford

1 anything more than \$150,000 for this patient. If they cost
2 \$151,000, my reinsurance would kick in. If I have an
3 aggregate of patients where I'm more than, you know,
4 \$100,000 above, then the reinsurance would kick in to pay
5 back Medicare.

6 So back to the original, the individual patient,
7 so I look at this as \$98,000 is still available to spend on
8 this patient. The hospital bill comes in, and it's
9 \$30,000. So I can see that, and it drops down then to
10 \$68,000. I do E&M codes, as I submit each of those bills,
11 and I submit the infusion codes and I submit my facility
12 fees, I can see that account, those charges being
13 subtracted from that account.

14 The reason I would use non-adjudicated claims is
15 I've been in this business long enough to know that when
16 Medicare adjudicates a claim, it never goes up. So I'm
17 managing to worst-case scenario, the most expensive it
18 would be. If Medicare then adjudicates it and lowers what
19 they paid for a given procedure or something, then that
20 leaves more cash in my account, but that's fine. And it's
21 easy to manage to.

22 So I look at this as a management tool. If they
23 go and see the surgeon and I discover the surgeon is doing
24 a whole bunch of extra imaging, all that imaging is then

1 visible to me, I have a way to intervene that or at least
2 to be able to say, you know, Surgeon X is always blowing
3 out my virtual account because they like to get a PET scan
4 every month, and I don't want them to do that. So maybe I
5 should use Surgeon Y who doesn't do those things. It gives
6 me information and insight into the practices of the entire
7 team of people taking care of that patient, and just having
8 that surgeon know that I'm aware of that sometimes is
9 useful or it can stimulate a conversation. So it lets me
10 manage each individual patient prospectively so that I can
11 intervene if I see something going over.

12 If one of my partners manages patients and they
13 get a PET scan every month, which I would consider an
14 optional thing because it's not required on the pathway,
15 then that gives me a time to sit them down and say, "What
16 are you doing? Stop doing that, unless you have a really
17 good clinical reason to do this."

18 So that makes it very much real time, and the
19 non-adjudication means that I'm looking at worst-case
20 scenario.

21 DR. TERRELL: So do you believe that Medicare can
22 provide that in its current systems, Barbara?

23 DR. McANENY: I don't know the answer to that.

24 DR. TERRELL: Okay.

1 DR. BERENSON: So let me ask the question. I
2 mean, I understand completely the logic of wanting to
3 monitor your spend on every individual patient, but sort of
4 two related questions. One is that a lot of the delay in
5 getting -- well, a lot of the delay is submission which --

6 DR. McANENY: Yes.

7 DR. BERENSON: And is there any way that you can
8 do that?

9 And the second part of the question is I think
10 that Medicare typically pays like within 15 days. So why
11 not use allowed charges rather than -- I mean, the
12 reduction from charges to allow charges is going to be
13 dramatic in many cases, and so why not just use the
14 adjudicated, the allowed charges, and work on all your
15 participants as you can, submitting claims promptly, rather
16 than holding them for a few months?

17 I guess those are my two related questions.

18 DR. McANENY: Yeah. So allowed charges would be
19 a reasonable surrogate for that. I just wasn't sure
20 whether Medicare would be willing to give that or not.

21 I figured if the charges are being submitted to a
22 large Medicare computer, they can also tag it to go into
23 another computerized list, an account set up. I didn't
24 figure that would be too difficult, so I don't know whether

1 or not Medicare could actually do that. And I don't have
2 any way of finding that out.

3 DR. BERENSON: All right. But you could work, I
4 assume -- I mean, the lag isn't between Medicare receiving
5 a claim and paying the claim. That's as opposed to
6 commercial insurance. We're talking they can deny, and it
7 takes months for appeal. Medicare typically doesn't do
8 that.

9 DR. McANENY: True.

10 DR. BERENSON: So you could work with allowed
11 charges if that were available to you, I assume, and then
12 do you have any strategies for ensuring that that surgeon
13 is submitting their claims promptly?

14 DR. McANENY: Well, so I think switching to
15 allowed charges would be acceptable. It would just be
16 probably a two-week delay, which is still --

17 DR. BERENSON: Right.

18 DR. McANENY: -- in the realm of being
19 manageable. So I wouldn't have any objections to that.
20 That might be easier.

21 Managing surgeons.

22 [Laughter.]

23 DR. TERRELL: Sorry.

24 DR. BERENSON: Okay.

1 DR. McANENY: Yeah.

2 DR. BERENSON: No, I understand. It was just --

3 DR. McANENY: But we -- but we know --

4 DR. BERENSON: -- such an emphasis, so --

5 DR. McANENY: If we know the -- if we know that
6 the -- we know when patients are getting things done --

7 DR. BERENSON: Right.

8 DR. McANENY: -- that are cancer-related. We
9 know when we refer somebody in to get a port placement. If
10 we know that that port placement is going to generate that
11 bill, you know, and we know that what Medicare pays that
12 particular facility or whatever it is for that, which I
13 currently don't often know, then we would be able to
14 subtract that account and then lean on people to submit
15 bills.

16 DR. BERENSON: Mm-hmm. Okay.

17 DR. McANENY: I mean, most of the time when we're
18 allowed to work with the people that we commonly refer to,
19 it's pretty easy to have conversations and explain what's
20 going on.

21 DR. BERENSON: Mm-hmm. Okay. That's helpful.

22 DR. TERRELL: Okay. Bruce, do you have any
23 questions regarding these issues?

24 MR. STEINWALD: Why don't you move on?

1 DR. TERRELL: Okay. So the next thing that we
2 were thinking about was really clarification about support
3 drugs versus, you know, the ones that are included in the
4 exclusion of drugs from the OPCs. Could you give us some
5 clarification about that, how that would be determined,
6 what's a support drug, what's not a support drug? How are
7 you determining that? Is it going to be a list based on
8 protocols?

9 I mean, obviously, a lot of these are symptom
10 drugs.

11 DR. McANENY: Right. They are symptom drugs.
12 They are the anti-emetics, there are bone-density drugs.
13 They are the dexamethasone we give to people and Benadryl
14 and not have reactions, et cetera.

15 I figured if we have the drugs out of there, I
16 didn't want -- in trying to avoid any sort of adverse
17 incentives, if a patient has a lot of difficulty with
18 nausea and vomiting, I didn't want to have an adverse
19 incentive of saying, "Well, I'm still just going to give
20 you Compazine.

21 DR. TERRELL: Yeah. I was getting ready to give
22 the Compazine example, but anyhow --

23 DR. McANENY: Yeah. "And just go home and throw
24 up. Here's Compazine and a bucket," and that's cheaper

1 than using some of the ones that have been shown -- that
2 have allowed us to move chemotherapy out of the hospital --

3 DR. TERRELL: Yep.

4 DR. McANENY: -- unit to the outpatient setting.
5 You know, it's like -- and those drugs, unfortunately, are
6 expensive. Why they are expensive is, A, not understood by
7 me and, B, not in my control. But they do work a whole lot
8 better than Compazine, and I just didn't -- I wanted to
9 avoid any of the reverse incentives from what Medicare is
10 worried about, but that people will elect not to use a drug
11 in order to hit the OCM target.

12 DR. TERRELL: Okay. So chemotherapy is included,
13 but not support drugs, and the reason you did that was to -
14 -

15 DR. McANENY: No. Chemotherapy is not included.
16 I wouldn't put any of the drugs in -- to the -- to the OPC.

17 DR. TERRELL: Okay.

18 DR. McANENY: Not support and not chemo.

19 The other thing is that we have learned, just
20 with years of the ASP process, that there is a distinct lag
21 time between when the ASP amount comes out and what we're
22 actually buying these drugs for, and that also factors into
23 the 2 percent because we'll see, you know, a significant
24 shift in every time they raise prices.

1 We have no control over the pharmaceutical
2 companies raising prices whenever they feel like doing
3 that, but we cannot afford to be penalized for the fact
4 that they raise their price, but the OPC hasn't adjusted it
5 yet because we don't think we can adjust it any better than
6 Medicare can with ASP. Does that make sense?

7 DR. TERRELL: Okay.

8 DR. McANENY: So if I -- if I'm using Kytril,
9 granisetron, for antiemetics and we factored in at the OPC
10 if we were to put that into the OPC at whatever its price
11 is -- and I don't even know off the top of my head, say 100
12 bucks, and the Medicare -- or the company decides it's now
13 going to be 120 bucks and I have to buy it at 120 bucks
14 because we're buying this stuff almost daily --

15 DR. TERRELL: Uh-huh.

16 DR. McANENY: -- we can't afford to store it on
17 our shelves for very long because it's expensive. So we
18 constantly are buying this stuff.

19 And so then I'm buying it for \$120, but ASP takes
20 six months to go up. So for six months, I'm well under
21 water with those drugs, and it happens with the support
22 drugs, just like it does with the chemotherapy drugs.

23 DR. TERRELL: All right. Questions, Bruce or
24 Bob, related to that?

1 MR. STEINWALD: One quick question. Is
2 accounting for discounts and rebates any sort of an issue?
3 Ages ago, I did some work at GAO where we tried to estimate
4 -- this was at the time that ASP+6 percent came in -- and
5 found -- estimating what hospitals were paying for a
6 variety of drugs and found that discounts can be accounted
7 for, but rebates are very difficult because they come in
8 after a period of time. And the hospital accounting
9 systems often couldn't relate the rebate to the specific
10 drug. Does that kind of issue occur also with your
11 oncology practice or no?

12 DR. McANENY: Absolutely. We struggle to figure
13 out what we're really paying for the drugs when they have
14 all these complex rebate formulas, and most oncologists
15 hate this, but it's a ball and chain that the GPO has
16 attached to our ankles to keep us with their system.

17 I would love -- this is a separate topic from
18 what I could do here because as much as I would love to
19 take on drug pricing and GPOs and the fact that in the
20 physician fee schedule space, the GPO and the distributor
21 is often the same company and rebates going back and forth
22 all over the place, it is incredibly opaque and it
23 shouldn't be. It's opaque to us, so it's hard for us to
24 predict prospectively what we're paying.

1 A year later, I can decide whether I was above or
2 under water on a given drug, and if you look at that chart
3 we sent in of the actual acquisition cost, for those who
4 had the rebates, we put it in there with and without
5 rebates for exactly this purpose.

6 So I don't think I can expect in one, one
7 submission here, to fix all the ills of drug pricing, but
8 that's why I figure we needed to carve all of the drugs out
9 of this process and then address that in a separate kind of
10 issue. But you're exactly right.

11 But our data does have rebates for about half the
12 practices that could figure it out.

13 MR. STEINWALD: Thanks for that.

14 DR. TERRELL: Bob, anything?

15 DR. BERENSON: No, I'm good.

16 DR. TERRELL: All right. Let's get into this
17 unavoidable versus optional cost.

18 DR. McANENY: Okay.

19 DR. TERRELL: How can you distinguish them
20 between each other? So if we buy your argument that the
21 unavoidable cost should be included, but not the optional
22 cost -- and I think that that would be consistent with a
23 lot of the rest of the logic that we've heard, so I don't
24 think we need to hear that logic because that -- I think

1 that's been consistent with the way you're thinking through
2 the whole proposal. But how are you going to distinguish
3 that?

4 DR. McANENY: Okay. So, as we have done our
5 diagnostic and therapeutic pathway design, in our pathways
6 we have placed in them the appropriate imaging, as I
7 mentioned. We created through COME HOME -- and I'm getting
8 some data blocking from our current EMR, but when we had
9 the previous EMR, we could extract compliance with not just
10 the regimen, but the imaging, et cetera. So there are
11 recommended procedures that should be part of a treatment
12 regimen, the echo again.

13 If you are not doing the echo, you're off
14 pathway. If you are doing the echo, you are on pathway.
15 If you do extra echoes, you are not on pathway for that,
16 and we can pull data that say the echo and recorder is the
17 standard of care. If you're doing something that is not
18 that, that would be an optional choice.

19 It's like choosing wisely. If you have a PET/CT
20 scan for an asymptomatic stage 1 breast cancer woman and
21 you do a PET/CT scan, you're off pathway, and that would be
22 considered optional. And that would not be included in the
23 OPC. So that cost would be one that you would just incur
24 that you'd be at risk for.

1 DR. TERRELL: So let me dig down a little bit on
2 your echo example. Let's say you've got a treatment that
3 involves Adriamycin, and echo is part of an evidence-based
4 pathway that's part of the OPC. But then this particular
5 patient ends up with -- you know, with an unexpected
6 cardiomyopathy, such that the guidelines suggest -- are not
7 necessarily the way that the clinicians think it ought to
8 be managed. Maybe they think that an echo needs to be done
9 more frequently or whatever. Maybe it's a, you know, viral
10 cardiomyopathy, and so it could look at the guideline level
11 as being like excessive utilization but might have a
12 clinical need.

13 With what granularity and how would you do it
14 such that you could actually adjudicate that in terms of
15 avoidable versus optional? You would want the patient, if
16 they truly need the echo, to get it. How are you going to
17 distinguish that?

18 DR. McANENY: I think if you look at the number
19 of variables that appear for clinical situations like that
20 --

21 DR. TERRELL: Yes.

22 DR. McANENY: -- you can figure out some of them
23 and exclude them as a problem. If this patient had a viral
24 cardiomyopathy prior to -- well, first of all, I wouldn't

1 use Adria in that sense.

2 DR. TERRELL: Yeah. I'm just, you know, making
3 an example.

4 DR. McANENY: Let's say if they had a -- if they
5 had something where they had submitted codes for that
6 disease prior to the beginning of the episode and we could
7 determine, then, that this was an entirely separate problem
8 from the cancer, then those expenses should be attributed
9 not to the cancer virtual account. So that's how I would
10 do some of it.

11 If people develop a problem during the
12 chemotherapy, we can start it with a cluster process that
13 my statisticians are talking about. You would be able to
14 see the outliers that would be in that case because not
15 very many people will do that. So that may be an outlier
16 for that particular example.

17 If that happened to somebody who was on an
18 anthracycline or Herceptin and developed a viral
19 cardiomyopathy, that would end the regimen. You would say,
20 "Nope, we're done. We're not going to give you this drug."

21 DR. TERRELL: You believe there's enough
22 granularity in your information sources from, I presume,
23 clinical data that you can do this with enough specificity
24 to make the distinction and --

1 DR. McANENY: I think that will require sort of
2 an appeals process. We can make the first cut based on
3 statistics, but as you know well as a practicing physician,
4 patients don't always fit in that. So I think there would
5 need to be -- and I think I mentioned this in the original
6 submission. That if the clinician felt this was an unusual
7 circumstance and whatever was being attributed to the
8 cancer virtual account really should not have been, there
9 should be a way to have an appeals process, similar to the
10 process of peer-to-peer review that is common in most
11 commercial plans.

12 DR. TERRELL: And that was really getting at my
13 next question with this which is, is this going to be the
14 next, you know, quagmire that would delay payment or just,
15 you know, increase complexity to collect payment because of
16 the need to have that appeal process?

17 DR. McANENY: Well, I think the place where this
18 would make a difference is when you are completing the
19 episode and looking at whether or not we were over or under
20 the target OPC.

21 DR. TERRELL: Okay. So it would be at the -- it
22 would be at the end, then. Okay.

23 DR. McANENY: Right. So if I say, gee, this
24 patient got an extra echo because they went into the

1 emergency department because they thought they were in open
2 AI or they had endocarditis or something, then I could say
3 that was maybe not related to the cancer therapy and be
4 able to discuss whether or not that should or should not be
5 considered when I'm looking at the cost of that patient
6 compared to their OPC account.

7 But the echo would have been paid for, assuming
8 that it was within Medicare's payment processes.

9 DR. TERRELL: Okay.

10 MS. PAGE: So this is Ann Page. This is a basic
11 question. So the clinical algorithms that then relate to
12 the OCPs, they would not include comorbid conditions; is
13 that correct?

14 DR. McANENY: Correct. And that's -- you know,
15 you brought up that question about case mix with comorbid
16 conditions, and that's a very interesting one because,
17 basically, I think as we do this, we don't really have good
18 data on whether or not having the comorbid condition does
19 increase cost, or do we not treat people as aggressively
20 when they have certain comorbid conditions, such as
21 cardiomyopathies? We treat diabetics all the time, but one
22 of the -- so that probably wouldn't make a big difference.

23 But what we can do with the data process of
24 looking at these clusters is we could do -- we can look at

1 that cluster and say, "Within the cluster for people with,
2 you know, stage 4 breast cancer, we see a certain group,
3 all of whom have diabetes, where they cost a little bit
4 more or they cost a little bit less. We don't know," and
5 be able to really do subgroups with that because we will
6 have the HCCs to be able to help predict.

7 So the goal with this is to become as precise for
8 a proposed target as it is possible to be, recognizing that
9 when you're dealing with human beings that, you know, there
10 will always be room for a clinician to talk to a clinician,
11 but also to be able to come up with -- with a range that is
12 expected.

13 I personally do not think that after we get more
14 precise with these that there will be much in the way of
15 shared savings at all. That if we do what we're trying to
16 do pretty well, we should be able to come up with a bundle
17 that says this is what we should be able to take and manage
18 patients for. But I look at shared savings as something
19 that diminishes to zero as you get increasingly accurate at
20 predicting cost, you know, with the idea that there will
21 need to be some reinsurance for variability that you can't
22 control.

23 DR. BERENSON: So to just clarify, because I
24 might have misunderstood the original proposal, I thought

1 you were saying the HCC could be used as a risk adjuster to
2 all -- to modify the target spend in an OPC, but you're not
3 saying that. You're saying you want to collect data,
4 comorbidities, and in a sense develop your own HCCs for
5 cancer, for cancer treatment.

6 DR. McANENY: Well, no, I think the HCCs as they
7 currently stand -- hypertension, congestive heart failure,
8 COPD, things like that -- that are listed as an HCC that
9 are prior to the diagnosis of cancer need to be adjusted
10 for. Absolutely.

11 DR. BERENSON: In the CMS HCC model, there's like
12 65 diagnoses with many sub-diagnoses. I mean, there's
13 about 3,000 ICD codes, I believe.

14 DR. McANENY: Right.

15 DR. BERENSON: And I guess the question I -- so I
16 think it predicts total spending, but it doesn't predict
17 total cancer spending. So there might be a different -- I
18 mean, congestive heart failure --

19 DR. McANENY: Right.

20 DR. BERENSON: -- may have a disproportionate
21 impact on, you know people with lower ejection fractions --

22 DR. McANENY: Right.

23 DR. BERENSON: -- who might be particularly
24 susceptible to cardiotoxicity in cancer treatment, but a

1 patient with Crohn's disease, maybe not.

2 So I don't --

3 DR. McANENY: Right.

4 DR. BERENSON: But you would use it at least
5 initially as your risk assessment to establish a target; is
6 that right?

7 DR. McANENY: It would, to some extent, but I
8 think that part of the value of an iterative process, where
9 you have both the clinical data and the claims data, is to
10 figure out which ACCs are going to make a difference.

11 For example, in your congestive heart failure
12 example, would I use less expensive drugs because I would
13 not be using Adriamycin or Herceptin in somebody who
14 already had that, so there would be savings? And the drugs
15 aren't in there, but there would be the -- the total cost
16 of care would be less because of that patient or more. I
17 don't think we really know yet.

18 DR. BERENSON: But in the -- that's a good
19 example. If you used a different drug regimen that would
20 be a different OPC, though, right?

21 DR. McANENY: Right, right. That's true.

22 So the question would be if we know, for example
23 -- let me use diabetes. That's a little easier because we
24 see a whole lot of diabetics, and hardly see very many

1 people who have severe congestive heart failure that we're
2 treating aggressively, but diabetics all the time.

3 We know that if I'm treating a diabetic and
4 they're going to get dexamethasone as part of their anti-
5 nausea regimen every three weeks, they're probably going to
6 have to see their primary care doctor every three weeks to
7 make sure that they don't end up in DKA in the hospital.
8 So there will be a slight increase amount of this.

9 And as we watch for those OPCs, recognizing that
10 diabetes may push that up a bit, we can manage that, and
11 then as we continue to collect data, we should be able to
12 be tighter on our predictions.

13 But my point I was trying to make at the
14 beginning of this part of the conversation was there's so
15 little data out there on how the HCCs interact with cancer
16 therapy, that it's really difficult to predict at this
17 point. And if we're going to create a system where we can
18 eventually bundle, which is what I believe the ultimate
19 goal would be, to be able to say, "We're going to pay you
20 \$100,000. Manage that patient. Buy them their surgery and
21 their radiation and everything else you need to do," and be
22 able to know that that's going on, we need a lot more data
23 on this than we currently have.

24 DR. BERENSON: Yep.

1 DR. McANENY: Because we don't --

2 DR. BERENSON: No, that's exactly right. I mean,
3 I'm very sympathetic to the idea that it wouldn't be to all
4 spending, total cost of care, but actually operationalizing
5 that is real challenging.

6 So one of the concerns about the appeal process,
7 it's probably manageable for a demonstration, but if this
8 went to scale with hundreds of oncologists participating,
9 it's hard to imagine what a manageable case-by-case appeal
10 process would look like, I guess.

11 DR. McANENY: Well, I think we will be able to do
12 the first cut pretty well. We have 120 oncologists in the
13 National Cancer Care Alliance, and the practices have
14 agreed to participate.

15 So, as we do that, we will have 75,000 new
16 patients per year going through this process, and we think
17 we can manage that, given the fact that everyone has pretty
18 much the same EMR and we can extract the data. And as we
19 work through this, we will figure out, you know, yes, you
20 need a 10 percent increase for somebody who's diabetic or
21 you need a 3 percent decrease for somebody with a terrible
22 heart because you're not going to treat them as
23 aggressively or whatever the facts turn out to be and then
24 be able to fine-tune that.

1 Where I look at the peer-to-peer interaction will
2 be when someone feels that a deviation from the pathway
3 processes is warranted in an individual patient, and I
4 think part of the difficulty in figuring out how the HCCs
5 will interact has been trying to do them in the aggregate.

6 In an individual patient, it is often pretty
7 obvious what's going on. It's just when you try to sum
8 them up together.

9 So I think you have to have some sort of process
10 in place to account for individual patient variation as
11 opposed to process variation. Does that make any sense?

12 DR. BERENSON: Yes. Thanks.

13 DR. TERRELL: All right. We have, it looks like,
14 about 20 minutes left. I've gone through the questions as
15 they have been -- you know, as we had them outlined, and
16 although we didn't do it exactly the way that we had it
17 outlined, I think you've touched on just about everything.

18 So I want to make sure, number one, that
19 everybody believes that's the case or if there's anything
20 that we need more clarification on that the conversation
21 has brought up. So I'm going to turn back to Bruce and Bob
22 about that.

23 MR. STEINWALD: I have no additional questions.

24 This is Bruce.

1 DR. BERENSON: I just have one, which I think you
2 responded to, but I wanted to get -- in the Q's and A's we
3 sent, but I wanted to just clarify because we did talk to
4 CMMI about the results of the COME HOME approach, which
5 saved a lot of money and seemed to be a good investment.

6 But where, if you know, did the ASCO PCOP cost --
7 I mean, payment levels come from? Was that just converted
8 from the grant that the COME HOME practices received into
9 how they actually deployed their time and staff to come up
10 with those numbers, or do you have knowledge of where those
11 numbers come from?

12 DR. McANENY: Okay. So a two-part answer to that
13 question. First of all, when we did COME HOME, we did a
14 time and motion study of how much time it took for nurses
15 to do the patient education, talking to patients on the
16 phone, checking on drug adherence, all the stuff we had
17 them do as part of COME HOME.

18 And when we costed that out, it came to --
19 between 220 to 250 per month because of regional variation
20 and salary. So that translated to the MEOS payment of
21 \$160.

22 For the ASCO PCOP process, I don't -- I entered
23 that process after they had already decided on the \$750 at
24 the first -- for the consult, but I think what they did, if

1 I -- and this was Blase Polite at University of Chicago.
2 What they did with that was they looked at how much time
3 outside of the original consultation did it take plus what
4 is the staff time to assemble data to be able to do all the
5 things that are the routine parts of an oncology new
6 patient visit, and then they attempted to measure how many
7 extra phone calls, et cetera, would come in for a patient
8 who is on active treatment and recognizing that for about
9 the first few months after a patient gets off active
10 treatment, they are -- you know, if they sneeze, they're
11 still scared it's the cancer, so they call up and use a lot
12 more services, and then, eventually, they sort of settle
13 down and go back to their more normal life.

14 So they put in those varying amounts trying to
15 estimate physician and clinic time managing those, but I
16 don't have the specific details. Did they do a time and
17 motion study? I would have to --

18 DR. BERENSON: I see.

19 DR. McANENY: -- defer to Blase for that.

20 DR. BERENSON: Okay. And then calculated rates
21 based on sort of Medicare fee schedule standards, you know
22 --

23 DR. McANENY: Yeah.

24 DR. BERENSON: -- how much they pay per minute or

1 something like that?

2 DR. McANENY: I believe that's how they did this.

3 DR. BERENSON: Okay. And so maybe we could -- so
4 you'd have no problem if we contacted them directly if we
5 feel a need, I assume?

6 DR. McANENY: Oh, yeah. I would contact him
7 directly. He's probably --

8 DR. BERENSON: Why don't you -- could you send us
9 his contact information?

10 DR. McANENY: I can, yeah.

11 DR. BERENSON: That would be appreciated. I
12 don't know whether we'll do that or not, but some of those
13 numbers look considerable, and it may be -- so that wasn't
14 -- go back to what the grant money for in the COME HOME
15 project was used for.

16 DR. McANENY: Okay. So we were able to pay the
17 practices to hire nurses to do -- well, to do -- first
18 responders, which were often not nurses, but people who
19 would ask the specific questions to find out if somebody
20 was really in trouble.

21 We paid for nurses on the phone to reach out to
22 patients and to accept incoming calls. We paid for
23 anything that was not payable by an E&M code. So if
24 somebody had a same-day visit, we didn't pay extra for

1 that.

2 We did pay for creating the pathways so that
3 people would get on the pathway calls and have reviewed the
4 literature and done all that. If people didn't show up on
5 the call, we didn't pay the practices for it.

6 We were able -- we spent some of the money on the
7 data extraction process so that we could compare the
8 pathways with compliance, drilling down to individual
9 doctor, individual patient level, so that we could measure
10 compliance for quality metrics, because part of what we
11 envision with this in terms of quality is what you're
12 really trying to find out for quality care in oncology for
13 the technical quality of care as opposed to the customer
14 service part of quality of care is: Do I know what I'm
15 doing when I'm selecting drugs and ordering imaging?

16 And so rather than just say for stage 3 colon
17 cancer, are you giving adjuvant chemotherapy within eight
18 months form surgery, which measures one tiny thing, we want
19 to measure our quality based on how often are you compliant
20 with the pathways that represent the evidence-based
21 standard of care for selecting imaging and selecting
22 chemotherapy because that is both more broad and more
23 specific than the OCM measurements.

24 And it's also more useful because then if I can

1 see that someone -- you know, my practice isn't doing well
2 on, you know, thyroid cancer, I can take action for that.
3 I can say what's going on here and let's have some CME on
4 this topic, and I can see if I can do a corrective action.

5 So we selected that for that reason. So creating
6 the pathways and creating the processes of electronically
7 extracting data so that it wasn't challengeable or it
8 wasn't labor intensive by physicians was very useful, and
9 part of it, we used to create the triage pathways that we
10 embedded into some EMRs, unfortunately not into the one we
11 switched to because they won't allow us to do that, but to
12 be able to get patients to the right side of service at the
13 right time.

14 We did pay for some of the after-hours staff and
15 the weekend staff because you never know whether or not
16 that's going to be utilized or not utilized. You know, if
17 you have people there for three hours on a Sunday and
18 nobody needs you, that's expense you have without the
19 income.

20 DR. BERENSON: Okay. And then the final question
21 I had on that was apparently the major cost reduction, was
22 it with breast cancer and reduction of ED visits? Do you
23 have any sort of theories as to why?

24 DR. McANENY: We did an interesting little

1 microstudy in the middle looking at the people who are more
2 likely -- when we said, "Oh, you need to be seen today,"
3 they would say no. And it was more often lung cancer
4 patients, and it was more often people who had either
5 transportation issues or no caregiver.

6 DR. BERENSON: Okay.

7 DR. McANENY: And what we found was that -- and
8 the other barrier was copays. If they were on a Medicare
9 Advantage plan, for example, and they had a copay for a
10 visit, they would -- they're going broke, so they wouldn't
11 do it.

12 But then when you panic at 2:00 in the morning
13 because you're short of breath and being short of breath is
14 very scary, they figure the ambulance is free, "I'll call
15 911 and get a free ride to the hospital because I think I'm
16 going to die. Who cares about a copay?" So we found that
17 that was a lot of the people who would go anywhere.

18 The breast cancer was -- first of all, it's a
19 large volume of the patients that are treated in an
20 oncology practice, and secondly, they tend to be women.
21 And no offense to the guys on the phone, but women tend to
22 respond better to instructions from physicians about "I
23 need to see you today. Please come in, and let's get you
24 some fluids for your dehydration," or whatever.

1 DR. BERENSON: Mm-hmm. So often it's --

2 DR. McANENY: That sounds somewhat sexist when I
3 say --

4 DR. BERENSON: -- an office visit in lieu or an
5 ED visit is what you were able to accomplish.

6 DR. McANENY: We -- yes. And we put in, into all
7 of our triage pathways at the end of the pathway when we
8 get to where do you -- you know, you need to do this or you
9 need to do that, we would always ask the question, "What
10 would you have done if we weren't here for you to call?"
11 and have -- you know, "Would you call your primary care
12 doctor? Would you go to the ER? Would you go to an urgent
13 care? Would you stay home and suffer? What would you do?"
14 And so we collected data on the number of ED visits that we
15 averted from that, and I don't have that data on the top of
16 my head.

17 DR. TERRELL: That would be consistent, some of
18 what you're saying, Barbara, with some of the experience we
19 had at Cornerstone in our care models, including our
20 oncology care model as it related to copays. So, as an
21 outside data source, that was certainly a big issue that we
22 had as early as 2013.

23 DR. McANENY: And transportation. That's a huge
24 issue.

1 DR. TERRELL: And transportation was another one.
2 That's exactly right.

3 DR. McANENY: A huge issue.

4 DR. TERRELL: Bob, do you have any other
5 questions?

6 DR. BERENSON: I'm done. I am done.

7 DR. TERRELL: All right. Well, I've got one more
8 thing I want to do, then, and that is to turn it back to
9 Barbara and say, were there things you were expecting us to
10 explore or ask that we didn't? And if so, this is your
11 opportunity to let us -- are there things that we should be
12 thinking about that we're not? You've now heard the types
13 of questions we were exploring. Are there things that we
14 need to be thinking about that we haven't?

15 DR. McANENY: Okay. So the first thing I would
16 want to say is that I very much want the oncology care
17 model to succeed and to have an alternative payment method
18 for oncology. I mean, that is the -- my ultimate goal
19 here, and I'm very concerned that because of the actuarial
20 risk that practices are taking under -- or supposed to take
21 in order to be an advanced APM under the oncology care
22 model, that no one will sign up for a two-sided risk. And
23 I don't know of any practices that are considering that
24 because we cannot manage actuarial risk. We can manage the

1 transactional risk of a given patient if we're given the
2 tools.

3 The problem is -- and what I'm trying to solve
4 with this particular model, with the MASON model, is to
5 give the practices the tools they need to do population
6 medicine by aggressively managing one patient at a time,
7 and I think that's really the Holy Grail for alternative
8 payment methods. We have to look at the population, but we
9 still treat patients one at a time, and we will need these
10 tools.

11 And I think with this group of practices, who
12 have the same EMR that is an oncology-specific EMR, the
13 willingness to work together to create something like this,
14 I think this is actually a very unique opportunity to merge
15 claims data and clinical data and modify what we're doing
16 using the data science processes we have to really come up
17 with accurate predictors of cost for oncology patients
18 while accounting for the individual variation of different
19 tumor types and different clinical situations.

20 So, obviously, some of the work, we cannot do
21 unless we get a go-ahead from someone. I am looking -- you
22 know, if CMS turns this down, I will look for other
23 funding, but if I find other funding, then someone other
24 than CMS will end up owning the processes. And I don't

1 think that's right. I would prefer not to see that happen.
2 I think it should come from CMS to be able to find a new
3 way to manage oncology patients more efficiently.

4 I think we need to embrace the variation that
5 occurs for individual patients and individual cancers, but
6 get rid of some of the unneeded variation of how people
7 manage patients in different practices and across different
8 parts of the country. And so I'm trying to do that.

9 We're also trying very hard to change the way we
10 measure quality from being a spot-check of an individual
11 thing to something that practices actually can use as a
12 tool to figure out when and where they need to focus
13 resources to do a better job.

14 DR. TERRELL: Well, we thank you for the
15 thoughtfulness and your passion, actually, about trying to
16 fix some very broken things.

17 We have, as you know, no control over what CMS
18 will do with the information that we provide them, but we
19 will continue to do the very best job we can to make sure
20 that we are able to articulate our understanding of what
21 you're proposing and make evaluations of it based upon the
22 10 Secretary's criteria under which we have to do so.

23 There has been, since you did your application,
24 the letter from the Secretary that says much of what

1 they're wanting to emphasize is going to be about something
2 that could be scalable and broad, and we believe that they
3 may have misinterpreted our understanding of what we were
4 trying to talk about when we talked about limited-scale
5 testing.

6 So we weren't talking about limited-scale testing
7 as being something for one or two little practices and then
8 try to -- we were talking about things that were well
9 thought through and could get tweaked by some of what
10 you're talking about now, such as a group of practices that
11 could work out some of the data that would be needed to
12 understand whether it could be implemented widely.

13 So part of what we will need to do as we are
14 understanding what you're proposing, since it's for a
15 particular group of practices, is think through how we're
16 going to do that within the context of scaling it based
17 upon the Secretary's criteria. So that's just sort of
18 where my head is as we are going further with this process.

19 DR. McANENY: So I would appreciate to comment on
20 that.

21 I think that there is value in starting with a
22 defined set of practices who are willing to cooperate and
23 deliver data in order to construct something that then can
24 be scaled, and I look at this as something that once we

1 know what an actual target could be -- and this -- these
2 group of practices stretches from Maine to Southern
3 California.

4 DR. TERRELL: Okay. Good.

5 DR. McANENY: So it is not a region. It is a
6 nationwide group of practices, and that the commonality is
7 that everyone is interested in working through this
8 problem. Because most of them are in the oncology care
9 model, none of them are going to take two-sided risk for
10 fear that they would, you know, lose the practice.

11 So I think there is value in starting with a
12 group and really doing intensive data collection and data
13 science, to come up with something that is then safe to
14 scale across the country, because what we cannot afford to
15 do is to throw something out nationwide and put the
16 infrastructure of care delivery at risk. We have to
17 protect that while we are creating a new system, and I
18 think we can do that.

19 And furthermore, I have found that for the things
20 like the triage pathways and being able to have pathway-
21 compliant therapy, I think it's eventually scalable beyond
22 oncology. For people who treat inflammatory bowel disease,
23 congestive heart failure, COPD, asthma, multiple diseases
24 that are chronic diseases with acute exacerbations, I think

1 these processes of figuring out how you predict and prevent
2 or manage those acute exacerbations are something that will
3 be very well amenable to pathways and very well amenable to
4 management of those side -- those complications, and
5 hopefully would be scalable outside of oncology.

6 DR. TERRELL: Well, thank you very much, and we
7 appreciate again what you've put forth. We're going to
8 give it our best, considerable process to make sure that we
9 articulate effectively what you're proposing and how it can
10 be assessed by the Secretary's criteria, and we look
11 forward to further interaction as our process goes on.

12 Bob and Bruce, Ann, do you all have time for a
13 quick call after we hang up so that we can sort of make
14 sure that we are all on with what we learned and where
15 we're going from here?

16 MR. STEINWALD: Sure.

17 DR. TERRELL: Okay.

18 DR. BERENSON: Yeah.

19 DR. McANENY: Thank you all very much for your
20 time, and if there's anything else I can answer, please
21 don't hesitate to reach out and let me try to clarify or
22 think through it.

23 DR. TERRELL: All right. Thank you, Barbara.
24 Bye-bye.

1 DR. McANENY: Bye-bye.

2 [Whereupon, at 1:59 p.m., the conference call
3 concluded.]

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