The US Oncology Network

September 10, 2018

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-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 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (CMS-1693-P)

Dear Administrator Verma,

On behalf of the National Policy Board and physicians of The US Oncology Network (The Network)[1], I thank you for the opportunity to comment on CMS-1693-P "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (CMS-1693-P)" (Proposed Rule), as published on July 27, 2018, in the Federal Register.

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 sixteen practices within The Network participating in CMS' Oncology Care Model (OCM). These oncology practices have made significant investments in practice transformation, changes to clinical workflow and fully embraced team-based care to improve patient outcomes and cost savings for the Medicare program.

As Medicare transitions toward value-based care, we believe robust participation in appropriate alternative payment models can better align the interests of both CMS (as the payer), and providers and patients. We all want payment policies that promote better patient outcomes, enable physicians to practice medicine that achieves those outcomes, and avoid restrictions that undermine 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. More information about The US Oncology Network can be found at www.usoncology.com.

The Network appreciates CMS' continued effort to reduce administrative burdens and streamline reporting to allow physicians to focus on delivering care to patients. However, several proposals included in the proposed rule would have the opposite impact for community oncology and if implemented, could threaten patient access to community-based cancer care. As the Administration pursues strategies to "put the patient first", The Network urges CMS to advance policies that improve the viability of private practicing physicians which will lower healthcare costs and expand access to care.

Due to the 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:

- Proposed Reform to Evaluation and Management (E/M) Visit Codes
- Proposed Update to Direct Practice Expense Inputs for Supply and Equipment Pricing
- WAC-Based Payment for Part B Drugs
- Medicare Telehealth Services
- Proposed Changes to the Quality Payment Program

Proposed Reform to Evaluation and Management (E/M) Visit Codes

CMS is proposing a significant reform to Evaluation and Management (E/M) codes for office visits for new and established patients. The Proposed Rule notes stakeholder concern over the compliance burden associated with required documentation. Out of a desire to reduce this burden, CMS proposes to consolidate the current tiered system for office visit payment—levels 2 through 5—to a single payment rate whereby the current documentation for a level 2 visit, with some alternatives, will be sufficient for all E/M office visits. While the current reimbursement rates range from $45 to $148 for established patients and $76 to $211 for new patients, the proposed single rate would be $93 for existing and $135 for new patients. The CPT codes corresponding to the current levels must still be reported, but only the single consolidated payment would be made. The Network appreciates CMS' recognition of the burden imposed by the current documentation requirements but has strong concerns about the proposal as constructed.

CMS acknowledges that the practical effect of this proposed policy will vary by specialty and practice, particularly where current level 4 and 5 constitute a large share of office visit payment, but asserts that the reduction in documentation burden will in part offset negative effects. To further ameliorate the effect of the new single payment rate, CMS proposes additional "add-on" G-codes, each with their own additional documentation requirements, for certain primary care visits and for visits of "inherent complexity" which could be billed by specialties which tend to use the current level 4 and 5 codes, such as endocrinology, oncology, urology, and others. CMS also proposes to modify its current "prolonged service" codes which require a one-hour threshold, to provide for an additional 30 minutes beyond the usual time required for an E/M code.

CMS is proposing an adjustment to the PE/HR calculation for all E/M codes of "approximately $136." In explaining this proposal, CMS notes, "We are concerned that such changes could produce anomalous results for indirect PE allocations since we do not yet know the extent to which specialties would utilize the proposed simplified E/M codes and proposed G-codes." In fact, we believe that this policy has a large, and potentially unintended, impact on oncology's Indirect Practice Cost Index (IPCI), a consequence that is not discussed but only alluded to in the proposed rule.

The $136/hour assumption is an average of the PE/HR across all specialties that bill E/M codes, weighted by the volume of those specialties' allowed E/M services. As a result, non-E/M codes would be significantly impacted, via changes in the IPCI. For medical oncology the change is extreme, the IPCI will drop 26.7 percent from CY2018 to Proposed CY2019. Nearly twice as many specialties will experience a reduction in the IPCI than experience an increase. For example, CPT 96409, a drug administration code used for the administration of chemotherapy, would experience a decrease in practice expense RVUs of about 12 percent (overall payment decline of 11 percent), based on the proposed policies. Even though the direct inputs (supply and equipment prices) went up slightly for this code, due to the change in the proposed IPCI value being used for 2019 it shows a decline in overall payment. Our understanding from discussions with CMS is that a new, pseudo-specialty for E/M codes was created by CMS and it is this policy that is driving the negative change in specialty IPCIs. The ramifications of these changes to the IPCI are unsustainable and could result in further consolidation of community oncology and decreased access to care for cancer patients.

Cancer treatment is inherently complex; oncologists must explain treatment plans in detail and help patients manage multiple conditions and alleviate side effects. As such, this proposal disproportionately affects cancer care because most oncology visits today are level 4 or 5 visits. CMS asserts that the negative impact on physicians who frequently bill level 4 or level 5 E/M codes will be partially offset by the reduction in documentation burden. Recognizing the need to ensure that reimbursement reflects resource intensity, CMS also proposes additional "add-on" G-codes that will increase reimbursement in certain cases. However, each G-code is accompanied by its own additional documentation requirements.

Regardless of coding rules, providers have an enduring obligation to document patient care for clinical purposes. In particular, we note that participants in the OCM are responsible for managing all aspects of a cancer patient's care for a six-month period, which will still require significant documentation despite this proposed change. For example, the patient's care team needs the most up-to-date information on the patient's medical history, physical examinations, lab results, imaging findings, clinical impressions, and management recommendations to appropriately plan and manage that patient's care. While we appreciate CMS' stated goal of simplifying documentation requirements for physicians, we are concerned that the proposal lacks recognition of the practical demands of cancer care. Moreover, the creation of "add-on" codes mitigates the benefit from the proposal and may actually increase oncologists' documentation burden.

Additionally, while CMS would reduce auditable documentation requirements for Medicare claims, there is no assurance that other payers, including Medicare Advantage plans, will follow suit. Physicians will likely still be faced with the burden of documentation for these plans. Even if other payers do follow suit, they will need time to change systems, modify provider agreements, and educate beneficiaries on the changes they may see in coinsurance. This would lead to a patchwork system of different levels of documentation for various patients, creating new and time-consuming hurdles for physicians.

CMS is also proposing a 50 percent reimbursement reduction to the lowest cost service when an E/M visit and a procedure occur on the same day. The reduced reimbursement would be re-allocated to increase reimbursement for the "add-on" G-codes to recognize time and complexity. CMS compares this reduction to the Multiple Procedure Payment Reduction (MPPR), which is a reduction in reimbursement by 50 percent for each additional procedure when multiple procedures occur during the same appointment.

CMS estimates the impact of the E/M proposal to oncology to be -7 percent without adjustments and between 0 to -3 percent with appropriate use of the "add-on" codes. However, in an analysis performed by the American Medical

Association on the impact of the proposed coding change and multiple procedure payment reduction – medical oncology is facing a 14 percent payment reduction. These proposed changes to E/M visits and its impact on the IPCI put additional economic pressure on community oncology practices and could further the trend in consolidation to hospital systems seen through the last decade. Again, while we appreciate CMS's commitment to reducing documentation burdens, the overall impact to community oncology makes this proposal untenable. For these reasons, The Network strongly urges CMS to not finalize its proposal to reform E/M visit codes and instead engage stakeholders to identify and analyze policies to achieve simplification of documentation and payment for E/M services that will result in reduced burden and improved patient care.

Proposed Update to Direct Practice Expense Inputs for Supply and Equipment Pricing

CMS contracted with StrategyGen to conduct a market research study to update the direct practice expense (PE) inputs for supply and equipment pricing. StrategyGen submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. CMS is proposing to phase in the updated direct PE input prices for supplies and equipment as recommended by StrategyGen over a four-year period, beginning in CY 2019. The Network appreciates CMS' effort to ensure current pricing information is used to appropriately value services but we have concerns with StrategyGen's methods and valuations and the lack of stakeholder input.

According to analysis conducted by the American Society for Radiation Oncology (ASTRO), several pieces of radiation oncology equipment are significantly undervalued. StrategyGen did not consider the cost of a complete SBRT system instead recommending only the price of a linear accelerator and not taking into account the necessary add on package needed to safely immobilize the patient and monitor motion to maximize dose deliver accuracy, and efficiently deliver either static fields or intensity modulated stereotactic irradiation. We have similar concerns with StrategyGen's valuation of the HDR Afterloader System.

The Network concurs with ASTRO's analysis and request to maintain current pricing for several radiation oncology equipment prices to provide stakeholders ample opportunity to properly research and analyze StrategyGen's data to ensure the use of accurate data and market pricing.

WAC-Based Payment for Part B Drugs

CMS is proposing to reduce the add-on payment for new drugs under Part B to Wholesale Acquisition Cost (WAC) plus 3 percent. CMS currently reimburses for drugs and biologic products that are produced or distributed under a NDA approved by FDA and are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File at WAC plus six percent.

We believe this proposal results from a misconception regarding the realities of the reimbursement methodology for Part B drugs. The current reimbursement methodology is designed to cover physicians' drug storage, handling, disposal and administrative expenses. In 2013, CMS began applying a 2 percent reduction imposed by sequestration to the amount paid for Part B drugs. Further reducing Part B payments for community providers will make it more difficult, especially for small and rural practices, to purchase certain drugs at the payment rate. In cancer care, Part B medicines are an essential component of treatment for many patients. And, unlike many drugs, oncologic drugs often require even more attention to handling and preparation. However, due to multiple reimbursement changes over the past

decade there has been a 30 percent shift in the site of care from the lower cost community setting to the higher cost hospital outpatient department[2]. This has had a disproportionately negative effect on community cancer clinics. Since 2008, 423 community oncology clinics have closed and 658 have been acquired by hospitals resulting in less choice for patients and higher costs for the health care system.

The Network appreciates the importance of holding down drug costs in cancer care. Indeed, we have been doing just that. Nearly a decade ago, physicians in The Network sought to strengthen relationships with patients and payers by selecting regimens that demonstrate value over volume and reduce non-evidence-based variability in treatment. As a result, we developed the Level I Pathways, evidence-based guidelines that re-direct the wide range of oncology treatments into more precise, clinically proven treatment options. The Pathways are physician-driven and designed to reduce variability, hospitalizations, and excessive care at the end of the life. According to a study in the Journal of Oncology Practice on patients treated both with and without the Pathways program, adherence to Pathways lowered overall costs of care with equal or better outcomes. The results included a 22 percent lower frequency of chemotherapy infusion visits, a 23% lower frequency of non-chemotherapy agents, and a 35 percent reduction in outpatient costs[3].

The Network urges CMS to reconsider the proposed reduction to the add-on payment for new drugs which could harm community-based oncology providers and do little to help cancer patients. As CMS looks for ways to manage costs, The Network encourages the agency to engage stakeholders and build upon strategies already working to hold down drug costs in oncology care.

Medicare Telehealth Services

Proposed Addition of Virtual Care Codes

The use of telecommunications in the day-to-day delivery of oncologic care is well documented and a mainstay in how provider and established patient interactions routinely transpire. We applaud CMS' recognition that time spent with patients via telecommunication methods merits reimbursement for provider time and resources. The Virtual Check-In Code (GVCI1) and the Evaluation of Asynchronous Images and Video Code (GRAS1) have important implications in the oncology setting, given that it is common for patients to experience disease and/or treatment complications while away from the clinic. Healthcare services provided via telecommunication methods are a normal and necessary component of oncology care delivery, whereby patients are encouraged to call—rather than go to an emergency room-- when symptom burdens are of concern and could require medical attention.

From a practical perspective, we note that a brief evaluation of the patient's health problem for purposes of assessing need for further medical evaluation (triage) is within scope of practice for the Registered Nurse. We believe that routinely tasking a healthcare provider to perform triage services will effectively limit provider ability to deliver care at top of licensure. We suspect this realization may result in limited use of the virtual care codes. Therefore, we respectfully ask that the Virtual Care Codes be expanded, including "incident-to" billing rules, for use by all medically licensed personnel, including the Physician, the Advanced Practice Provider, and the Registered Nurse.

[2] Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Milliman, April 2016

[3] https://www.ncbi.nlm.nih.gov/pubmed/20539725

It is well known that cancer patients undergoing complex treatments for their illness may experience a simple or life-threatening problem at any time. In many cases, in-home management of problems is preferred, and would be best served through frequent telecommunication follow-up to limit exacerbation of the problem and avoid an emergency department visit. Therefore, we suggest that it would be clinically inappropriate to apply any frequency limitation on the use of either Virtual Care Code. Similarly, established timeframe limitations bound by E/M code application within the previous seven days and 24 hours following a telecommunication event, will likely render the virtual care codes far less useful in the oncology setting. We suggest that removal of timeframe limitations would enhance patient access and promote appropriate in-home clinical management of healthcare problems. We endorse separate payment for Virtual Care Codes be made in all cases, except where the patient is instructed during the virtual care event to call 9-1-1 or to proceed to an emergency department for evaluation.

As communication technology continues to evolve, we anticipate increasing opportunities and efficiencies for delivering high quality healthcare. We suggest that multiple communication technology platforms be considered acceptable. Certainly, telephonic (audio only) interactions are often sufficient, as are email and other messaging services – with or without enhanced visual transmission. We suggest that separate consent for each service would likely be an unnecessary burden to the patient and the provider, and could be obtained instead through the general communication consent that is already required and covers all reasonable communication methodology options.

Telehealth Service Limitations

We recognize that Medicare telehealth services are limited by statutory restrictions based in Section 1834(m) of the Social Security Act relative to geographic dependencies and practitioner types for furnishing telehealth services. These restrictions are known to limit access to care across a wide sector of patients having one or more chronic, serious illnesses. We are encouraged that there is recent recognition of need for expanding telehealth services by allowing for exclusion of renal dialysis patients being treated at home and individuals with acute stroke from the telehealth geographic limitations.

Like dialysis and acute stroke patients, those undergoing complex and often debilitating treatments for a cancer diagnosis sometimes encounter durable challenges with mobility, cognitive, functional and other handicaps. These handicaps may be temporary or permanent, and frequently result in hardship and/or decreased access to care when the patient resides outside of a designated “originating site.” Existing and proposed telehealth service restrictions place an unfortunate burden on many cancer patients to meet face-to-face requirements for payment of services, even in circumstances where in-home virtual care could have been applied effectively.

The Medicare Telehealth Services list of applicable HCPCS/CPT Codes idealize what is currently possible for telehealth services. Pharmacologic management, advance care planning, psychosocial screening, nutrition counseling, and smoking cessation are only a few examples where broad application of telehealth services could be mobilized to better support patients undergoing cancer treatments, enabling improved physical, psychological, and even spiritual wellness. It is difficult to rationalize how overall health status and physical challenges experienced by cancer patients might somehow differ from physical challenges of dialysis and/or acute stroke patients, as these and other serious illnesses regularly demonstrate signs of progressive morbidity.

We propose that patients having severe illness be allowed to benefit from virtual care opportunities and respectfully request that limitations relating to geography and patient setting for telehealth services be further broadened to include populations having a cancer diagnosis – regardless of geographic location. We support and endorse legislative action to amend the underlying statute to broaden telehealth rules and urge the Administration to recommend such

changes to the Congress. We hope and anticipate that virtual care modalities will truly be advanced and embraced for all as a practical means for delivering high quality patient care in a timely manner to patients having greatest need.

Proposed Changes to the Quality Payment Program Year 3

The US Oncology Network supports more than 1,400 physicians that participate in the Quality Payment Program(QPP), including almost 900 that participate in the Oncology Care Model (OCM). We appreciate the opportunity to provide the following feedback based on our experience in the program.

Merit-based Incentive Payment System (MIPS)

Implementation of the Bipartisan Budget Act of 2018

In particular, we are pleased to see CMS implementing key changes to the program passed in the Bipartisan Budget Act of 2018 including:

- delay of Improvement Scoring until 2024 payment year,
- phase-in of weighting the Cost performance category, and
- applying MIPS adjustments only to "covered professional services"

As we noted in our previous comments, we believe these changes will help will help clinicians gain experience in the program and offer a planned timeline for performance changes to which payment will be subject.

MIPS Eligible Clinicians

The Clinical Social Worker (CSW), as a functional member of the multidisciplinary oncology care team, provides a critical and practical role in patient care — principally for those with more serious illness and/or multiple and challenging psychosocial needs. In some cases, it is the CSW skill set that leads to break- down of individual barriers to care so that appropriate service provisions are enabled. Current emphasis on quality measures in oncology further define need for CSW participation within the full scope of high quality cancer care delivery.

Oncology Clinical Social Workers (OCSW) continue to be frequent contributors of care interventions highlighted in multiple MIPS quality metrics. It is typical, for example, for the OCSW to be called on to address various psychosocial screening and interventional needs, advance care planning, undesirable health behaviors, and family or caregiver issues. We believe these, and other health concerns, are best served through collaboration between the OCSW and oncology healthcare providers.

The Network fully support CMS' proposal to include the Clinical Social Worker as a MIPS Eligible Clinician and wholly endorse the notion that these professionals are both qualified and necessary contributors to patient care. Furthermore, we believe the CSW is one who will continue to contribute meaningfully to the types of MIPS quality measures deemed more durable and sustainable over time. We thank CMS for making this important rule change proposal.

Low Volume Threshold Opt-In Policy

CMS proposes additional criteria to the low volume threshold based on clinicians who provide less than 200 or fewer covered professional services as well as providing an option for clinicians to op-in to the MIPS program if they exceed one or two, but not all of the three low-volume threshold criteria. We support the proposed opt-in policy and believe

giving Eligible Clinicians and groups the opportunity to voluntarily report under MIPS to try out the program, and subsequently opt into the program when they are prepared to participate, provides opportunity for those who'd like to transition their payment towards quality. We do, however, believe CMS should consider a policy that allows for those low volume providers who opt-in to avoid a negative payment adjustment under MIPS as they transition if they are below one or two of the low volume thresholds.

MIPS Performance Period for Quality and Cost Categories

In the proposed rule, CMS reiterates the policy laid out in last year's rule that the performance period for the MIPS Quality Category for 2018 will be the full year. We believe the performance period should be more consistent with other performance periods in this year's proposed rule, notably the Advancing Care Information and Improvement Activities categories. This is particularly important for medical and radiation oncology since the quality measures for which they will be accountable have changed in 2018 and adjustments will need to be made.

We do, however, agree with the proposal that for the Cost category, the performance period should be 12 months to allow for more robust feedback as CMS phases in the cost performance category over the next three years.

Small Practice Bonus

CMS proposes to continue the small practice bonus finalized in last years' rule but changes it to be added to the Quality performance category rather than the final score. We support this policy to encourage small practices to participate in the Quality Payment Program through MIPS or participation in APMs. Given the additional burden for small practices to adopt and finance the necessary infrastructure and technology for MIPS and APMs, this bonus would help alleviate some of these challenges.

Complex Patients Bonus

For performance year 2019, CMS proposes to extend the complex patient bonus. We support this proposed policy and CMS' intent to promote access to care for complex patients and prevent a disadvantage in scoring for those providers caring for these patients. For both medical and radiation oncology, the patients we treat are more complex than average and a bonus score to account for this would assist our physicians in the transition. We support this proposed policy and encourage CMS to consider including this as a longer-term policy for future years as well.

Waiver of the Requirement to Apply MIPS Payment Adjustment to Certain Payments in Section 1115A Models

CMS proposes to use its waiver authority to not apply MIPS payment adjustment factors to certain payments under Section 1115A models. CMS in particular indicates it intends to use this waiver on the Monthly Enhanced Oncology Services (MEOS) payments in the OCM model but would apply the waiver to any payments made outside of the model. We recognize and understand CMS' explanation of using this waiver to ensure OCM practices have consistent MEOS payment amounts. While we support the use of the waiver in this case, we do believe CMS should also remove the MIPS adjustment from counting toward the total cost of care in the model.

<u>Alternative Payment Model (APM) Policies</u>

Nominal Amount Standard

CMS has proposed and requested comment on maintaining the revenue-based nominal amount standard at 8 percent through performance year 2024. Eight percent risk on Medicare Part B is still considerable with the maturity level of most APMs, and assuming it also includes drug reimbursement, we support maintaining this standard. We believe this

standard should not be increased in future years to allow for a recognized standard for multi-year models. The Network supports this standard being maintained and consistent in the other payer advanced APM criteria.

All-Payer Combination Option

The Network supports CMS' continued implementation of the All-Payer combination option to include additional other payers, including commercial, to be included in the calculation for Qualifying Professional (QP) status under the program. We believe this expansion into the Medicare Advantage and commercial arenas will allow for more specialty-specific APM options and expand clinician participation. We support CMS providing options for payers to voluntarily submit models for determinations prior to the performance year as well as being able to submit for multi-year determinations based on the model contract.

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-1693-P. We are grateful to be able to engage in substantive discussions and welcome practice site visits with CMS officials. If you have any questions regarding issues raised in this letter, please contact Ben Jones at Ben.Jones@usoncology.com.

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