September 11, 2023

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure,

On behalf of The US Oncology Network (The Network), which represents over 15,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to comment on the "Medicare Program; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS-1784-P)" Proposed Rule.

The Network is one of the nation's largest and most innovative networks of independent, community-based oncology physicians, treating more than 1.2 million cancer patients annually in more than 450 locations across 28 states. The Network unites over 2,300 like-minded physicians around a common vision of expanding patient access to the highest quality, state-of-the-art care close to home and at lower costs for patients and the health care system. We are 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, affordable care in the most efficient manner. To facilitate your review, we would like to highlight our comments on the following proposals:

- **Overall Payment Rates**: We express concern with the continued cuts to the Physician Fee Schedule while the Hospital Outpatient Prospective Payment System continues to see increases, furthering site-of-service payment disparities and incentives for consolidation.
- **Implementation of G2211 (O/O E/M Visit Complexity):** We support implementation of G2211 for 2024.
- **Services Addressing Health-Related Social Needs:** We support CMS' proposal to establish coding and billing for CHI and SDOH.
- **Telehealth Services, Direct Supervision:** We support CMS' proposal to continue defining "direct supervision" to permit virtual presence through December 31, 2024, and beyond.
- **Dental and Oral Health Services:** We support CMS' proposal to cover dental services prior to Medicare-covered chemotherapy, CAR T-cell therapy, and the administration of high-density bone-modifying agents when used in the treatment of cancer.
- **AUC Pause and Reevaluation:** We are encouraged by CMS' plans to pause AUC efforts and reevaluate the program, but we ask CMS to quickly determine if the AUC program will exist in any form in the future and consider ways to help salvage investment to date.
- **Advanced APM QP Thresholds:** EOM participants are unlikely to meet existing QP thresholds, in part because CMMI reduced the number of eligible patients, so we support relaxing the existing QP threshold scores and extending the Advanced APM bonus.

- **Buffer Stock OPPS Proposal:** If CMS decides to create separate payment to establish and maintain a buffer stock of cancer medicines in the inpatient or outpatient setting, the agency should create a similar payment to establish and maintain a buffer stock in the physician office setting.

CY 2024 Physician Fee Schedule (PFS) Proposed Rule

Oncology Impact
In reviewing the CY 2024 PFS proposed rule, the specialty impact table (Table 104) suggests a modest impact to oncology, specifically a +2 percent impact to hematology/ oncology and a -2 percent impact to radiation oncology and radiation therapy centers. This is primarily driven by the proposed implementation of the complexity add-on code, which is anticipated to be used more frequently in medical oncology. However, as CMS notes, the specialty impact table does not account for the impact of the Consolidated Appropriations Act of 2023 (CAA, 2023). Factoring in the statutorily-required update to the conversion factor for CY 2024 of 0 percent, the one-time 2.5 percent increase for 2023 and the onset of the 1.25 percent increase for 2025 provided by the CAA, 2023, as well as the statutory budget neutrality adjustment, the proposed conversion factor (CF) for CY 2023 is $32.75, a decrease of $1.14 (-3.34 percent) from the CY 2023 CF of $33.89.

PFS Methodology is Outdated
This is the fourth straight year CMS has called for a reduction in the conversion factor and reimbursement under the physician fee schedule. While Congress has thankfully passed legislation to mitigate some (but not all) of these proposed cuts, inflation and practice expenses have continued to rise. The cost of staffing and interest rates continue to grow. According to the American Medical Association, when adjusting for the full impact of inflation on practice costs, Medicare physician payment has declined by 26 percent from 2001 to 2023. This dynamic is exacerbated by budget neutrality adjustments. Federal Medicare law requires CMS to apply a budget neutrality adjustment when aggregate changes in program payment are projected to increase or decrease by more than $20 million. While The Network understands the statutory nature of this requirement, we believe it acts as a detriment to patients, to the physician community as a whole, and to oncology in particular. For example, radiation oncology will see payment reductions in CY 2024 due to implementation of the third year of the clinical labor pricing update as well as the complexity add-on code. We urge CMS to work with Congress to update the PFS methodology and stop these now-annual payment cuts.

Impact on Consolidation
At the same time, Medicare payment rates for facilities paid on the Hospital Outpatient Prospective Payment System (OPPS) continue to increase. For CY 2024, CMS is proposing to increase OPPS payments by 2.8 percent. This growing disparity is unsustainable. Medicare's failure to ensure physician payments keep pace with inflation, combined with year over year cuts, contributes to market consolidation and the reduction in independently practicing physicians. Increasing payment to hospital-owned physician offices while decreasing payment to independently-owned physician offices increases costs in the short and long term to patients and the Medicare system. We support Section 110 of the recently-introduced H.R. 5378, the Lower Costs, More Transparency Act, which would empower the Department of Health and Human Services to devote resources toward assessing the aggregate impact of agency-issued regulations on the consolidation of providers and payers in Medicare.

Implementation of G2211 (O/O E/M Visit Complexity)
In the CY 2021 PFS, CMS recognized the complexity associated with treating cancer patients by finalizing an add-on code for evaluation and management (E/M) services. In part CMS said, "We continue to believe that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that result in a comprehensive, longitudinal, and continuous relationship with the patient and involves delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set." While The Network was encouraged to see CMS acknowledge that the PFS does not adequately reimburse

physicians delivering comprehensive, coordinated, team-based care, Congress subsequently delayed implementation of the add-on code to offset reductions in the conversion factor.

We appreciate CMS' continued recognition that the O/O E/M office visit complexity add-on code "reflects the time, intensity, and [practice expense] resources involved when practitioners furnish the kinds of O/O E/M office visit services that enable them to build longitudinal relationships with all patients and to address the majority of patients' health care needs with consistency and continuity over longer periods of time." Overall, The Network supports CMS' proposal to move forward with implementation of G2211 for CY 2024.

However, we note that G2211 does not increase reimbursement for global services, including global surgical codes or radiation treatment management, even though these specialties are providing cancer care to the same complex patients and E/M services are a component of these bundles. Surgical care and radiation therapy are critical components of a cancer patient's treatment, and surgeons and radiation oncologists are a key part of that patient's care team with whom they have a continuous relationship. The global service bundles predate the creation of this complexity code and therefore could not have been taken into account. Therefore, we encourage CMS to consider allowing use of this complexity-code for codes that have an E/M component but don't bill for E/M separately. In our view, a separate add-on payment would be more economical than accounting for it directly in the global bundle since not all patients would warrant use of the complexity code.

Services Addressing Health-Related Social Needs
Practices in The Network are committed to helping patients navigate their cancer journey. This includes utilizing shared decision-making to create treatment plans for each patient with elements like social work, nutrition, survivorship, financial counseling, patient assistance programs, advance care planning, and palliative care. On a more granular basis, practice personnel are helping patients get to their appointments and pick up and take their medications, contextualizing health education, coordinating care, building patient self-advocacy skills, and tailoring support as needed, all to ensure patients can start and complete their treatment. The Network appreciates CMS' recognition that this work is not explicitly recognized in current coding and therefore undervalued.

Community Health Integration (CHI) services
CMS is proposing to establish separate coding and payment for Community Health Integration (CHI) services. As proposed, CHI services could be furnished monthly, following an initiating E/M visit (referred to as the CHI initiating visit). The Network strongly supports CMS' proposal, and we appreciate the opportunity to offer feedback on the creation of these codes.

CMS is proposing that the CHI initiating visit would serve as a prerequisite to billing for CHI services, during which the billing practitioner would assess and identify SDOH needs. While CMS is also proposing to create a new standalone G code for a 5-15 minute SDOH risk assessment that is furnished in conjunction with an E/M visit, it is unclear whether providers would be able to bill for an SDOH assessment with a CHI initiating visit. We encourage CMS to clarify that the SDOH risk assessment be used, and billed for, in the CHI initiating visit to help the provider identify SDOH needs of patient and refer for CHI services.

CMS also seeks comment on whether professional services other than E/M visits, such as annual wellness visits (AWV), should be considered the prerequisite initiating visit for CHI services. In these situations, the CHI services would not necessarily be furnished consistent with the proposed "incident to" requirements for payment. CMS notes that an E/M visit can be billed in addition to the AWV when medical problems are addressed during an AWV encounter. In order to provide additional support and services to all patients, The Network believes CHI initiating visits should be offered and allowed at a variety of visits.

Subsequent CHI visits would be performed by a community health worker (CHW) or other auxiliary personnel incident to the professional services of the practitioner who bills the CHI initiating visit. CMS is proposing that

all auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements and authorized to perform them under applicable State laws and regulations. While CMS proposes core competencies necessary for auxiliary personnel, we believe CMS should go further, and specify which disciplines/ professions or other non-physician specialty types can perform CHI services. Specifically, we believe the definition of certified or trained auxiliary personnel should include social workers, navigators, CHWs, and nurses who are trained to help manage patients' SDOH needs.

CMS proposes HCPCS code GXXXI for community health integration services performed by certified or trained auxiliary personnel, under the direction of a physician or other practitioner, 60 minutes per calendar month; however, it is unclear whether the 60 minutes represents cumulative time across the entire care team or just one individual. The Network encourages CMS to clarify it applies to the entire care team as typically there would be many individuals helping with this service.

CMS seeks comment on the typical amount of time practitioners spend per month furnishing CHI services to address SDOH needs and the number of months practitioners typically furnish these services. In the oncology setting, time per month per patient varies from 1 hour to 4 hours, depending on the complexity of the patient's needs. The typical duration also varies, but some oncology patients benefit from continual assistance for 3-4 months or longer.

CMS seeks confirmation of its assumption that most CHI services would involve direct contact between the auxiliary personnel and the patient, and that a substantial portion would be in-person, but a portion might be performed via two-way audio. The Network disagrees with this assertion. Patients with SDOH needs typically have transportation and technology challenges. Forcing these patients to take time off of work, arrange transportation to their appointment (many times from caregivers who work), or use technology they do not have would be shortsighted. CMS should encourage these services to be performed in the manner that is easiest for the patients.

CMS also seeks comment on whether the agency should require patient consent for CHI services. The Network believes that if patients are going to be billed for CHI services in any way, patient consent should be required. This would also give the patient the opportunity to decline services and/or notify the clinic if they are receiving CHI services elsewhere.

Last, CMS seeks comment on additional service elements that CMS should consider including in the proposed CHI service codes in the future. The Network recommends CMS include Advance Care Planning. This would align with the current CHI proposal, under which auxiliary personnel can help the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s) and educate the patient on how to best participate in medical decision-making. ACP helps align patient care with their personal values and preferences and it is auxiliary personnel who typically have ACP conversations and help patients complete advance directive documents; therefore, they should be allowed to assist with and bill (under the CHI code) for ACP.

Social Determinants of Health Risk Assessment
CMS is proposing a new standalone G code, GXXX5, for a 5–15-minute SDOH risk assessment that is furnished in conjunction with an E/M visit. The Network supports this policy, and as outlined above, recommends that the SDOH risk assessment be conducted as part of the CHI initiating visit. The Network also supports CMS' proposal to add this code to the Medicare Telehealth Services List. While it is preferable for the patient to complete an SDOH assessment in person, patients should also have the ability to complete the assessment over two-way audio or telehealth.

CMS notes that appropriate follow-up after an SDOH assessment is critical for mitigating the effects of the identified, unmet SDOH need on a person's health. CMS seeks comment on whether agency should require,

as a condition of payment for SDOH risk assessment, that the billing practitioner also have the capacity to furnish CHI, PNI, or other care management services or have partnerships with community-based organizations to do so. While The Network notes that determining how best to help a patient after an SDOH need has been identified is challenging, we agree with CMS that if a patient is going to be screened, there should be means for follow-up with the patient and effort to address any identified patient needs.

Principal Illness Navigation
CMS is proposing new coding for Principal Illness Navigation (PIN) services that are intended to be similar to CHI services but for patients with serious illness where SDOH needs may be fewer or not present. The Network appreciates CMS' recognition that patients with serious, high-risk diseases such as cancer have greater navigation needs; however, we believe creating a parallel set of services to the proposed CHI services may be duplicative and create confusion. Instead, we encourage CMS to consider including PIN services under CHI.

Telehealth
PHE Transition and Beyond
CMS clarifies that certain telehealth flexibilities previously extended until 151 days after the end of the PHE, by the CAA, 2022, have been extended until December 31, 2024, in accordance with the amendments made by provisions of the CAA, 2023. The Network continues to believe that the availability of appropriate telehealth services enhances the delivery of cancer care and should remain an accessible tool to patients and providers on a permanent basis. We are pleased CMS and Congress worked together to provide a transition period after the expiration of the PHE, but we continue to believe allowing patients to see their providers from their homes, regardless of distance, should be made permanent Medicare policy. Therefore, we strongly encourage CMS and Congress to maintain beneficiary access to appropriate telehealth services by permanently eliminating Medicare's geographic and originating site restrictions.

Direct Supervision
During the COVID-19 Public Health Emergency (PHE), CMS changed the definition of "direct supervision" as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence. While the COVID-19 pandemic created significant challenges in cancer care, it also facilitated innovation and learning, and CMS' temporary policies allowing flexibility helped spur these advancements. Allowing direct supervision through virtual presence enabled some Network practices to reach more patients. For example, providers were able to staff satellite locations and provide chemotherapy infusions through remote supervision which enabled more patients to receive treatment closer to home. We appreciate CMS' recognition of an abrupt transition to pre-PHE policy requiring the physical presence of a supervising practitioner given new patterns of practice that were established during the PHE. Without extending this policy, which is currently scheduled to expire on December 31, 2023, Network practices who used this flexibility may need to hire new physicians or relocate others. Therefore, The Network supports CMS' proposal to continue defining "direct supervision" to permit virtual presence through December 31, 2024.

CMS seeks comment on extending this policy for CY 2025 and beyond, including whether virtual direct supervision of certain types of services is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. The Network supports extending this policy beyond December 31, 2024. Not only is this flexibility critical for maintaining and increasing access to care in rural areas, but practices across the country would benefit from this policy given the physician shortage. Extending it on a permanent basis would allow practices to extend hours in locations that struggle for coverage, have limited space, and/ or need to offer longer service for the patient base. A virtual supervision option would help practices mitigate disruptions from future pandemics, extreme weather events, and other external factors, as

well as staffing shortages. That said, we agree with CMS that it is critical to balance patient safety concerns with the interest of supporting access and preserving workforce capacity for medical professionals. Some services carry a higher risk of safety concerns and should only be provided under direct, non-virtual supervision. For example, regarding radiation oncology, we share the American Society for Radiation Oncology's (ASTRO) position that direct, non-virtual supervision is necessary for the delivery of stereotactic radiosurgery, stereotactic body radiation therapy, brachytherapy or weekly treatment management. Therefore, The Network encourages CMS to issue detailed future rulemaking to clarify which services can be supervised virtually under this policy for CY 2025 and beyond.

Dental and Oral Health Services
In the CY 2023 PFS final rule, CMS finalized a proposal to provide payment for additional dental services, beyond the more limited services currently covered under Medicare FFS payment policies, that are "inextricably linked to, and substantially related and integral to, the clinical success of, certain other covered medical services." The Network was pleased CMS finalized its proposal to provide payment for dental exams and necessary treatments prior to treatment for head and neck cancers starting in CY 2024.

For CY 2024, CMS is proposing to permit payment under Medicare Parts A and B for dental examination and medically necessary treatment to eliminate oral or dental infection prior to Medicare-covered chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and the administration of high-density bone-modifying agents when used in the treatment of cancer. The Network continues to believe there is a clear, inextricable link to dental evaluation and services and successful cancer treatment. We agree with CMS that chemotherapy and CAR T-cell therapy can suppress the immune system and allow low grade dental infections to flourish. Similarly, bisphosphonates (bone resorptive agents) can cause osteonecrosis of the jaw. Dental health is important to successful cancer treatment, and we support CMS' proposal to cover dental exams and related services prior to beginning these treatments. We ask CMS to clarify the term "*high-dose"* bisphosphonate therapy as there is a standard dose for cancer patients and using the term "high-dose" may create confusion.

Request For Information: Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding
CMS is seeking comment on the process for determining which drugs should be included on the Self-Administered Drug (SAD) lists maintained by the Medicare Administrative Contractors (MACs). SAD exclusion list determinations impact patient access and reimbursement. The Network urges caution in revising this process to encourage consistency because it could inadvertently limit coverage and access.

Additionally, CMS is seeking comment on complex non-chemotherapeutic drug administration to determine appropriate coding and payment and whether policy guidelines should be revised for how these services are furnished and billed. The Network agrees with ASTRO's recommendation regarding radiopharmaceuticals. Per the National Cancer Institute, radiopharmaceuticals are a class of drugs that deliver radiation therapy directly and specifically to cancer cells. This is another example where cancer treatment is rapidly advancing with the potential to be highly effective with fewer side effects. However, access to this promising therapy in the freestanding setting is impeded by current reimbursement policy. While radiopharmaceuticals are considered a "drug" under the Hospital Outpatient Prospective Payment System (OPPS) and reimbursed at Average Sales Price (ASP) +6 percent, under the PFS, radiopharmaceuticals are not considered a "drug," and therefore considered a carrier-priced procedure by the MACs. As a result, community-based cancer practices are reimbursed significantly less than HOPDs for this therapy, often at rates less than the cost of acquisition. The Network shares ASTRO's recommendation and encourages CMS to treat radiopharmaceuticals as a drug under the PFS, as it does under the OPPS, and reimburse at ASP + 6 percent.

Appropriate Use Criteria (AUC) Pause and Reevaluation
CMS is proposing to pause implementation of the AUC program for reevaluation and to rescind the current AUC program regulations from § 414.94. The Network is encouraged by CMS' plans to pause AUC efforts and

reevaluate how the program could best benefit patients, providers, and payers in the future, or to truly declare that the program is not viable. We recommend CMS determine quickly if the AUC program will exist in any form in the future. Providers, Clinical Decision Support Mechanism (CDSM) vendors, and Provider Led Entities (PLEs) have invested years of effort, technology development, and incremental dollars to prepare for the eventual launch of the AUC program. We encourage CMS to recognize the time and financial resources that providers, CDSMs, and PLEs have invested over the past 5 years and, if CMS chooses to sunset the program, to consider finding ways to compensate these entities for their effort and progress.

Network physicians and care teams have invested years' worth of time in education and adoption of the AUC program. Further, our LogicNets CDSM & Ontada iKnowMed EHR partners have invested significant hours and dollars in product and content development and integration. Extensive efforts have also been spent to digitize AUC algorithms based on National Comprehensive Cancer Network (NCCN) guidelines. We partnered with NCCN as our PLE to develop an expanded catalogue covering 58 cancer diagnoses, well beyond the eight base Priority Clinical Areas, to help oncologists ensure they could engage all patients on evidence-based imaging pathways.

Based on this experience, we collectively appreciate the challenges and effort to establish sustainable people, process, technology, and data to deliver on the AUC program. While we see the value of clinical decision support in enabling pathway adoption, we agree with CMS that this should not be accomplished at an exceptional burden to providers and at the risk of delaying or limiting access to care. We support CMS' proposal to reevaluate the AUC program due to the inability to deliver on timely, accurate, and appropriate claims processing. We also encourage CMS to quickly determine the fate of the program so we can decide if additional efforts or investments are needed to prepare for a future with AUC or not.

To help salvage the provider, CDSM, and PLE AUC efforts to date, we encourage CMS to consider incentivizing the use of clinical decision support through greater reimbursement for providers that utilize AUC as part of their advanced diagnostic ordering and furnishing process, which would not be hindered by CMS claim processing service levels. CMS could promote AUC adoption through providing perpetual MIPS bonus points based on AUC uptake. CMS should also consider expanding the Clinical Areas of focus, while ensuring more consistency in delivery across CDSMs on development and PLEs on content efficacy. The experience with the AUC program is a good reminder of the need for thorough assessment of the overall burden and feasibility of new programs on healthcare stakeholders, including CMS, before launching new programs.

Clinical Laboratory Fee Schedule
CMS is proposing to implement provisions of CAA, 2023 (P.L. 117-328) that delayed the application of the 15 percent payment cut to the clinical laboratory fee schedule as well as the next round of data reporting. However, without additional Congressional action, these payment reductions will go into effect on January 1, 2024. Clinical laboratories are critical in supporting timely diagnoses and prognostic monitoring for cancer patients. We again urge CMS to work with Congress to prevent these devastating cuts to clinical laboratory reimbursement.

CY 2024 Quality Payment Program (QPP) Proposed Rule

Request for Information (RFI): Promoting Continuous Improvement in MIPS
CMS seeks comment on how it could modify its QPP policies to encourage clinicians' continuous performance improvement, including through more rigorous performance standards, emphasizing year-to-year improvement, or requiring clinicians to report on different measures or activities than the ones on which they have shown consistently high performance. The Network respectfully submits comments on the following questions raised by CMS:

- *What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?* The Network believes that clinicians and practices should have the option to report the same Improvement Activities for subsequent years. However, in order to ensure continuous improvement to patient care, The Network is in favor of requiring practices to document and attest to enhanced patient care or experience of care as a result of incremental activities associated with the Improvement Activities. This could be validated by CMS through standard MIPS audits.
- *Should CMS consider in future rulemaking policy changes to assess performance to encourage continuous performance improvement, such as increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?* No, The Network does not believe specific measures within an MVP measure set should be required for reporting. This is due to the challenges associated with different EHR systems that cannot capture the required data to support all measures. Moreover, it is often not feasible to aggregate data accurately across EHR systems when a clinician or practices switches technology mid-year. The MVP measure sets are already specialty-specific and restrictive. Selecting the top four measures should be at the discretion of the participant, based on what is meaningful at their practice and to their patients.
- *Should it consider creating additional incentives to join alternative payment models to foster continuous improvement, and if so, what incentives?* Yes, as explained in greater detail below, The Network urges CMS to work with Congress to relax the current (and increasing) Qualifying Provider (QP) threshold requirements and extend the Advanced APM bonus to continue incentivizing participation in Advanced APMs.

Advancing Cancer Care MIPS Value Pathway (MVP)
The Network worked closely with the American Society of Clinical Oncology (ASCO) and CMS to develop an oncology-specific MVP that focuses on measures that are meaningful to the oncology clinicians and that aligns with existing and proposed CMMI programs. In the CY 2024 QPP rule, CMS is proposing to add 4 quality measures to the Advancing Cancer Care MVP:

- Q487: Screening for Social Drivers of Health (Collection Type: MIPS CQMs Specifications)
- Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQMs Specifications)
- (Measure ID TBD): Gains in Patient Activation Measure (PAM) Scores at 12 Months (Collection Type: MIPS CQMs Specifications)
- PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to Start of Targeted Therapy (Collection Type: QCDR)

The Network supports the continued evolution of the Advancing Cancer Care MVP to integrate meaningful, oncology-specific quality measures and improvement activities to drive enhanced oncology patient care. The Network agrees with the proposal to include Q487 Screening for Social Drivers of Health to emphasize the patient voice and highlight areas of continued patient need; however, The Network believes greater benefit could be achieved by expanding future iterations of the measure to not only look at the screening rate, but rather to assess whether care teams have developed a plan to address areas of need identified by the screen and to assess patient outcomes. For example, whether the practice been successful in meeting the patient's need for transportation assistance in order to stay on their treatment regimen.

The Network supports the addition of PIMSH13: Mutation Testing for Stage IV Lung Cancer Completed Prior to Start of Targeted Therapy. This measure was developed in partnership between The Network and McKesson in order to foster appropriate biomarker testing and use of available targeted treatments. These types of oncology-specific quality measures are more meaningful to oncologists and reflect key areas of patient care that highlight guideline-compliant, appropriate patient care. Similarly, The Network endorses the development and inclusion of Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors.

CMS proposes to include a new patient-reported outcome measure as part of the Advancing Cancer Care MVP, (Measure ID TBD): Gains in Patient Activation Measure (PAM) Scores at 12 Months. The PAM score (and changes in PAM scores) are predictive of health behavior, clinical outcomes, and costs, and can indicate the degree to which these interventions are occurring. The underlying assumption is patients that receive high-quality care, including interventions such as coaching and support, will increase their activation (ability to manage their disease), and improve their ability to self-manage over time. The Network cautions against the inclusion of this new survey tool and measure for the Advancing Cancer Care MVP for several reasons.

The Network finds the PAM measure to be duplicative, and notes there are already two patient-reported survey measures included in the Advancing Cancer Care MVP. First, the Screening for Social Drivers measure that utilizes screening tools, such as the NCCN Distress Thermometer, serves as a tool to assess areas of patient need where they may feel social drivers that impact their care, ability to manage their health and achieve health improvements as a result. It can be inferred that through improvements to the NCCN Distress Thermometer score, the patient is engaged in their healthcare decisions and ability to manage their disease. As mentioned above, The Network encourages CMS to improve upon the current Q487 Screening for Social Drivers of Health measure to monitor successful interventions and patient outcomes, rather than simply capturing screening rates. This would achieve more meaningful quality care results than adding another screening tool to the Advancing Cancer Care MVP.

Second, the CAHPS for MIPS Clinician/Group Survey is also part of the Advancing Cancer Care MVP. Instead of adding the PAM survey tool/measure, The Network believes it would be appropriate to also include NQF2651 CAHPS® Hospice Survey and NQF005 CAHPS Cancer Care and allow clinicians to receive credit for the use of any one of these CAHPS surveys. We note that the OCM used the CAHPS Cancer Care survey, which provides more patient-reported information specific to cancer care, which made the survey results more meaningful and applicable to oncologists and CMS. It is important to note that we consider the CAHPS survey to count as one measure with multiple options.

In summary, the Advancing Cancer Care MVP already includes two patient survey measures. Adding a third screening measure to the MVP may lead to patient and care team screening fatigue and less meaningful, actionable results. We encourage CMS to look toward national standards and governing bodies, like ASCO and NCCN, to dictate appropriate screening tools, measures, and target outcomes related to oncology care and avoid more general, non-specialty specific tools. Instead of adding a third screening tool with the proposed PAM measure, The Network encourages CMS to focus on improving the existing patient survey measures to be more oncology-specific and outcome-focused.

MIPS Performance Category, Measures and Activities

Quality Performance Category

CMS is proposing to expand the quality measure collection type options to include Medicare Clinical Quality Measures for Accountable Care Organizations (ACO) Participating in the Medicare Shared Savings Program (Medicare CQMs). This would create a third version of measure specifications for the same quality measure used in the MIPS program. The Network opposes this approach. Creating an ACO-specific measure specification creates additional burden on both practices and health care vendors (i.e., EHR vendors, registry vendors, and health care IT vendors) to maintain the same measure based off of multiple specifications. Moreover, the measure benchmark will not be the same across the different collection types, leading to confusion and non-comparable results.

CMS is proposing to raise the data completeness requirement from 70 percent to 75 percent data completeness for 2024-2026 and 80 percent for 2027. Although the goal of this initiative is to improve the accuracy of the measures and reduce the likelihood of MIPS participants selecting their most favorable data, the reality is that this requirement places undue burden on clinicians and/or practices who change EHR systems mid-year. With the multiple reporting options for the many quality measures, aggregating data may not

be feasible or possible to have enough data. The Network recommends that CMS maintain the existing data completeness thresholds until quality measures have been transitioned to digital quality measure specifications that enable interoperability and more complete data sets for quality measure calculations.

Cost Performance Category
After reviewing the 2022 MIPS Preliminary Results, The Network is concerned by several cost measures where the attribution and measure methodology are not functioning as intended. This has a significant, negative impact on medical oncology clinician and practice performance. In July 2023, we shared these concerns with CMS and its contractor Accumen, and we provided specific recommendations to modify the measure methodology utilized in 2022 and future program years. Below is a brief summary of that submission:

- Total Per Capita Cost Measure (TPCC): TPCC is intended to measure the overall cost of care delivered to a patient with a focus on primary care. In order to ensure a focus on primary care, additional clinicians are excluded from attribution if they meet the criteria for one or more service exclusions in the following categories: global surgery, anesthesia, therapeutic radiation, and chemotherapy. However, in practice, medical oncology care teams are the recipient of inappropriately attributed patients who are on active chemotherapy or surveillance.
- Medicare Spending Per Beneficiary (MSPB): The MSPB Clinician measure is intended to assess the cost to Medicare for services provided to a patient during an MSPB Clinician episode, which comprises the period immediately prior to, during, and following the patient's hospital stay. While the MSPB methodology excludes services which are considered unrelated to the episode, the current methodology does not accurately adjust for or exclude patients who are on active chemotherapy treatment. This has a significant impact on the episode cost and is inflating costs for medical oncology practices. Further, while this measure includes Part B drugs, it does not include Part D drugs, which introduces additional variability between patients.
- Chronic Conditions – Diabetes, Asthma/ Chronic Obstructive Pulmonary Disease (COPD): The current methodology specifies that patients with claims that include ICD-10 diagnosis codes for diabetes and Asthma/COPD may trigger attribution for clinicians. However, many Network clinicians include diagnoses in their medical record documentation, as well as medical billing, to indicate that the chronic condition is clinically significant and factored into, or altered, cancer treatment and management decisions. Such complications of care do not indicate that the oncologist is primarily managing diabetes, asthma, or other conditions and should not result in attribution to such episode-based cost measures.

Ultimately, the flaws in methodology listed above have an unfair, inappropriately negative impact for medical oncologists and their care teams' ability to achieve high—and representative—performance for cost measures that are intended to reflect quality, cost-effective care. The Network believes that immediate action must be taken regarding the current 2022 MIPS Results to avoid unfairly scoring medical oncologists and their extended APP care teams. Special attention needs to be paid to 2022 MIPS Results Targeted Reviews and Acumen feedback to improve representative cost performance and outcomes.

Request For Information: Publicly Reporting Cost Measures
The Network strongly discourages any public reporting of cost measures until current methodology has been validated for specialty clinicians and specialty care settings. Current cost measure results indicate flawed measure methodology that negatively impacts specialty clinicians. Publicly posting information related to these results would potentially lead to misconceptions about the cost of care provided by certain specialty clinicians or practices.

Improvement Activities Performance Category
The Network supports CMS' proposal to add six additional improvement activities that address maintenance requests from the public, and that address priority areas, including clinician well-being, interoperability, patient safety, and expanding use of telehealth.

Promoting Interoperability Performance Category
CMS is proposing to lengthen the performance period from 90 days to 180 days. The Network cautions that the proposed 180-day performance period may hinder clinicians who change CEHRTs mid-year as they will be limited in reporting period options. The dates available for the transition to the new CEHRT will likely be out of the control of the clinician. In addition, when there are changes to the Promoting Interoperability measures or requirements for the CEHRT, clinicians may have a narrow window from the time the CEHRT updates are completed, to implement new workflows and achieve sufficient points in this MIPS category.

CMS is proposing to remove the third exclusion option for the Prescription Drug Monitoring Program (PDMP) measure of "Querying a PDMP would impose an excessive workflow or cost burden prior to the start of the performance period." Small practice providers have the PI category automatically reweighted; however, with the increasing benchmarks and limited reporting requirements for Quality, small practice providers may need to report PI to improve their composite score to avoid penalty. Both large and small practices are struggling with staff shortages following the PHE, therefore reviewing the PDMP may cause excessive workflow challenges.

CMS is proposing to require providers who achieve QP or partial QP status in a Shared Savings Model, regardless of track, to report Promoting Interoperability. The Network believes this proposal is unnecessary and could create additional reporting burden. CMS is also proposing that in order to qualify as an Advanced APM, all eligible clinicians participating in the APM Entity must use CEHRT. The later proposal already promotes the use of technology without imposing an additional reporting burden on clinicians who are very active in their AAPM.

MIPS Final Scoring Methodology
CMS is proposing to update the criteria it uses to assess the scoring impacts of coding changes, apply its scoring flexibilities, and require eCQM measure specifications to be able to be shortened to a nine- month performance period. Specifically, CMS proposes to (i) replace the 10 percent threshold factor and instead assess the overall impact of changes to ICD-10 codes on the measure numerator, denominator, exclusions, and exceptions that could produce misleading or harmful results or change the scope or intent of the measure; (ii) assess according to measure collection type (eCQM, MIPS CQM, Medicare part B claims) the impacts of the changes and corresponding decision (shorten performance period to 9 months, keep 12 months, or suppress); and (iii) specify that the performance period for eCQMs may be shortened to 9 months (since currently a 12-month reporting period is specified). The Network agrees with the proposal to update the criteria that CMS uses to allow for increased flexibilities. It is appropriate to determine the potential impact to the integrity of the quality measure before determining if a measure should have a shortened performance period or suppressed.

Moreover, suppressing a quality measure should be a last resort, as practices plan to target quality initiatives at the beginning of the year and work towards achieving performance as a focused quality initiative across their practice. When measures are suppressed at the end of the year, this is discouraging and undermines the work of the care team to achieve high performance in a particular area of patient care. The Network believes that if a measure intent is maintained and the scoring impact is minimal, then even with mid-year changes to ICD-10 codes, practices should be able to report the quality measures. The Network would advise that, instead of truncating the performance period or suppressing the measure, alternatively, CMS should consider omitting the performance year from National Benchmark calculations.

MIPS Payment Adjustment

CMS is proposing to use the mean of final scores from the 2017 – 2019 MIPS performance periods (2019 – 2021 MIPS payment years) to set the MIPS performance threshold. This would increase the performance threshold for the 2024 MIPS performance period/ 2026 MIPS payment year to 82 points. The Network does not agree with this approach. There are several critical factors that have caused the MIPS program performance to be inflated since the inception of the program; specifically:

- The quality category included bonus points for end-to-end reporting, high priority, and outcome measures that improved measure scoring;
- There has been a minimum 3-point floor for quality measures that has been eliminated for all practices except those qualifying as a small practice;
- The COVID Public Health Emergency and Extreme and Uncontrollable Circumstances hardship allowed many practices to forego MIPS reporting, leading to an inflated benchmark consisting of only those practices that anticipated being a top performer; and
- The cost category was not scored during the 2017-2019 performance periods.

Therefore, the mean final scores from the inception of the MIPS program does not accurately reflect the potential scores that are achievable for 2024. In addition to the points above, as evidenced by the 2022 MIPS Performance Results that were released in August 2023, the 30 percent Cost Category weight has led to a significant impact on overall MIPS performance. A threshold of 82 points would not reflect the mean final score that could be fairly achieved under today's program standards. Alternatively, The Network advises that CMS take into consideration the unique circumstances that impacted scoring since the inception of the MIPS program and utilize adjusted data to determine a more accurate mean final score that accounts for inflated performance as a result of bonus points, EUC hardships, and the lack of a cost category score; a more accurate reflection of current participation and payment adjustments must be achieved in order to set a reasonable Performance Threshold. Lastly, CMS notes that the incremental and gradual increase is no longer required by section 1848(q)(6)(D)(iv) of the Act, so it is unclear why increasing the threshold is necessary at this time.

Table 51: Possible Values for 2024 PP/2026 MIPS PY Threshold

Performance Year	2017	2018	2019	2020	2021	2017-2019
Mean	74.65 points	87 points	85.61 points	89.47 points	89.22 points	82.06 points

QCDRs and Qualified Registries: Third Party Intermediary Support of MVPs

CMS proposes to clarify that a qualified clinical data registry (QCDR) or a qualified registry is required to support MVPs pertinent to the specialties they support, including all measures and improvement activities available in the MVP with two exceptions. CMS seeks comment on the two exceptions. First, CMS proposes that if an MVP includes several specialties, then a QCDR or a qualified registry is only expected to support the measures that are pertinent to the specialty of their clinicians. The Network supports this proposal. It would impose undue burden on QCDRs and qualified registry vendors to support quality measures that are not relevant to their customers.

Second, CMS proposes that QCDR measures are only required to be reported by the QCDR measure owner. In instances where a QCDR does not own the QCDR measures in the MVP, the QCDR may only support the QCDR measures if they have permission to do so. The Network agrees with this proposal. The Network participates in a collaboration with Practice Insights QCDR and has developed many custom QCDR measures that are specific to oncology. These measures are complex, requiring access to detailed clinical data captured through EHRs. It would not be appropriate to require other third-party vendors to support QCDR measures

where the vendor may not have access to the required data or the in-house expertise to code the quality measures accurately. We agree that requiring permission to utilize another QCDR vendor's measures should be required.

Health IT Vendors
In the proposed rule, CMS acknowledges that many vendors serve in capacities as qualified registries, QCDRs or health IT vendors with similar technology. CMS has proposed to eliminate the category of "health IT vendor" as a distinct type of third-party intermediary in order to improve the integrity of program data. The Network agrees with this approach to ensure that there are consistent data validation and audit requirements for all third-party intermediaries. Any vendor who offers MIPS measure calculations and data submission should be held accountable for all data validation requirements set forth by CMS.

QP Determinations and the APM Incentive
In the CY2024 PFS proposed rule, CMS reviews the statutory eligibility and incentive structure for clinicians participating in Advanced APMs to achieve APM QP status. The Network strongly supports implementation of effective value-based care models and urges CMS to continue incentivizing Advanced APM participation. While we understand the requirements for achieving QP status are set statutorily, we appreciate CMS' recognition that the increasing thresholds and lowered incentives for participation could affect the willingness of eligibility clinicians to participate in Advanced APMs.

Currently, the threshold score for an APM entity is calculated in one of two ways, either the payment amount method or patient count method. The threshold score using the payment count method is calculated by dividing: (1) the aggregate of payments for Medicare Part B covered professional services furnished by the APM entity group to attributed beneficiaries during the QP performance period; by (2) aggregate of payments for Medicare Part B covered professional services furnished by the APM entity group to all attribution-eligible beneficiaries during the QP performance period. The threshold score using the patient count method is calculated by dividing: (1) the number of attributed beneficiaries to whom the APM entity group furnishes Medicare Part B covered professional services; by (2) the number of attribution-eligible beneficiaries to whom the APM entity group furnishes Medicare Part B covered professional services. The current threshold for full QP status is 50 percent of payments or 35 percent of patients; it is proposed to increase these thresholds to 75 percent of payments or 50 percent of patients for performance years beginning with 2024. The current threshold for partial QP status is 40 percent of payments or 25 percent of patients; this is proposed to increase to 50 percent of payments or 35 percent of patients for performance years beginning with 2024. Achieving full or partial QP status exempts practices from MIPS for the same reporting year.

The Network has long been a leader in APM participation and represented approximately 25 percent of physicians in the Oncology Care Model (OCM), a voluntary, 6-year pilot program from the Centers for Medicare and Medicaid Innovation (CMMI). For the new Enhancing Oncology Model (EOM), 12 Network practices, representing over 1,000 physicians, are participating in the APM that started in July 2023. With over 70 percent of The Network providers participating in the EOM, this represents 50 percent of total providers participating in the EOM. The Network is enthusiastic about the EOM and are encouraged by the successful start of the new program. However, based on the status of average QP threshold scores by Advanced APMs in performance year 2019, The Network is concerned about the ability of future EOM practices to achieve the current (50 percent of payments / 35 percent of patients) thresholds, and achieving future thresholds of 75 percent of payments/ 50 percent of patients will be even more challenging. According to CMS, for OCM participants, the average payment threshold score was 53 percent (just barely meeting the 50 percent threshold), and the average patient threshold score was 21 percent (far below the 35 percent threshold). Compared to the OCM, because the EOM includes a smaller, targeted list of 7 cancer types, there will inevitably be a smaller population of payments and patients, making the existing targets challenging to achieve and the higher thresholds nearly impossible to meet.

Along with raising the QP status thresholds, CMS is proposing to base QP status on the *Individual Clinician* rather than the *APM Entity*. The Network opposes this proposal as this approach is not appropriate for specialties that provide team-based care and focus on equal access to quality care for all patients through practice-wide initiatives. Participation in the APM is at the TIN-level; under the team-based care model clinicians share in the care of patients who are not directly attributed them. The additional administrative tracking and reporting tasks, caused by the requirement to assess at the individual clinician level, is an unnecessary burden. Further, there is a risk that changing the approach to achieving QP status may inadvertently direct patients to specific providers to ensure that they meet QP thresholds, rather than scheduling patients with the first available clinician. This may delay the time to initial consult and have a negative impact on patient care.

Additionally, after performance year 2022 (payment year 2024), there is no further statutory authority for a 5 percent Advanced APM Incentive Payment for eligible clinicians who become QPs for a year. In performance year 2023 (payment year 2025), CMS maintained a modest 3.5 percent Advanced APM Incentive Payment, but it is proposed to eliminate this starting 2024. Beginning in performance year 2024 (payment year 2026), the update to the QP conversion factor for QP-eligible clinicians is 0.75 percent, and the update to the general conversion factor is 0.25 percent.

The EOM requires participating practices to accept 2-sided risk on Day 1 and also reduces the upfront payment amount to fund enhanced services. For additional context, practices are taking on a very high level of monetary risk in a total cost of care model, meaning they are responsible for any costs a patient encounters during an episode, not just the cost of their cancer treatment. In summary, practices are being asked to do more with less (while taking on more risk) at the same time that the reward for participating is lower, given the sunsetting 3.5 percent lump sum bonus and the much lower 0.75 percent Medicare payment adjustment. We note there are significantly fewer practices participating in the EOM and the factors outlined above are deterring participation. This is especially true for practices who did not participate in OCM and did not make earlier investments in software or staffing that are necessary for successful participation in a model like the EOM. If CMS wants to incentivize physicians to participate in risk-bearing, alternative payment models, that risk must be recognized by CMS and QP status with AAPM bonus must be a viable option for high performing practices that want to avoid MIPS. ***The Network urges CMS to work with Congress to relax the current QP threshold scores and extend the Advanced APM bonus to continue incentivizing participation in Advanced APMs.***

OPPS Buffer Stock Proposal

In the CY 2024 OPPS (CMS-1786-P) proposed rule, CMS proposes to create a separate payment for the costs of establishing and maintaining access to a buffer stock of essential medicines. “Buffer stock” is defined as a 3-month supply. “Essential medicines” refers to a list of 86 medicines identified as critical for minimum patient care in acute settings. CMS seeks comment in a number of areas including whether the agency should expand the list of essential medicines to include those used in the treatment of cancer. The Network is very concerned about shortages for drugs used in cancer treatment and encourages CMS to both address the underlying drivers of shortages and identify ways to mitigate existing drug shortages. That said, today, over 50 percent of outpatient cancer care is provided in the community-based (physician office) setting. While well-intentioned, The Network is concerned that any policy to encourage stockpiling in one setting could exacerbate shortages in another setting. Furthermore, the mechanism for sharing inventory across sites of service is unclear, especially in highly competitive markets. Therefore, if CMS decides to create separate payment for establishing and maintaining a buffer stock of drugs used in the treatment of cancer in the inpatient or outpatient setting, the agency should create a similar payment to establish and maintain a buffer stock in the physician office setting.

Conclusion

On behalf of The US Oncology Network, thank you for the opportunity to provide comments on Proposed Rule CMS-1784-P. We welcome the opportunity to discuss the issues outlined above and any 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,

Debra Patt, MD, PhD, MBA
Chair, Public Policy & Reimbursement Committee
National Policy Board
The US Oncology Network