The US Oncology Network

September 6, 2016

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
7500 Security Boulevard
Baltimore, MD 21244-1850

**RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017 (CMS-1654-P)**

Dear Acting Administrator Slavitt:

On behalf of the National Policy Board and physicians of The US Oncology Network,[1] I thank you for the opportunity to comment on CMS-1654-P, "Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2017" (Proposed Rule), as published on July 15, 2016, in the *Federal Register*.

The US Oncology Network (The Network) is committed to working with the Centers for Medicare & Medicaid Services (CMS) to enhance the delivery of cancer care and protect patient access to high-quality care in the most efficient manner. This commitment is demonstrated by the thirteen oncology practices within The Network, with 787 providers across the country, that have been selected to participate in CMS' Oncology Care Model (OCM). These practices have accepted the risk of participating in the pilot with the shared goal of improved patient outcomes and cost savings for the Medicare program. We believe it is in the mutual best interests of CMS and patients to have robust physician participation in alternative payment models. We need payment policies that enable physicians to practice medicine so that patient outcomes are improved, not jeopardized through restrictions that threaten the viability of treatments and services.

[1] The US Oncology Network is one of the nation's largest networks of community-based oncology physicians dedicated to advancing cancer care in America. Like-minded physicians are united through The Network around a common vision of expanding patient access to high-quality, integrated cancer care in communities throughout the nation. Leveraging healthcare information technology, shared best practices, refined evidence-based medicine guidelines, and quality measurements, physicians affiliated with The US Oncology Network are committed to advancing the quality, safety, and science of cancer care to improve patient outcomes. The US Oncology Network is supported by McKesson Specialty Health, a division of McKesson Corporation focused on empowering a vibrant and sustainable community patient care delivery system to advance the science, technology, and quality of care. More information about The US Oncology Network can be found at www.usoncology.com.

We urge CMS to consider the potential of the OCM pilot and future oncology-centered payment models in the course of this rulemaking.

Because there are a number of provisions in the Proposed Rule that impact the delivery of oncology care, we have organized our comments by issue area to facilitate your review:

- Flow Cytometry Interpretation
- Radiation Therapy Codes
- PE Inputs for Digital Imaging Services
- Phase-In of Significant RVU Reductions
- Validating RVUs of Potentially Misvalued Codes
- Medicare Telehealth Services – Advance Care Planning
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services
- G-Code Values Established by the *Patient Access and Medicare Protection Act*

**FLOW CYTOMETRY INTERPRETATION**

Flow cytometry is an integral part of diagnostic pathology. The US Oncology Network offers a community-based laboratory model to the benefit of its patients that is not replicated by reference labs. When proposing reimbursement rates, it is important for CMS to take into account community-based laboratories for which high-volume reference laboratories do not serve as an accurate comparator. Otherwise CMS risks compromising oncology patient access to this important diagnostic technology.

The US Oncology Network is deeply dismayed that CMS disagreed with a number of the RUC's recommendations for clinical labor time, equipment, and supplies. In downgrading the RUC recommendations, CMS is once again proposing significant cuts for the flow cytometry family of codes (CPT Codes 88184, 88185, 88187, 88188, 88189).

The US Oncology Network has 18 sites that centralize lab testing under a unique and efficient hub-and-spoke model, with 11 of these sites also performing flow cytometry. Under this model, multiple sites collect the blood samples and perform blood counts in-house and send the chemistry testing to one of the regional labs. Physicians within The US Oncology Network treat more than 800,000 patients annually. By offering flow cytometry services, The Network practices are able to provide high-quality services to their patients. This commitment to quality is demonstrated through participation in CMS' OCM by 13 practices within The US Oncology Network practices, 10 of which offer flow cytometry testing.

Key considerations that support maintaining the viability of flow cytometry services include:

> Quality: Leukocytes are fragile. Storage and transportation to distant central labs may result in poor sample quality, which can lead to inaccurate results and the need to repeat studies.

Accuracy: Test accuracy is maximized when sample quality is preserved as a result of minimal transportation and storage time. Furthermore, testing processes are standardized across The US Oncology Network with established panel markers, which reduces costs and errors through possible unnecessary testing by establishing predictable turnaround times. Accuracy of tests is also improved when the testing method is consistent, and conducted by the same technicians, thus decreasing interpretation errors. The Network labs perform delta checks (comparing laboratory test results with results obtained on previous samples from the same patient), which reference labs oftentimes cannot do because they lack historical results.

Efficiency: Because samples are received at the core lab from the satellite labs within two hours (or collected at the core lab itself), a rapid diagnosis can be made, thereby preventing any delay in choosing an emergent treatment protocol. This is particularly important for The Network sites that have been selected for the OCM to demonstrate a commitment to better quality, improved patient outcomes, and practice efficiency. Oftentimes, commercial labs, where full clinical data are not available, perform extra tests that may not be required for an individual patient but are "routine." The result is extra costs with no added value to patient care.

Patient experience: Finally, we believe that patient experience is important when weighing the effects of drastic cuts on flow cytometry. Patients benefit when sample collection and testing can occur within the same network of oncology practices. If flow cytometry becomes financially unviable there will be an adverse effect on the types of services available to patients within the oncology practice.

Based on an internal analysis, if the proposed cuts are finalized, nine of the eleven core labs within The Network will be operating at a deficit, with only two operating at a breakeven point. If any of these labs were to stop providing these valuable services for the cancer patients we serve, patient outcomes will be compromised because the freshest flow cytometry specimens provide higher cell viability, resulting in higher quality of data and better patient diagnosis. **The US Oncology Network strongly urges CMS not to finalize the proposed cuts to CPT Codes 88184, 88185, 88187, 88188, 88189.**

In addition, CMS believes it may be more accurate to have a single CPT code that describes the technical component of flow cytometry on a per patient case basis. We believe the current coding structure does not incentivize the use of less reagents, and, in fact, penalizes labs that appropriately test fewer markers. Moving to a single code structure would be consistent with the vast majority of lab tests, would simplify billing processes, and may make development of more cost-effective panels financially desirable. **The US Oncology Network strongly supports further examination of a single CPT code but urges CMS to freeze CPT Codes 88184 and 88185 at the current CY 2016 rates while such examination occurs.** Labs cannot be expected to provide flow cytometry at a financial loss while they hope for a new coding structure that more appropriately reflects the cost of providing the service**.**

## RADIATION THERAPY CODES

CMS has identified CPT Codes 77332, 77333 and 77334 (treatment devices, design and construction, simple, intermediate and complex) and 77470 (specialty treatment procedure) as potentially misvalued codes based on high expenditure screens. With respect to CPT 77332, 77333 and 77334, The US Oncology Network believes that the RUC recommendations for the work RVUs for these CPTs represents a fair review of an appropriately performed survey by the specialty and that CMS does not provide adequate justification for the 0.09 RVU per service reduction in the codes.

With respect to CPT 77470, CMS has expressed concern that the description and vignette related to this code expresses "different and unrelated treatments being performed by the physician and clinical staff for a typical patient, and this presents a disparity between the work RVUs and PE RVUs" and seeks comment to determine if two G-codes may be a potentially more accurate method of valuing and paying for this service.

CPT 77470 represents the additional physician and clinical staff work necessary to provide therapy for patients receiving one of the following: chemotherapy concomitant with radiation, brachytherapy sequential to external beam irradiation, retreatment of the same site, or treatment to a region immediately adjacent to a recently treated region to a tolerance dose of radiation. The common factor of all of these interventions is that the newly treated region is less tolerant of treatment and the physician and physicist must interact in order to make sure that the summation of the two treatments do not result in catastrophic patient injury.

Non-coplanar treatments, multi-portal treatments, or other interventions are employed to anticipate prior or future radiation, and similar modifications to treatment are also added to recognize the effect of the chemotherapy in reducing repair of radiation damage. The physician designates to the clinical staff (physicist, dosimetrist, and therapist) where the conventional treatment must be modified, the clinical staff perform the modifications as described above, and then the physician must confirm the effects of the treatment modification. This is an iterative process. **As such, The US Oncology Network believes it would not make sense to bifurcate the service into physician service (work RVUs) and clinical staff service/treatment planning equipment (PE RVUs) and urges CMS to maintain CPT 77470 as it is currently constructed.**

## PE INPUTS FOR DIGITAL IMAGING SERVICES

In the Proposed Rule, CMS proposes a new price for the Picture Archiving and Communications Systems (PACS) equipment and proposes to add the professional PACS workstations to numerous CPT codes in the 7000 series. However, CMS indicates they are, "not proposing to add the [professional PACS workstation] item to codes that are therapeutic in nature, as the professional PACS workstation is intended for use in diagnostic services. We are therefore not proposing to add the item to codes in the Radiation Therapy section (77261 through 77799)."

The US Oncology Network disagrees with the proposal to exclude radiation therapy codes. Radiation oncologists use professional PACS workstation for the purpose of fusing diagnostic

information from MRIs and nuclear medicine studies (primarily PET scans and SPECT scans) with the planning CT scan that is performed prior to the development of a radiation therapy treatment plan. In addition, the CT dataset from the cone beam CT scan that is performed on a daily basis (IGRT) is deformed by the PACS workstation in order to compare with the original planning CT scan so as to determine when patients need to be re-planned due to changes in patient weight, size, or changes in tumor conformation as the tumor shrinks in the course of daily treatment. **The US Oncology Network supports CMS's valuation for professional PACS workstation (ED053) at $14,616.93 but strongly urges CMS to add ED053 to the following CPT codes for radiation therapy: 77261, 77262, 77263, 77293, 77295, 77301, 77321, 77387, 77014, G6017, and 77470.**

**PHASE-IN OF SIGNIFICANT RVU REDUCTIONS**

In commenting on the CY 2016 Medicare PFS proposed rule, we noted that for services with drastic payment reductions, practices must have adequate time to adjust and, importantly, to determine whether they can continue to support the delivery of those services to Medicare beneficiaries. By statute, if total RVUs for a service, except for new or revised codes, are decreased by an estimated 20 percent or more, the adjustments shall be phased-in over a two-year period. While we disagreed with CMS' decision to implement a maximum 19 percent reduction for the first year of a two-year phase-in period, we appreciate that CMS has proposed to continue its policy of a maximum 19 percent reduction for those codes with phase-in values in the previous year. This proposal will help blunt otherwise deleterious effects that drastic reductions to flow cytometry are expected to have on oncology practices across the country as they determine whether to continue providing this important diagnostic service to their patients.

**VALIDATING RVUS OF POTENTIALLY MISVALUED CODES**

In the Proposed Rule, CMS describes the work of two contract entities, The Urban Institute and the Rand Corporation, engaged to develop validation models for RVUs. While CMS does not indicate whether or how it might use the results of these contractors' work, it does point out that the Urban Institute's report related to work RVUs will be publicly available later this summer. CMS also reports that the Rand Corporation's report on a validation model to predict work RVU's is posted on the CMS website. While CMS does not make any proposals related to these reports in this Proposed Rule, we note that in the past CMS has made RVU adjustments in final rules based on RUC reports which were not encompassed in a proposed rule and then took comment while the changes were in effect for a calendar year. **We urge CMS to refrain from using any findings in either of these two reports without notice and an opportunity for public comment in a future proposed rule.**

**MEDICARE TELEHEALTH SERVICES — ADVANCE CARE PLANNING**

The US Oncology Network supports CMS' proposal to add advance care planning CPT codes 99497 and 99498 to the telehealth list on a category 1 basis for CY 2017. We agree with CMS' assessment that adding these codes will increase access to advance care planning services for Medicare beneficiaries who live in rural areas, and/or would otherwise need to travel long distances to obtain services that can effectively be provided through telemedicine.

In our CY 2016 Medicare PFS proposed rule comment letter, The Network offered strong support for the establishment of separate payments (CPT codes 99497 and 99498) for advance care planning services provided to Medicare beneficiaries by physicians and other qualified health professionals. We thank CMS for finalizing separate payments for advance care planning services.

The US Oncology Network is proud to support the *My Choices, My Wishes* ℠ program launched in April 2013 to assist patients with advanced cancer to:

- Identify personal values and goals for care;
- Communicate effectively with clinicians and loved ones about what is and is not important in their care; and
- Develop a personal definition of "living well" within the context of serious illness.

*My Choices, My Wishes* supports full documentation of these advance care planning activities within an electronic medical record system, including formal advance directive documents and health care proxy designations that may evolve through the discussion process.

*My Choices, My Wishes* has been implemented in 91 sites of service within The US Oncology Network, reaching more than 30,000 cancer patients. Its integration within the patient's plan of care is viewed as important and requires a focused effort on the part of practice staff to assure that patients wanting to have these discussions are enabled to do so. Best practices have evolved to include a multidisciplinary approach utilizing trained physician, advanced practice provider, and social worker skill sets.

In our past comments, we strongly encouraged CMS to specifically include licensed clinical social workers as eligible to bill for advance care planning services. We understand that currently these codes can be billed by the physicians and non-physician providers whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Nonetheless, The US Oncology Network continues to hold the position that allowing clinical social workers to bill for 99497 and 99498 would be consistent with current practice. In The US Oncology Network today, approximately one quarter of all advance care planning services are performed by social workers. While it is typical for a physician to initiate a discussion with a patient about long-term treatment options and planning, patient-centered counseling that allows patients to make the best, informed decisions about their care and assistance with the preparation of advance directive documents usually occurs with a mid-level provider or social worker. **We hope that CMS will evaluate the creation of an exception to allow billing of 99497 and 99498 by clinical social workers so that the role of the social worker can be appropriately expanded to include routine advance care planning services.**

## APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

There are many clinical situations in which oncologists order and furnish advanced diagnostic imaging services, thereby subjecting them to the requirements of the Medicare Appropriate Use Criteria (AUC) Program as set forth in the Protecting Access to Medicare Act (PAMA) of 2014. In our comments to CMS in response to the CY 2016 Medicare PFS proposed rule, we expressed serious concerns with the compressed timeline for meeting a statutory deadline of January 1, 2017. We thank CMS for recognizing the complexity associated with implementing the law and for its decision to delay implementation. We understand that the AUC consultation and reporting requirements may begin as early as January 1, 2018, but believe the implementation date must be dictated not only by the availability of clinical decision support mechanisms (CDSMs) but also by their integration into electronic health record (EHR) systems, and physician and claims processing readiness.

In the CY 2016 Medicare PFS Final Rule, CMS stated that, ideally, multiple CDSMs would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology systems. As CMS correctly noted in the rule, this would minimize the burden on provider teams and avoid duplicate documentation. We agree and believe that if the first qualified CDSMs are not specified until June 30, 2017, a January 1, 2018, effective date may prove to be an unreasonable timeline for integrating CDSM modules into EHRs. While a CDSM may be independent from certified EHR technology, an overriding objective of this program should be to minimize burdens on ordering and furnishing professionals of advanced diagnostic imaging services. To achieve that objective, a timeline that is long enough to allow for integration of CDSM modules into EHRs is imperative.

*Defining Clinical Decision Support Mechanisms.* In its proposed definition of a CDSM, CMS states that a qualified CDSM within or available through certified EHR technology would incorporate relevant patient-specific information into the assessment of the appropriateness of an applicable imaging service. We suggest that to increase the accuracy of AUC, patient-specific information should factor into the assessment of the appropriateness of advanced imaging technology regardless of whether a CDSM is incorporated into or independent from an EHR. We also request CMS consider universal patient-specific information for AUC assessment by clinical condition.

*Priority Clinical Areas.* The Network supports the concept of establishing priority clinical areas in order to determine outlier ordering professionals. We believe the program goal should be to eliminate inappropriate utilization where it is most pervasive, rather than targeting ordering professionals at the margins by including as priority clinical areas those situations where advanced diagnostic imaging tests will be rarely inappropriate. We suggest that CMS defer to the American Board of Internal Medicine's *Choosing Wisely* initiative as a starting point for identifying priority clinical areas.

*Requirements for Clinical Decision Support Mechanisms (CDSMs).* The US Oncology Network offers the following comments to the proposed requirements for qualified CDSMs:

*1. Qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas. However, every qualified CDSM does not need to make available every specified applicable AUC.*

We believe that every qualified CDSM need not make available every specified applicable AUC beyond the priority clinical areas. The Network appreciates the importance of reducing administrative burdens on professionals who will order advanced imaging tests across a wide range of conditions. We believe, however, that there needs to be flexibility for specialty physicians to purchase and utilize CDSMs that are specific to their scope of practice. For example, many oncologists/oncology practices will order advanced imaging tests but we believe it is unnecessary for an oncology practice to purchase a CDSM that includes AUC for chest pain. We believe the benefits of more narrowly tailored CDSMs are threefold: 1) it will spur innovation of CDSM development and broaden the number of CDSMs available to providers; 2) it will help ensure that more applicable AUC find a "home" in a CDSM; and 3) it should minimize CDSM-acquisition and EHR integration costs if demand exists for specialty-focused CDSMs. **Therefore, we ask CMS to modify its proposal to allow for qualified CDSMs that are tailored to the types of advanced imaging ordered by a practice or physician.**

Under our recommended modification to this proposed requirement, we suggest that providers who acquire and use a more narrow, or specialty-specific, CDSM could use the free CDSM as a "back-up" for consulting applicable AUC for priority clinical areas not addressed in their CDSM. We believe this proposal gives ordering professionals flexibility without compromising the ability to consult AUC for all priority clinical areas. Alternatively, CMS could require consultation of AUC for priority areas based on an ordering threshold. Providers who rarely order advanced imaging tests for a particular priority clinical area would not be required to consult AUC for that clinical area.

We ask CMS to take this proposal a step further by requiring ordering professionals to only consult applicable AUC for priority clinical areas. Consequently, furnishing professionals would only need to document required information to CMS on priority clinical areas. We believe this modification to CMS' proposal would further reduce the burden on ordering and furnishing professionals. Under this proposal, nothing would preclude a CDSM from including a larger library of applicable AUC, but the ordering and furnishing professionals would know from the outset which clinical scenarios trigger the consultation, documentation, and reporting requirements. This would also prevent scenarios in which an ordering professional consults a CDSM with a broader library of applicable AUC only to find out that the applicable AUC for a clinical scenario doesn't exist. We suggest that our recommended modifications to this requirement constitute a reasonable phased approach to the program's implementation.

*2. Qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified practice-led entity (PLE).*

We appreciate CMS' proposal to require that CDSMs must be able to incorporate AUC from more than one PLE. However, because a CDSM is not required to incorporate specified applicable AUC from more than one qualified PLE, the likely result is that some AUC from

qualified PLEs will not be incorporated into CDSMs. This means that specialty physicians may find themselves unable to use applicable AUC developed by specialty-specific PLEs. We believe this scenario can be mitigated, per above, by allowing specialty-specific CDSMs. Furthermore, there is some question, if CDSMs must be able to incorporate AUC from more than one PLE, whether there should be standardization in the way that AUC are received by CDSM developers. We suggest that there should also be some type of validation step that is required by CDSM developers to make sure that AUC have been correctly translated into the CDSM. This could be accomplished by instituting a pilot phase of the AUC Program.

*3. Specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered must be made available within the qualified CDSM.*

We believe this is an important objective but suggest that some standardization is needed of what information must be made available within the qualified CDSM, how this information is provided to CDSM developers, and how the information is displayed in CDSMs.

*4. The qualified CDSM must clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.*

We believe this is an important requirement because, as CMS states in the proposed rule, it is important that the ordering professional knows which AUC is being consulted and to have the option to choose one over the other if more than one criterion applies to the clinical scenario. Furthermore, if a CDSM includes AUC from multiple qualified PLEs, then ordering professionals must be prompted to select which AUC to consult. We do not believe a CDSM should be allowed to have a default appropriate use criterion. When more than one criterion exists for a clinical scenario, the ordering professional must take the action of selecting a criterion to consult.

*5. Qualified CDSMs must provide ordering professionals aggregate feedback in the form of an electronic report on an annual basis (at minimum) regarding their consultations with specified applicable AUC.*

The US Oncology Network agrees with this request. While AUC have been used by commercial insurers, they often assign this to radiology benefit managers who run the AUC through a "black box" algorithm with no feedback to ordering professionals that allows them to understand the managers' ordering patterns. In addition to providing ordering professionals aggregate feedback on an annual basis regarding their consultations with specified applicable AUC, all CDSMs, including the free CDSM, should be required to provide ordering professionals information on their ordering patterns compared with those of their peers.

*6. All qualified CDSMs must reapply every five years.*

The US Oncology Network does not object to this requirement and five years provides some level of predictability for ordering physicians. However, if a qualified CDSM reapplies and does

not receive re-qualification, then the ordering professional should be allowed a grace period from the consultation requirements while he or she acquires and transitions to a new CDSM.

## G-CODE VALUES ESTABLISHED BY THE PATIENT ACCESS AND MEDICARE PROTECTION ACT

In the *Patient Access and Medicare Protection Act of 2015*, Congress provided a special rule for certain radiation therapy services as follows:

> *"The code definitions, the work relative value units under subsection (c)(2)(C)(i), and the direct inputs for the practice expense relative value units under subsection (c)(2)(C)(ii) for radiation treatment delivery and related imaging services (identified in 2016 by HCPCS G-codes G6001 through G6015) for the fee schedule established under this subsection for services furnished in 2017 and 2018 shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016."*

As a result of this provision, treatment delivery code definitions and valuations should be the same as those contained in the CY 2016 PFS Final Rule. However, one significant and large exception is G6011, a conventional treatment delivery code for 4 Mv or less photon treatment delivery. CMS proposes to reduce reimbursement for G6011 approximately 11 percent. CMS also proposes small changes to other radiation therapy G codes which are subject to the RVU freeze established by PAMA. **The US Oncology Network believes these proposed changes are not consistent with the statute and urges CMS not to finalize these proposed changes.**

## CONCLUSION

On behalf of the National Policy Board of The US Oncology Network and our more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, we thank you for the opportunity to provide our comments on Proposed Rule CMS-1654-P. We are grateful to be able to engage in substantive discussions and welcome practice site visits with CMS officials.

Sincerely,

Lucy Langer, MD
Chair, National Policy Board
The US Oncology Network