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April 25, 2017

Physician-Focused Payment Model Technical Advisory Committee
C/o U.S. DHHS Assistant Secretary of Planning and Evaluation Office of Health Policy
200 Independence Avenue SW
Washington, DC 20201

Via Email: PTAC@hhs.gov

Re: **Comments on Oncology Bundled Payment Program Using CNA-Guided Care**

Dear Committee Members,

Thank you for the opportunity to submit comments on the Oncology Bundled Payment Program Using CNA-Guided Care submitted by Hackensack Meridian Health and Cota, Inc. We support this proposal, and offer a few recommendations to ensure that palliative care is fully integrated into the model, in accordance with the American Society of Clinical Oncology guidelines.[i]

The Center to Advance Palliative Care (CAPC) is a national organization dedicated to ensuring that all persons with serious illness have access to high-quality palliative care. Palliative care is medical care focused on providing relief from symptoms and stresses, with the goal of improving quality-of-life for both the patient and family. It is appropriate for any patient with serious illness, regardless of diagnosis or prognosis, and can be provided alongside curative treatment. The provision of palliative care has been shown to improve patient experience and satisfaction,[ii] reduce caregiver burden,[iii] and increase survival[iv]; it has also been shown to reduce needless hospital admissions and re-admissions management[v], and through these gains in quality, it reduces costs.[vi]

We applaud Hackensack Meridian Health (HMH) and Cota Inc.'s proposal to use a digital classification system to accurately pinpoint oncology patient characteristics so they can be grouped and treated appropriately. As we have mentioned in our previous comments,[vii] it can be beneficial to create tiered payment models that direct more resources to patients with higher acuity levels who are expected to live for several years with serious illness. We also appreciate HMH and COTA Inc.'s inclusion of palliative care-relevant measures around pain, treatment goals and advance care planning. Given this, we have two recommendations to ensure that all patients in the Oncology Bundled Payment Program receive palliative care services as appropriate.

Our recommendations for improvement are as follows:

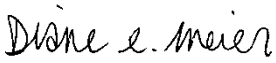
- → **Articulate the criteria for which patients will receive specialty-level palliative care services, ranging from consultation to ongoing co-management**. It is our understanding the HMH intends to fully integrate palliative care into the model's treatment bundles, varying the intervention by patient intensity level (low, medium, and high). Specifying which palliative care services are included in the bundles for each level will help ensure that patients receive appropriate care.

- → **Revise the quality measure "Hospice/Palliative Care Referral Documented."** We are concerned that many clinicians continue to conflate palliative care and end-of-life care, which can lead to late or non-referrals. While this risk is mitigated by the fact that HMH's

model will provide palliative care services based on information captured at diagnosis, we recommend that HMH break this measure into two separate quality measures: one capturing whether the patient was referred to palliative care (appropriate for almost every patient in the model), and one capturing whether the patient was referred to hospice (only appropriate if the patient has an expected prognosis of six months or less and is willing to forgo curative treatment). This will help clarify the denominator population for each measure and ensure that treating clinicians make appropriate referrals.

Thank you again for the opportunity to submit these comments. Please do not hesitate to contact myself or Stacie Sinclair, Senior Policy Manager at Stacie.Sinclair@mssm.edu if we can provide any additional detail or assistance.

Sincerely,



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[i] *Integration of Palliative Care Into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline Update*. Betty R. Ferrell, Jennifer S. Temel, Sarah Temin, Erin R. Alesi, Tracy A. Balboni, Ethan M. Basch, Janice I. Firn, Judith A. Paice, Jeffrey M. Peppercorn, Tanyanika Phillips, Ellen L. Stovall, Camilla Zimmermann, and Thomas J. Smith Journal of Clinical Oncology 2017 35:1, 96-112

[ii] *See e.g.* MO Delgado-Guay et al. *Symptom distress, interventions, and outcomes of intensive care unit cancer patients referred to a palliative care consult team*, 115(2) Cancer 437-45 (2009); David Casarett et al., *Do Palliative Consultations Improve Patient Outcomes*? 56 J Am Geriatric Soc'y 593, 597-98 (2008) (discussing results indicating that palliative care improves quality of end of life care).

[iii] *See* Laura P. Gelfman et al., *Does Palliative Care Improve Quality? A Survey of Bereaved Family Members*, 36 J Pain Symptom Manag 22, 25 (2008) (explaining results showing palliative care consultation services improve family-centered outcomes); P Hudson et al. *Reducing the psychological distress of family caregivers of home-based palliative care patients: short-term effects from a randomized controlled trial*, Psycho-Oncology (2013)(Advance online publication. doi: 10.1002/pon.3242) (finding that short palliative interventions can augment caregivers' feelings of preparedness and competence in supporting a dying relative).

[iv] *See* Jennifer S. Temel et al., *Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer*, 363 New Eng J Med 733, 739 (2010) (finding that palliative care prolonged survival of cancer patients).

[v] *See* C Nelson et al., *Inpatient palliative care consults and the probability of hospital readmission*, 15(2) Perm J 48-51 (2011) (finding that palliative care consultations reduced six month readmissions from 1.15 admissions per patient to 0.7); S Enguidanos et al., *30-day readmissions among seriously ill older adults*. 15(12) J Palliat Med 1356-61 (2012) (finding that receipt of palliative care following hospital discharge was an important factor in reducing 30-day hospital readmissions); L Lukas et al., *Hospital outcomes for a home-based palliative medicine consulting service*, 16(2) J Palliat Med 179-84 (2013) (finding that total hospitalizations, total hospital days, total and variable costs, and probability of a 30-day readmission were significantly reduced after enrollment in a home based palliative care program).

[vi] *See* R. Sean Morrison et al., *Cost Savings Associated with US Hospital Palliative Care Consultation Programs*, 168 Arch Intern Med 1783, 1785 (2008) (stating "patients receiving palliative care consultation had significantly lower costs" than usual patients who did not); Joan D. Penrod et al., *Hospital-Based Palliative Care Consultation: Effects on Hospital Cost*, 13 J

Palliat Med 973, 976 (2010) (finding "palliative care during hospitalizations was associated with significantly lower direct hospital costs."); R. Sean Morrison et al., *Palliative Care Consultation Teams Cut Hospital Costs for Medicaid Beneficiaries*, 30 Health Aff. 454, 457 (2011) (finding overall results show patients who received palliative care had significantly lower costs than patients who did not); Peter May et al., *Palliative Care Teams' Cost-Saving Effect is Larger for Cancer Patients with Higher Numbers of Comorbidities*, 35 Health Aff. 44, 53 (2016) (finding that adults with advanced cancer who received palliative care consultation within two days of admission had 22 percent lower costs than those receiving usual care if their comorbidity score was 2-3, and 32 percent lower costs if their comorbidity score was 4 or higher).

vii Center to Advance Palliative Care (CAPC). "Requested modification to the Advanced Care Model (ACM): Two-tier pricing model." Submitted April 19, 2017.

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April 27, 2017

Physician Focused Payment Model Technical Advisory Committee
c/o Angela Tejeda
Office of the Assistant Secretary for Planning and Evaluation
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically: PTAC@hhs.gov

Dear PTAC Members,

The American Society for Radiation Oncology (ASTRO) is pleased to submit comments on the *Oncology Bundled Payment Program Using CNA-Guided Care* as submitted by Hackensack Meridian Health and Cota Inc. We appreciate this opportunity to comment and look forward to further engagement should this model be considered for implementation.

ASTRO members are medical professionals, practicing at community hospitals, academic medical centers, and freestanding cancer treatment centers in the United States and around the globe, and who make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy.

ASTRO appreciates the premise of the *Oncology Bundled Payment Program Using CNA-Guided Care* model in that it seeks to address variations in care. We agree that reductions in practice variation can maximize efficiencies, improve quality and ensure better patient outcomes. In general, we are concerned that the model does not adequately consider the role of radiation oncology, which is a key component of cancer treatment for many patients.

The model seeks to use the Cota Nodal Address (CNA) Guided Care system to classify patients into designated treatment care plans or "lanes". The basis for these care plans is not evident in the proposal. We are specifically interested in whether the system utilizes clinical treatment guidelines such as those issued by ASTRO or other professional organizations. A transparent description of care plans, based on professional guidance from broadly based multi-specialty peer panels, is essential to an effective evaluation of the potential for Medicare patients to receive an appropriate level of care. Additionally, ASTRO is interested in understanding more about the data analysis prepared to identify adverse variance. Is the adverse variance due to

differences in medical oncology prescribing patterns or is it a broader analysis that covers all treatments in the continuum of cancer care? We also note that the Appendix A compendium of Quality Measures for each of the disease sites fails to list any clinical measures related to Radiation Oncology, a deficiency that would need to be addressed before an evaluation of either the treatment lanes or quality measures could occur. Finally, the model purports to cover all costs inclusive of surgery, medical oncology, radiation oncology, and diagnostics; however, it is unclear how payments would be distributed among various providers within the participating facility.

Thank you for the opportunity to provide written comments. ASTRO is committed to ensuring that radiation oncology can fully participate in an alternative payment model that will drive greater value in cancer care. The Oncology Bundled Payment Program Using CNA-Guided Care does not clearly delineate the role of radiation oncology. We would urge PTAC to consider the implications this has on the field of radiation oncology as it reviews the application. If you have any questions, please contact Anne Hubbard, Director of Health Policy, at 703-839-7394 or Anne.Hubbard@ASTRO.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

April 27, 2017
Physician-Focused Payment Model Technical Advisory Committee
C/O Angela Tejeda
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Re: Public Comment – Oncology Bundled Payment Program Using CNA Guided Care

Dear Members of the Physician-Focused Payment Model Technical Advisory Committee (PTAC):

The National Association of ACOs (NAACOS) appreciates the opportunity to provide feedback on the Oncology Bundled Payment Program Using CNA Guided Care, a specialty model currently under PTAC's review. While NAACOS supports voluntary bundled payment models, we strongly oppose mandatory bundled and episode-based payment models. Current CMS policies related to the intersection of bundled and episode payments with ACOs hampers ACOs' ability to succeed and has the potential to divide specialists and primary care providers and diminish population health efforts.

The overlap of bundled and episode payment programs with ACOs creates conflicts when patients attributed to an ACO are also evaluated under a bundled payment program. Under current CMS policy, a bundled payment participant maintains financial responsibility for the bundled payment episode of care and any gains or losses during that episode are linked to the bundled payment participant and removed from ACO results following the close of the performance year. While CMS is testing an alternative policy by excluding Next Generation and Track 3 ACO beneficiaries from certain episodes, this exclusion does not apply to Track 1 or Track 2 beneficiaries, which comprise the majority of ACO beneficiaries. The problem is exacerbated by the fact that ACOs are not permitted to participate as bundlers. ACOs focus on, and make considerable investments in care coordination and improving care transitions to manage post-acute care effectively. Many successful ACOs credit these efforts for allowing them to achieve shared savings.

NAACOS believes any PTAC recommended episode models should be voluntary, and allow ACOs to voluntarily participate in such models. At a minimum, the savings generated should not be taken away from the ACO entity. Rather, ACO patients should be excluded from the bundle or episode payment. The current policy used by CMS creates conflicting program goals, and hampers ACOs' ability to succeed by deducting the savings from the ACO, when these savings are often generated in large part from the ACO's care coordination activities. Further, CMS has yet to fully evaluate the effects of overlap for existing bundled and episode payment model tests such as the Bundled Payments for Care Improvement Initiative (BPCI). NAACOS has called on CMS to conduct a rigorous analysis to determine the effect of overlapping value-based programs, including the interplay between bundled payment programs and ACOs before moving forward with additional programs. For example, it is critical that CMS examine not only spending changes for the bundled payment or episode but also any potential changes in overall volume of these episodes. Further analysis on the effect of bundled and episode payment models must be done taking total cost and volume of services into account before expanding such models.

It is critical that PTAC protect the goals of population health focused delivery models. These models, such as the ACO model, are just now gaining momentum and an evidence base to learn from. It is critical that we allow these models to realize their full potential. Therefore, it is important that PTAC's work does not undermine these efforts. NAACOS supports the exploration of new payment models, which will ultimately benefit all who are working to reform health care delivery and payment models to better support patients and to contain costs while providing exceptional care. However new payment reform efforts must work in tandem with existing models to prevent impeding on the progress organizations such as ACOs have worked so hard to accomplish to date. When considering new payment models, we urge PTAC to refrain from approving models which exacerbate the problem of siloed care by pitting population health models against other, more segmented approaches to reform.

Specialists play a key role in containing costs and coordinating a patient's care in the effort to focus on population health. It will be critical to work on including these specialists in population health focused models such as ACOs, rather than further isolating specialists with their own episodes without also including them in ACO efforts. NAACOS has concerns that PTAC's actions may result in a proliferation of siloed, specialty-focused care models. This has the potential to diminish the focus on population health, and the entirety of a patient's care.

In closing, we urge PTAC to consider these issues when evaluating specialty-focused care models such as the Oncology Bundled Payment Program Using CNA Guided Care. It is critical that new payment reform efforts complement, rather than compete with the work of existing delivery reform efforts. When considering new payment models, we urge committee members to refrain from approving models which exacerbate the problem of siloed care by pitting population health models against other, more segmented approaches to reform.

Respectfully,

Clif Gaus, Sc.D.
President and CEO
National Association of ACOs

April 27, 2017

BY ELECTRONIC DELIVERY

Jeffrey Bailet, MD
Committee Chairperson
Physician-Focused Payment Model Technical Advisory Committee

Assistant Secretary for Planning and Evaluation, Room 415F
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Oncology Bundled Payment Program Using CNA-Guided Care

Dear Chairperson Bailet:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Oncology Bundled Payment Program Using CNA-Guided Care Proposal (Proposed Model)[1] that has been submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. Our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

While BIO recognizes the need to ensure that the PTAC functions efficiently, we raise threshold concern with the short timeframe for public comment and transparency elements for this Proposed Model and additional models in the future. Given that this is BIO's first engagement with PTAC on a proposal, we intend to use this opportunity to identify the hallmarks of an Alternative Payment Model or advanced Alternative Payment Model (APM) that meet the critical, shared goals of ensuring patient access to innovative medicines and sustaining biopharmaceutical innovation. Specifically, BIO's members and other stakeholders have identified the following as criteria an APM must meet to achieve these goals:

- Allow patients and providers to choose from the range of available treatment options and support the tailoring of care to individual patient needs and preferences on the basis of existing scientific and clinical evidence;
- Adapt to the evolving field of medicine in a timely manner;

[1] Proposal for PTAC: Oncology Bundled Payment Program Using CNA-Guided Care, March 2017. https://aspe.hhs.gov/system/files/pdf/255906/OncologyBundledPaymentProgramCNACare.pdf.

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- Incorporate mechanisms to ensure patients' timely access to new-to-market therapies;
- Ensure that quality measures are appropriate and meaningful to patients in the context of the patient population that an APM serves;
- Recognize that current and future healthcare system spending on prescription drugs can offset spending on other healthcare items and services over the short- and longer-term;
- Invite and incorporate feedback from a diverse array of external stakeholders throughout the development and implementation of the model; and
- Increase transparency in the model process, by making all methodologies analyses of the model used throughout the process publicly available and include a description of the evidence and information sources utilized in their development.

While we appreciate that this Proposed Model intends to focus on multiple elements of cancer care, not solely drugs and biologicals, the balance of this letter provides feedback on the Proposed Model in the context of each of these criteria.

I. APMs should prioritize patient/provider decision-making and the tailoring of care to individual patient needs and preferences, in accordance with existing information.

The Proposed Model relies on oncology bundled payments in which care choices are modulated by the prior outcomes of similar patients drawn from real world data. As a threshold matter, we encourage the organization proposing this model, Hackensack Meridian Health (HMH), to provide further model transparency by releasing the details of the 27 Cota Nodal Addresses (CNAs) into which patients can be grouped under the Proposed Model. Stakeholder comments on these categories could improve their refinement to the benefit of the model's development and implementation. In the CNAs, we further ask HMH to consider and address how a reliance on historic real world data could impact the patient/provider decision making process, and ultimately access to the most appropriate therapy, that may be different than the ones previously used in similar patients, as new treatment options become available in a personalized medicine approach to care.

In the model, HMH is proposing "a comprehensive bundle payment including prospective cost of care for 'unrelated services' and prospective cost of care for the oncology bundle. Through the Medicare Shared Savings Program (MSSP), HMH is relying on the CMS prediction of annualized cost. To supplement this forecast HMH and Cota will provide a second cost based on predicted expense of the oncology episode. The combined cost will provide total cost of care for an entire year for each patient enrolled, and will become the bundled payment for the oncology episode." [2] BIO is concerned that the Proposed Model relies on a total cost of care metric that is built based on retrospective data, and will not be able to reflect advancements in the care of oncology patients that result in changes in the total costs of care. We ask HMH to consider developing a mechanism to appropriately project and trend forward assumed cost pertaining to innovation and advancements in care needed to proactively account for changes in cost of care. BIO is concerned that without

[2] Proposal for PTAC: Oncology Bundled Payment Program Using CNA-Guided Care, p 12.

such ability to adjust payments to account for advancements in care, patients could suffer at the expense of underutilization or lack of access to appropriate treatments, and asks HMH to work to further address and protect beneficiaries from this possibility. Further, we also ask for clarification on all aspects of care that would be included in the bucket of 'unrelated services', and as to how a diagnostic that determines a patient has a specific disease is included in the bundled payment.

II. APMs should adapt to the evolving field of medicine in a timely manner and incorporate mechanisms to ensure patients' timely access to new-to-market therapies.

In the Proposed Model, HMH notes that providers will be required to choose a "lane" at the start of a patient's treatment, and that all costs for that lane—as well as lane-specific quality measures—will then apply forthwith. BIO is concerned that this approach is not sufficiently flexible to allow clinical care to progress appropriately and could discourage providers from making an appropriate lane change in order to maximize shared savings potential, thus impacting patient outcomes and treatment. Specifically, oncology treatment is an evolving dynamic that is based on a patient's individual characteristics, the specific pathophysiology of his/her disease, and clinical and even environment factors impacting his/her response to treatment. Thus, requiring providers and patients to stick to a single lane of treatment chosen at the outset of care may stifle the ability of providers to reassess treatment regimens to better fit real-world clinical circumstances. While we understand that providers whose patients require such a lane change would not be financially penalized but simply asked to exit the model, we note that not allowing for this flexibility may have broader ramifications on the ability to translate and scale the Proposed Model to other settings and may also limit what can be learned from the outputs of the model.

HMH does recognize that "[i]n oncology, one of the biggest changes in care delivery will be the introduction of new therapies and corresponding healthcare utilization." [3] HMH goes on to propose that, in response to these changes, they will "define provisions in the bundle price that reflect the reality of additional reimbursement for drug costs and associated treatment services on a yearly basis for the affected bundles."[4] Exactly how HMH will define these provisions and estimate the costs of new-to-market therapies (or new indications of existing therapies or updated treatment guidelines) is not clear. While BIO appreciates and supports the proposal to exempt outliers from total-cost-of-care calculations to avoid penalizing providers who treat particularly complex cases of cancer, this is not sufficient to ensure patient access to therapies that become available mid-year.

Instead, BIO strongly urges HMH to postpone inclusion of utilization of new-to-market therapies from the total-cost-of-care calculations for at least two or three years after a therapy comes to market. This will allow providers for whose patients these new therapies are appropriate to continue to participate in the model but not be financially penalized for using a therapy for which the cost is not yet incorporated into the prospective bundled payment. This delay in inclusion of these therapies for two or three years also will allow HMH to better understand the benefits, costs, and cost offsets of such therapies before

[3] *Id* at p 14.
[4] *Id.*

including them into the estimate of the total cost of treating a specific patient participating in the model. Additionally, BIO believes that during this timeframe, before inclusion in the bundle, these new-to-market therapies should be reimbursed adequately under the standard Average Sales Price (ASP)-based methodology to further ensure patient access to the most appropriate form of therapy. Adequate reimbursement is critical to sustaining the incentives that spur future innovation and the Proposed Model should detail how the bundle will be updated to include new-to-market therapies after this initial time period.

III. APMs should ensure that quality measures are manageable and appropriate in the context of the patient population that an APM serves, relying upon recognized standards for treatment and important outcomes.

Under this Proposed Model, the exact mechanisms for incorporating patient-reported outcomes and patient preferences are unclear. While the proposal does note that Cota and HMH "will monitor patient-reported outcomes, such as patient satisfaction with the care provider team" and that "[t]his has traditionally been measured [] through surveys[,]" no additional detail is provided on exactly how patient perspectives will be taken into account.[5] HMH should specify which patient reported outcomes instruments will be utilized and the anticipated timing of collection and use as a part of the treatment decision-making process. We also would ask that HMH consider further classification of quality measures based on end user (e.g. patient, physician practice, ancillary provider, CMS, etc.) and detail which measures will be collected frequently and used to ensure manageable measures that guide clinical decision-making and avoid placing undue burden on participating providers. This additional detail on measures should include information to ensure that quality incentives in the Proposed Model are equal to or greater than the cost containment incentives and provide further clarity on transparency in reporting out of these quality measures, to avoid any situation that would compromise quality of care for patients served in this APM. Further, one of the benefits of HMH taking on the financial risk of a bundled payment is that it allows the hospital system to establish only up-side risk for providers as well as incentives for providers to improve care coordination and other patient-centric services, but this type of risk structure could lead to overly prescriptive requirements in the treatment pathways used.

Further, BIO encourages HMH to consider the inclusion of shared decision-making tools and quality measures (e.g., documented use of patient decision aids) as a method to improve knowledge transfer and promote patient engagement in health care choices. While shared decision-making tools are not a substitute for clinical communication, such instruments can prepare and empower patients and their families to make better healthcare choices with clinicians. Evidence suggests that poor quality of communication between patients and practitioners limits the patients' knowledge of prognosis and treatment options, management of symptoms, and use of treatments consistent with their preferences.[6,7] Moreover, shared decision-making can ensure that medical care better aligns with patients'

[5] *Id* at p 21.
[6] Fellowes D,Wilkinson S, Moore P. communication skills training for health care professionals working with cancer patients, their families and/or careers. Cochrane Database Syst Rev. 2004 ;(2):CD003751.
[7] J Pain Symptom Manage. 2012 Dec;44(6):866-79. doi: 10.1016/j.jpainsymman.2011.11.009. Epub 2012 Jul 21.

preferences and values.[8] Shared decision-making has the potential to provide numerous benefits for patients, clinicians, and the health care system, including increased patient knowledge, less anxiety over the care process, improved health outcomes, reductions in unwarranted variation in care and costs, and greater alignment of care with patients' values. [9] Durand, Carpenter, Dolan, et. al demonstrated via a systematic review and meta-analysis of randomized controlled trials that shared decision-making interventions have a positive effect on disadvantaged groups and health inequalities. The results showed that shared decision-making intervention increased knowledge, informed choice, participation in decision-making, decision self-efficacy, preference for collaborative decision making and reduced decisional conflict.[10]

In addition to our concerns around inclusion of patient outcomes and shared decision-making, BIO has concerns around assuring that the quality measures in the Proposed Model keep up with the latest scientific advances and broadly recognized guidelines for delivery of care to highly vulnerable cancer patients. As an example, the quality measures detailed in Appendix A of the Proposed Model are of concern for the following areas[11]:

- *Measures for all disease groups*: These measures include "Aprepitant prescribed with high emetic risk chemotherapy".[12] We would recommend that the measure include all NK-1 products as is prescribed by the National Comprehensive Cancer Network (NCCN) Guidelines for highly emetogenic chemotherapy.[13,14]

- *Breast Measures*: The oncology component of the breast quality measures includes "Trastuzumab received by patients with AJCC stage I (T1c) to III Her2/neu positive breast cancer".[15] Currently, the American Society of Clinical Oncology is in the process of updating the National Quality Forum-endorsed measure to incorporate changes in available treatment and practice guidelines.[16] In the Proposed Model, HMH should incorporate the updated measure when it becomes available.

- *Lung Measures*: The oncology component of the lung quality measures includes "Platinum doublet first-line chemotherapy or EGFR-TKI (or other targeted therapy anti PD1 with documented DNA mutation PD1 +) received by patients with initial AJCC stage IV or distant metastatic NSCLC with performance status of 0-1

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[8] Barry, Michael J., Edgman-Levitan , Susan. Shared Decision Making — The Pinnacle of Patient-Centered Care. New England Journal of Medicine 2012;9:780-781.
[9] Lee, E, and Emanuel, E. Shared Decision Making to Improve Care and Reduce Costs. N Engl J Med. 2013; 368:6-8.
[10] Durand M-A, Carpenter L, Dolan H, Bravo P, Mann M, et al. (2014) Do Interventions Designed to Support Shared Decision-Making Reduce Health Inequalities? A Systematic Review and Meta-Analysis. PLoS ONE 9(4): e94670. Available at: https://doi.org/10.1371/journal.pone.0094670. Accessed April 11, 2017
[11] *Id* at p 26.
[12] *Id* at p 29.
[13] NK-1 products include: aprepitant, netupitant/palonosetron, rolapitant.
[14] National Comprehensive Cancer Network Guidelines.
[15] Proposal for PTAC: Oncology Bundled Payment Program Using CNA-Guided Care, p 26.
[16] Giordano et al. Systemic Therapy for Paitens with Advanced Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer: American Society of Clinical Oncology Pracitce Guideline. Journal of Clinical Ongology, 32, no. 19 (July 2014) 2018-2099. Available at: http://ascopubs.org/doi/pdf/10.1200/jco.2013.54.0948.

without prior history of chemotherapy."[17] Recently, the National Pharmaceutical Council (NPC) released a report *on Improving Oncology Quality Measurement in Accountable Care* that addresses the use of immune checkpoint inhibitors as subsequent therapy in patients with Metastatic Disease.[18] BIO believes this NPC measure represents an example of a missed opportunity to advanced cancer care in the development of this model and requests that the model ensure quality measures are in line with indicated treatment and work to include the latest advancements in care delivery.

These are three examples of areas in which HMH, and the PTAC in future models, should work to ensure that such APMs address the latest indications, access to advanced care, and most appropriate quality measures in line with clinical and stakeholder experts. BIO further urges HMH to review stakeholder consensus on areas of care, such as the *Advancing Oncology Care Quality in the Era of Immuno-oncology and Other Evolving Treatments*,[19] which provides a broad range of stakeholder feedback and in particular on prioritization of quality measures and advancement of quality of care; and work to ensure quality measures are consistent with widely recognized cancer guidelines, such as those put forward by NCCN. BIO believes that in this Proposed Model, and future models, PTAC should ensure robust oversight into quality measures to provide focus and ensure patient care is not sacrificed.

Finally, the providers participating in this Proposed Model may also be participating in other value-based models ongoing at HMH. BIO asks HMH to identify whether providers participating as part of the clinically integrated physician network (CIN) who are eligible to participate in the Proposed Model are also allowed to participate in other ongoing HMH models. Though it is clear that only fee-for-service Medicare patients who are not otherwise participating in ongoing payment models are included in the Proposed Model, it is not clear whether that applies to their physicians as well. HMH also notes that it participates in the MSSP, and as such, HMH has "developed workflows to optimize care while minimizing waste."[20] Thus, it is unclear how HMH will identify whether observed improvements in care coordination and other patient-centric services are the result of their structuring of the Proposed Model versus their participation in the MSSP versus some combination of participation in both. If providers are allowed to participate in more than one model, we urge HMH to identify exactly how the impact of the Proposed Model will be identified and evaluated among the impact of other models in which the provider is participating. Additionally, the ability of providers to exit the model based on lane changes our outlier care could confound the results, and should be appropriately accounted for in all model analyses.

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[17] Proposal for PTAC: Oncology Bundled Payment Program Using CNA-Guided Care, p 29.
[18] Valuk T, Blaisdell D, Dugan D, Westrich K, Dubois RW, Miller RS, McClellan M. Improving Oncology Quality Measurement in Accountable Care. National Pharmaceutical Council, Discern Health April 2017. http://www.npcnow.org/system/files/research/download/npc-improving-oncology-quality-measures-final.pdf
[19] Avalere Health. Dialogue Proceedings: Advancing Oncology Care Quality in the Era of Immuno-oncology and Other Evolving Treatments, January 2017. http://go.avalere.com/acton/attachment/12909/f-041c/1/-/-/-/-/Avalere%20Dialogue%20Proceedings%20for%20Oncology%20Care.pdf.
[20] Proposal for PTAC: Oncology Bundled Payment Program Using CNA-Guided Care, p 10.

IV. APMs should recognize that spending on prescription drugs can offset other types of healthcare spending in the short- or longer-term.

HMH proposes that the bundle payment will cover a 12-month period of time. While we have detailed concerns above about accounting for updates in treatment cost, BIO is also concerned that this methodology does not take into account the cost offsets to the healthcare system provided by the appropriate use of innovative oncology therapies, given the short period of time over which costs are measured. Especially in the case of chronic disease treatment, the benefits of the therapy can be realized over the course of years, and cutting short the estimate of timeframe over which costs and cost offsets are calculated can shortchange the estimation of the impact of the therapy. Though we recognize the operational challenges of establishing a multi-year bundle, we encourage HMH to explore this further in the development of the Proposed Model to better reflect the realities of clinical treatment.

V. APMs should invite and incorporate feedback from external stakeholders throughout development and implementation.

There is a PTAC process for obtaining public feedback, but it is unclear how this feedback will impact HMH's model, and whether and how HMH intends to solicit stakeholder feedback throughout the development and implementation process. While the PTAC provides an opportunity for external stakeholder feedback, we raise concerns that the short timeframe for comment will prevent groups with limited resources—including patient advocacy organizations—from participating in this feedback process. To address this, BIO recommends that PTAC allow at least 30 days for comment, which is similar to public comment period timeframes for certain federal regulations, to ensure a transparent and inclusive process for all interested stakeholders. The Proposed Model describes initiatives to improve patient education and understanding of their treatment options it is unclear whether this will include helping patients understand the elements of the model, its purpose, the incentives it establishes, and how it may affect patient care. Additionally, (as we understand it) PTAC works with the entity proposing the model during its review period to obtain additional information. This information should be shared with the public and in a timeframe that allows public comment. Further, throughout the process of the model, proposed performance evaluation metrics detailed in the Proposed Model should be made public in order for stakeholders to provide feedback and express any concerns.[21] These are all critical elements of proactive patient engagement, and we urge the PTAC to ensure that HMH provides a pathway for this type of engagement moving forward.

VI. APMs should make all methodologies publicly available and include a description of the evidence and information sources used in model development.

In the proposal, HMH notes that they are simultaneously developing a pilot program with a managed care plan for oncology that will closely resemble the Proposed Model. BIO asks HMH to clarify the differences and similarities between these two models, how they will

[21] *Id* at p 3.

interact, and how lessons learned from one will be applied to the other. We also urge HMH to explain the rationale behind the decision to undertake development of the Proposed Model at this time, rather than wait to better understand the results of the managed care plan model already under development and presumably closer to being implemented.

HMH notes that "[a]s part of the MSSP program, HMH utilizes an outside vendor to monitor patient satisfaction. This will be added to the Bundle program."[22] It is critical to not only understand how changes in the payment for and delivery of care are affecting patients, but to make patients and their advocates *active* participants in guiding those changes. The patient satisfaction surveys that HMH references are *passive* monitoring rather than active engagement, and it is unclear exactly what questions they contain, how they have been used in the past, patients' proclivity to complete them, whether they have been validated, and exactly how the information that is gleaned from these surveys will be used as an input into refining the Proposed Model during its development and implementation. Additionally, methodologies for calculating the Cota Analytics measures (e.g. overall survival, progression free survival, etc.) should be made transparent to ensure that no incorrect assumptions are made about lines of therapy when evaluating these clinical outcomes. Given the importance of patient engagement and accuracy in analytic measures, HMH should clarify these issues before moving forward with the Proposed Model.

III. Conclusion

BIO reiterates our appreciation for the opportunity to comment on the proposed model, and we look forward to working with PTAC to improve the efficiency and effectiveness of its process to promote the development and testing of APMs that will improve patient health outcomes and decrease overall healthcare costs, while simultaneously improving patient access and sustaining the incentives for future innovation. Please feel free to contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Vice President
Healthcare Policy & Research

[22] *Id* at p 11.

COLLEGE of AMERICAN PATHOLOGISTS

April 27, 2017

Ann Page, Office of Health Policy, Assistant Secretary for Planning and Evaluation (ASPE)
Designated Federal Officer for PTAC
Physician-Focused Payment Model Technical Advisory Committee (PTAC)
c/o Angela Tejeda
ASPE
200 Independence Ave. SW
Washington, DC 20201
Via email to: PTAC@HHS.gov

RE: Oncology Bundled Payment Program Using CNA-Guided Care Proposal

Dear Ms. Page:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Oncology Bundled Payment Program Using CNA-Guided Care proposal. The CAP is a national medical specialty society representing over 17,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals, and federal and state health facilities.

The CAP offers these comments in the interest of assuring the PTAC receives input from physicians who are designated as participating in proposed models and therefore represent impacted specialties, to achieve greater clarity and care coordination in this and future proposals submitted to the PTAC. Engaging participating specialties in model development should be required to assure a cohesive model is proposed, which has credible prospects to improve coordination of care and meet the other required criteria under the Medicare Access and CHIP Reauthorization Act for physician-focused payment models.

While the model as proposed is limited to the Hackensack Meridian Health's clinically integrated network (CIN) at its outset, it indicates possible expansion beyond the CIN to the broader Hackensack Meridian Health System and even adaptation across the United States. The potential breadth of the model underscores the importance of engaging participating specialists/specialty societies in model development, to ensure objectives including care coordination and patient protections are achievable.

As to those objectives, the CAP is supportive of the submitters' articulated goals of optimizing clinical outcome of each individual patient and reducing the cost of care for the population served. On its face, though, how the model is intended to operate and affect participating clinicians is unclear. Using pathology as an illustrative example, the

impact on pathologists from a read of the proposal cannot be clearly discerned for the following reasons:

- The proposal indicates a bundled payment will encompass all payments for an oncology episode over a year including medical, radiation, surgical oncology, pharmacy, *diagnostic*, technical, and inpatient/outpatient fees associated with the episode. This strongly implies that pathology services are included in the bundle, but this is not clear.

- Pathologists are only expressly mentioned one time in the core proposal. The reliance on "carefully coordinated diagnostic and pathologist commitment to provide timely interpretation of specimens for diagnosis" is provided as an example of ancillary provider buy-in being a potential barrier to the model's success. By virtue of the essential services they provide, pathologists are already focused on providing timely interpretation. The quality measures arrayed in Appendix A of the proposal do at various points include certain aspects of testing: nodes pathologically examined and pathology reports completed. This seems to imply pathologists would be part of the model, but as these described characteristics are baseline elements of pathologist performance, what it means for pathologists to participate remains a question.

As illustrated by the above, physician roles and expectations appear to us disjointed and do not hang together cohesively and coherently. This level of confusion and gap in model logic may arise from failure to consult with physicians/specialties proposed to participate or be otherwise involved in the model. The CAP was not consulted on the development of this model which is of even greater consequence should the model be adapted for national expansion as it contemplates. It is unclear how pathologists would meaningfully participate in the model, how they would be reimbursed for their integral contributions to the oncology episodes, or how they would be able to increase the quality of care for patients.

Models are clearly stronger, more effective, and aligned more closely with the PFPM criteria with the input during the development process of specialists proposed to participate in the model. The CAP welcomes the opportunity to engage with submitters of all models that encompass pathology services during the development process.

We thank you for the opportunity to comment on the proposed Oncology Bundled Payment Program. Should you have additional questions, please do not hesitate to contact Sharon West, JD, Director, Economic and Regulatory Affairs at swest@cap.org or 202-354-7112.

Cc: Jonathan Myles, MD, FCAP, Chair, Economic Affairs Committee, CAP
W. Stephen Black-Schaffer, MD, FCAP, Vice-Chair, Economic Affairs Committee, CAP