The US Oncology Network

September 27, 2019

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-1715-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; CY2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion (CMS-1715-P)

Dear Administrator Verma:

On behalf of the National Policy Board and physicians of The US Oncology Network ("The Network"), I thank you for the opportunity to comment on "Medicare Program; CY2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; and Amendments to Physician Self-Referral Law Advisory Opinion (CMS-1715-P)" (Proposed Rule), as published on August 14, 2019, 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. We are one of the nation's largest and most innovative networks of community-based oncology physicians, treating more than 850,000 cancer patients annually in more than 400 locations across 25 states. The Network unites over 1,400 like-minded physicians around a common vision of expanding patient access to the highest quality, most cost-effective integrated cancer care to help patients fight cancer, and win.

To facilitate your review, we have broken our comments into the following sections:

CY2020 Physician Fee Schedule (PFS) Proposed Rule

Maintenance of conventional Treatment Delivery, IMRT and Image Guidance Codes (G6001-G6015)
For 2020, CMS is proposing to maintain the radiation therapy conventional treatment delivery, Intensity Modulated Radiation Therapy (IMRT) and image guidance codes, which have been frozen at 2016 rates through 2018, per the Patient Access and Medicare Protection Act (PAMPA), and extended through 2019, per the Bipartisan Budget Act of 2018.

The Network appreciates CMS' recognition of the need to ensure payment stability while the radiation oncology community prepares for the implementation of the radiation oncology (RO) model, and strongly supports CMS' proposal to retain the payment rates for these G codes through at least 2020.

We also strongly encourage CMS to consider our comments in response to the radiation oncology model proposed rule (CMS-5527-P). The Network has long advocated for an alternative payment model (APM) to promote quality outcomes and provide payment stability in RO, but we have very real operational and financial concerns with the RO model as proposed. As further detailed in our comments on the proposed RO model to CMS, The Network urges CMS to adopt its recommendations in order to maintain access to quality radiation treatment and the viability of freestanding radiation therapy centers.

Proposed Update to Direct Practice Expense Inputs for Supply and Equipment Pricing
In 2018, 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 included as direct PE inputs. In The Network's comments on the CY2019 PFS proposed rule, we concurred with the American Society for Radiation Oncology (ASTRO) analysis, which determined that several pieces of radiation oncology equipment were significantly undervalued. Specifically, we found that the proposed prices for the HDR Afterload (ER003) System, the IMRT Treatment Planning (ED033) system, and the SBRT LINAC (ER083) system are all significantly undervalued. These issues remain in the CY2020 PFS proposed rule, and we urge CMS to conduct additional market research and solicit additional stakeholder input.

Proposed Reform to Evaluation and Management (E/M) Visit Codes
In the 2019 Physician Fee Schedule proposed rule, CMS proposed to consolidate the current tiered system for office visit payment—levels 2 through 5—to a single blended payment rate whereby the current documentation for a level 2 visit, with some alternatives, would be sufficient for levels 2-4 E/M office visits. While the then-current reimbursement rates ranged from $45 to $148 for established patients and $76 to $211 for new patients, CMS proposed the single blended rate of $93 for existing and $135 for new patients. In our comments on the CY2019 proposed rule, The Network noted that 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 would have disproportionately affected cancer care because most oncology visits today are level 4 or 5 visits. Therefore, we appreciated CMS' decision in the CY2019 final rule to modify its proposal and defer implementation until January 1, 2021, thereby providing the stakeholder community time to develop an alternative.

In the CY2020 PFS proposed rule, CMS is proposing to largely adopt the work of the American Medical Association's (AMA) joint CPT/ RVUs Update Committee (RUC) for E/M levels, documentation, and payment values for CY2021. As proposed, CMS would retain 5 levels of E/M coding for established patient visits, while codes for new patient visits would be reduced to 4 levels. The E/M code level would be chosen based on time or medical decision-making (MDM) and would only require taking of history and performance of physical exam as medically appropriate. The Network applauds CMS for acknowledging stakeholder concerns and revising its prior decision, including its adoption of the AMA RUC-recommended values for payment of office/outpatient E/M visits.

The Network appreciates the steps the agency is taking to address the administrative burden associated with data reporting and billing requirements. The Network also supports the proposal to require only as medically appropriate the performance of history and physical exams to determine coding level; which will

further relieve the administrative burden of requiring what are often duplicative exams during office visits. We also support the proposal to allow clinicians to choose the E/M visit level based on either MDM or time.

CMS notes that the RUC-recommended values for the revised office/outpatient E/M visit codes would more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, but that the revalued office/outpatient E/M code set itself still does not appropriately reflect differences in resource costs between certain types of office/outpatient E/M visits. Therefore, CMS proposes to simplify, consolidate and revalue the HCPCS add-on codes finalized last year for CY2021 for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and to allow a single new code to be reported with all office/outpatient E/M visit levels. The Network supports a system that recognizes patient complexity and reimburses physicians based on accounting for their time and expertise. Additionally, given how commonly E/M services are billed and the confusion last year surrounding which specialties the add-on codes applied to, we ask CMS to clarify there is no limit on specialties for the applicability of this new add-on code.

Physician Supervision Requirements for Physician Assistants (PAs)
CMS is proposing to modify existing regulations on physician supervision of PAs to provide that the statutory physician supervision requirement for PA services would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed. In the absence of State law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services. The Network appreciates CMS' recognition of the state's role in determining scope of practice requirements and supports this proposal.

Review and Verification of Medical Record Documentation
CMS is proposing broad modifications to existing documentation policy so that physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives could review and verify (sign and date), rather than re-documenting, notes made in the medical record by other physicians, residents, nurses, students, or other members of the medical team. The Network applauds CMS for its commitment to reducing administrative burden on physicians through the Patients over Paperwork Initiative.

While broadly supportive, The Network seeks clarification on the impact of the proposal to split/shared visits. Under current regulations, to be able to bill under the physician for work the advanced practice provider (APP) provided in a hospital setting, the APP and the physician each must document their findings, then combine both notes into a single charge. We do not believe the proposed rule addresses shared/split service scenarios specifically, and The Network seeks guidance on whether a physician would be able to co-sign the work of an APP, for instance, and what documentation or procedural steps would be required.

Malpractice (MP) Relative Value Units (RVUs)
In the CY2018 PFS Proposed Rule, CMS proposed to update MP RVUs based on updated MP premium data obtained from state insurance rate filings. For radiation oncology, data were only available from 23 states, and therefore this specialty did not meet CMS' 35-state threshold, which determines whether or not a specialty is deemed to have premium data sufficient to construct a unique risk factor. The Network stated its support for CMS' proposal at that time to rely on MP premium data for diagnostic radiology for this purpose, as we concurred that premiums are broadly similar to this specialty.

In the proposed CY2020 update, CMS proposes the following changes to expand the specialties and amount of premium data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs.

1. CMS is proposing to change its schedule for updating its malpractice premium data from every five years to every three years, to align with the PFS GPCI updates.
2. CMS is proposing the following methodological improvements to the development of MP premium data:
    a. Downloading and using a broader set of filings from the largest market share insurers in each state, beyond those listed as "physician" and "surgeon" to obtain a more comprehensive data set.
    b. Combining minor surgery and major surgery premiums to create the surgery service risk group, which yields a more representative surgical risk factor. In the previous update, only premiums for major surgery were used in developing the surgical risk factor.
    c. Utilizing partial and total imputation to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings, which sometimes use unique specialty names.
3. CMS is proposing to assign a risk factor of 1.00 for TC-only services, which corresponds to the lowest physician specialty-level risk factor.

The Network broadly supports CMS' efforts to improve the accuracy of MP data; however, we echo ASTRO's concerns about inconsistencies that have led to the undervaluation of certain specialties. CMS proposes to set the risk factor for "TC-only" services at 1.0 "because we do not have sufficient comparable professional liability premium data for the full range of clinicians that furnish TC-only services." CMS goes further to ask for information that would support assignment of alternative risk factor for TC-only services. We urge that CMS not make the proposed change at this time, since it lacks necessary information, and instead await information from effected specialties in the coming year for proposals in future rulemaking.

Comment Solicitation on Opportunities for Bundled Payments under the PFS
CMS seeks comment on opportunities to expand the concept of bundling to improve payment for services under the PFS and more broadly align PFS payment with the broader CMS goal of improving accountability and increasing efficiency in paying for the health care of Medicare beneficiaries. Specifically, CMS seeks new options for establishing PFS payment rates or adjustments for services that are furnished together.

The Network believe robust participation in appropriate alternative payment models can best align the interests of CMS (as the payer), providers, and patients. As CMS notes, one of the mechanisms currently employed to support innovative payment and service delivery models is the Center for Medicare and Medicaid Innovation (CMMI). The Network is proud to support more than 900 physicians participating in the Oncology Care Model (OCM), an episode-based, bundled payment model through CMMI aimed at improving coordination, appropriateness of treatment, and access to care for beneficiaries undergoing chemotherapy. Since the OCM's first payment period beginning July 1, 2016, Network practices alone have realized more than $80 million in savings for Medicare through participation in the OCM. Most importantly, in our view, these savings are a byproduct of the improvements in patients care directly resulting from the practice transformation and investments in better care made by The Network's OCM practices.

As CMS seeks to identify future savings opportunities, The Network encourages CMS to maintain its commitment to high-quality, patient-centered care through the development of voluntary, episode-based

alternative payment models. Additionally, we ask CMS to consider the downstream impacts of any future bundled payments within the statutory framework of the PFS to ensure they do not further the trend of consolidation in the oncology space, which has decreased access to community-based care and increased healthcare costs as patients are forced into more expensive care settings.

Stark Advisory Opinion Process

In 2018, CMS issued a Request for Information (RFI) to gather public input on how to address unnecessary burden created by the physician self-referral law, including how it may impede care coordination. In response to the RFI, many health systems and provider groups urged CMS to update the regulations governing its advisory opinion process on physician referrals to reduce provider burden and uncertainty around compliance with the Stark Law. Therefore, CMS is soliciting comment on potential changes to its advisory opinion process to address these stakeholder comments.

The in-office ancillary services exception (IOASE) to the "Stark" law preserves the longstanding practice of bringing together advanced treatment options when the service or procedure is ancillary to the original patient diagnosis. The provision enables our community-based practices to provide convenient, integrated and less expensive high-quality care. It allows clinicians to provide some services in the office setting, including advanced diagnostic imaging (MRI, PET, and CT scans), radiation therapy, anatomic pathology, and physical therapy, when complex and detailed supervision, location, and billing regulatory requirements are met. This provision is of particular importance to cancer care in the community setting in that it provides patient access to chemotherapy, radiation therapy and advanced imaging together - all under one roof with a coordinated team of caregivers.

The IOASE provision ensures patient access to fully comprehensive cancer care that spans the entire continuum of care while avoiding multiple or unnecessary visits to different sites – saving both time and money. It protects the doctor-patient relationship by ensuring there is only one treatment "team" managing a patient's course of care, and it improves coordination and communication between all physicians and caregivers through the use of a uniformed medical record, allowing for seamless treatment with different modalities and avoidance of unnecessary care. Importantly, the provision saves CMS and the healthcare system valuable funding by offering care in the most cost-effective setting. As CMS seeks input on barriers to care coordination, The Network urges CMS to recognize the critical role of IOASE in integrated cancer care.

Additionally, while most cancer patients across the United States have access to integrated care in their communities, previous regulatory actions are impeding access for others. In 2008, CMS issued a clarification limiting the ability of physicians to refer patients to "under arrangement" facilities. This clarification resulted in the prohibition of referrals for emergency radiation treatment if the initial visit occurred in a hospital, emergency room or during hospital rounds. CMS has ruled that since the patient was not first seen in the physician's practice, any external referral to a facility in which the physician has an ownership would violate the Stark Law. This has a significant impact on cancer patients in areas where there are few radiation therapy facilities, potentially causing patients to travel long distances for their radiation treatment or incur higher treatment costs at hospital-based radiation therapy centers. We urge CMS to revisit this broad policy to ensure that cancer patients are able to obtain emergency radiation treatment in their community as necessary and appropriate.

Proposed Changes to the Quality Payment Program Year 4

Merit-based Incentive Payment System (MIPS)
CMS is proposing the following changes to the MIPS program for CY2020:

- Increase the performance threshold from 30 points in 2019 to 45 points in 2020 and 60 points in 2021;
- Reduce the Quality performance category weight from 45% in 2019 to 40% in 2020, 35% in 2021, and 30% in 2022; and
- Increase the Cost performance category weight from 15% in 2019 to 20% in 2020, 25% in 2021, and 30% in 2022.

We are pleased to see CMS continuing to phase-in weighting in the Cost performance category. As we noted in our previous comments, we believe these changes 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
We appreciate CMS revisiting the inclusion of Clinical Social Workers (CSW) as MIPS-eligible clinicians. The 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.

CMS is soliciting comment on applicable measures for a Clinical Social Work (CSW) specialty set (Table Group B). While some of these measures may not be applicable in the oncology patient population, The Network agrees that they are appropriate measures for these clinicians. We suggest that Quality Measure #047, Advance Care Plan, be added to this measure set, as counseling patients in this area is an inherent skill of these professionals and an important intervention not limited to oncology patients.

We continue to strongly support the inclusion of CSWs 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.

MIPS Value Pathways
Beginning in the 2021 performance year, CMS is considering restructuring MIPS under a new MIPS Value Pathway (MVP) framework, in effort to align and connect measures and activities across the Quality, Cost, Promoting Interoperability, and Improvement Activities performance categories of MIPS for different specialties or conditions. <u>While we appreciate CMS' intent to streamline the existing MIPS requirements and make them more meaningful to participating clinicians, The Network cautions that the MIPS Value Pathways framework as proposed may have the opposite effect.</u>

Foremost, we are concerned that the proposed specialty-specific measure bundles would be mandatory. This would prevent physicians from identifying additional areas of clinical concern based on their specific patient population or targeted areas for improvement and from aligning initiatives across a variety of value-based care programs or payer needs. Additionally, not all specialties will have the same number of measures in their bundle, making it challenging to compare across clinicians/specialties and raising concerns about equitable assessment. Further, we believe switching to new measure development for new MVPs will exacerbate the reporting burden, rather than reduce it. As a result, the reporting will be viewed as more obligatory than meaningful, which will reduce physician buy-in, an element critical for the program's success.

We are also concerned about the role of Qualified Clinical Data Registries (QCDR) under this new framework, including how QCDRs will be able to participate in the design and development of specialty-specific MVPs and how they will collaborate to share MVPs if CMS continues to support custom QCDR measure development. Last, CMS is proposing to begin MVP implementation in 2021, which will be a particularly critical time for practices as they adjust to a higher MIPS performance threshold and two-sided risk. The Network encourages CMS to continue engaging with stakeholders to improve the existing MIPS program, or, at a minimum, consider additional flexibility for the measures included in the MVP program.

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-1715-P. We welcome the opportunity to discuss the issues outlined above and other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncology.com.

Sincerely,

Marcus Neubauer, M.D.
Chief Medical Officer
The US Oncology Network