The US Oncology Network

September 6, 2022

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-1770-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

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 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1770-P)" Proposed Rule.

The Network is one of the nation's largest and most innovative networks of community-based oncology physicians, treating more than 1.2 million cancer patients annually in more than 450 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, 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 and Requests for Information (RFIs):

- **Overall Payment Rates**: We express concern with the decreasing conversion factor and rising inflation rate.
- **Dental and Oral Health Services**: We support Medicare coverage of dental services that are inextricably linked to the clinical success of treatment for cancer.
- **Telehealth Services:** We support the permanent elimination of Medicare's geographic and originating site restrictions.
- **Advancing Cancer Care MIPS Value Pathway**: While we were pleased to see CMS propose the Advancing Cancer Care MVP, we have concerns regarding the proposal and strongly encourage CMS to postpone its release until 2024.
- **Advanced APM QP Thresholds and Partial QP Thresholds**: We support extending the existing QP threshold scores and the 5% Advanced APM bonus.

CY 2023 Physician Fee Schedule (PFS) Proposed Rule

Oncology Impact
In reviewing the CY 2023 PFS proposed rule, the specialty impact table (Table 138) suggests minimal impacts to the oncology community, namely a -1% impact to hematology/oncology and a -1% impact to radiation oncology and radiation therapy centers. However, as CMS notes, the specialty impact table does not reflect the CY 2022 3.0% increase in PFS payment amounts that was included in the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71) and is scheduled to expire on December 31, 2022. Factoring in the expiration of the 3.0% increase, as well as the statutory budget neutrality adjustment, the conversion factor (CF) for CY 2023 is proposed to be $33.08, a $1.53

decrease (-4.4%) from the CY 2022 CF of $34.61. This decrease is in line with the payment reductions in our internal analysis of the CY 2023 PFS proposed rule and would occur during a period of unprecedented challenges in cancer care—delays in screening, increased therapeutic complexity, and increasing risk of comorbid illness for patients with cancer.

PFS is Not Keeping Pace with Inflation
In June 2022, inflation, as measured by the Consumer Price Index (CPI-U), rose at the fastest 12-month pace since November 1981, 9.1%. Taken together with the proposed 4.4% reduction in the CF relative to CY2022, real (inflation adjusted) reimbursement in the PFS will decline dramatically. The CY2023 budget neutrality adjustment (-1.55%) contributes significantly to this reduction in real payments. In fact, consumer prices have significantly outpaced increases in the conversion factor over time. A recent analysis of price trends and the PFS CF[1] indicates that the CF remains virtually unchanged since its introduction in 1992, increasing just 12.5% compared to 101.9% overall inflation during the same period.

Not only does the PFS fail to capture the broader impact of inflation, the current direct and indirect practice expense (PE) RVU methodology does not account for a number of specialized oncology resources. As we noted in our comments on the CY 2022 PFS proposed rule, direct PEs do not account for clinical labor and supplies for oncology pharmacists, admixture technicians, patient navigators, closed system transfer devices, and some advanced medical equipment. Indirect PEs do not account for resources required for clean rooms, accreditations, compliance requirements, and health information technology systems. It is these very services whose costs are increasing in the current inflationary environment. While we appreciate CMS' decision to phase-in the clinical labor pricing update over four years, drug administration and cancer care continues to bear the brunt of these changes, with some infusion services seeing double digit payment reductions in Year 2. We also note CMS recognized the PFS doesn't adequately reimburse physicians for delivering comprehensive, coordinated, team-based care when it created the complexity add-on code for evaluation and management services in the CY 2021 PFS, but implementation of that code was delayed until 2024 by Congress to help offset the cost of mitigating the projected CY 2021 cut.

Growing Payment Disparities Across Sites of Service
At the same time, Medicare payment rates for facilities paid on the Hospital Outpatient Prospective Payment System (OPPS) continue to increase. For CY 2023, CMS is proposing to update OPPS payment rates by 2.7%. This translates to Medicare paying, on average, 50% more for the exact same radiation oncology services provided in the hospital outpatient setting compared to those provided in the physician office setting. Medical oncology has an even greater disparity, with OPPS rates for drug administration 168% higher when provided in the hospital outpatient setting. This growing disparity is simply unsustainable. Medicare's failure to ensure physician payments keep pace with inflation, combined with year over year cuts, contributes to market consolidation and the drop in independently practicing physicians. According to the Physicians Advocacy Institute,[2] hospitals acquired nearly 5,000 physician practices (58,000 individual physicians) from just 2019-2021, resulting in an 11% increase in the percentage of hospital-employed physicians. This hurts patient access to care and actually increases costs for both the Medicare program and patients in the long run.

Independent Practices Remain under Strain
More than two years since the onset of the COVID-19 pandemic, community cancer continues to face significant challenges. As expected, we are seeing the effects of delayed screenings, as patients present with more advanced cancers. We are also experiencing workforce shortages and pressure to increase wages in an inflationary environment, as the clinical oncology workforce, comprised of medical physicists and dosimetrists as well as physicians and advanced practice providers, is highly skilled and in limited supply. Changes in workflows to accommodate more flexible hours, remote work, supply chain shortages, and ever-changing COVID protocols are necessary but can be disruptive. In combination, practice operations and finances are continuing to feel considerable strain.

Further, while the COVID-19 public health emergency (PHE) remains in effect, the moratorium on the 2% Medicare sequester cut expired on July 1. Absent congressional action to waive the statutory Pay-As-You-Go (PAYGO) Act, an additional 4% sequester will go into effect in early 2023. While The Network recognizes that CMS is not responsible for

[1] https://avalere.com/wp-content/uploads/2022/06/How-Statutory-Management-of-Healthcare-Inflation-Impacts-Providers-%E2%80%93-Extended-Analysis.pdf
[2] http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/PAI-Research/PAI%20Avalere%20Physician%20Employment%20Trends%20Study%202019-21%20Final.pdf

the physician payment "cliff" resulting from the expiration of these policies, we urge the agency to work closely with Congress to address these looming fiscal challenges by providing a positive adjustment to the PFS conversion factor, waiving the statutory 4% PAYGO requirement, and providing some element of inflationary relief.

Dental and Oral Health Services

CMS is proposing 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." Additionally, CMS notes the Medicare Benefit Policy manual states that the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is currently covered and payment may be made under Medicare Part A and Part B for this service; CMS is proposing to codify this policy and clarify that it may be furnished in both the inpatient and the outpatient setting. CMS also seeks comment on dental exams and medically necessary diagnostic and treatment services prior to treatments for head and neck cancers, such as radiation therapy with or without chemotherapy, or the initiation of immunosuppressant therapy, such as those used during cancer treatments, where the standard of care is such that it is clinically advisable to eliminate the source of infection prior to proceeding with the necessary medical care, or the standard of care for the primary medical condition would be significantly materially compromised if the dental services are not performed.

The Network strongly supports finalizing the current and proposed policies with the additional clarification that dental services be covered prior to cancer treatment related to the mid-neck through skull (rather than just head and neck), if deemed necessary by the patient's radiation oncologist. Today, receiving a comprehensive oral examination and dental treatment (if necessary) prior to receiving radiation therapy is the standard of care. Without dental clearance, treatment may not be as effective or may lead to additional complications or infections. Unfortunately, it is very common for our patients to not have dental coverage; Medicare coverage of medically necessary dental services prior to radiation therapy would be a cost-effective way of preventing care delays and improving clinical outcomes. Additionally, any patients on bone health agents should receive dental evaluations to avoid complications. The Network believes there is a clear, inextricable link to dental evaluation and services and successful cancer treatment and encourages CMS to finalize this proposal.

Telehealth Services

CMS is proposing to implement provisions in the Consolidated Appropriations Act of 2022 (CAA, P.L. 117-103), that extend the Medicare telehealth flexibilities created under the COVID-19 PHE declaration for an additional 151 days after the PHE ends. The flexibilities remove the geographic and originating site restrictions and allow audio-only telehealth visits. The Network appreciates the telehealth flexibilities provided during the PHE, which not only allowed our practices to maintain continuity of cancer care in the early months of the pandemic but have since become a valuable tool in the everyday delivery of care. While not a panacea, we believe the availability of appropriate telehealth services enhances the delivery of care and should remain an accessible tool to patients and providers on a permanent basis. We are pleased CMS and Congress are working together to provide a transition period after the end of the PHE, and support the House passed- Advancing Telehealth Beyond COVID-19 Act, which would extend these flexibilities until December 31, 2024, but we 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 ensure beneficiary access to appropriate telehealth services by permanently eliminating Medicare's geographic and originating site restrictions. The COVID-19 pandemic, notwithstanding the losses and hardship it has brought, has been a catalyst for change in healthcare. As the paradigm of care delivery has shifted to supporting patients where they are, failure to continue to support medical services at home via telemedicine would be inadequate provision of clinical resources to Medicare beneficiaries. Telemedicine is a life-saving care delivery tool that is critical for Medicare beneficiaries with cancer.

In implementing the CAA of 2022, CMS proposes a list of services that will be removed from the Medicare Telehealth Services List after 151 days following the end of the PHE. This list includes services such as the radiation treatment management services code family (77427). Consistent with our comments in previous years, The Network agrees that it is appropriate to remove this code from the Medicare Telehealth Services list once the PHE ends, due to the weekly, in-person visits and physical examination required.

Clinical Laboratory Fee Schedule

CMS is proposing to implement provisions of Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71) that delayed the application of the 15% 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, 2023. 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.

Chronic Pain Management Services

CMS is proposing to create two new HCPCS codes for chronic pain management and treatment services for CY 2023, GYYY1 and GYYY2. The Network supports this proposal and believes it will be useful for cancer patients with chronic pain.

Single-dose or Single-use Vial Refunds for Discarded Drugs

Pursuant to the Infrastructure Investment and Jobs Act (P.L. 117-58), CMS is implementing the requirement for manufacturers to provide a refund to CMS for certain discarded amounts from a single-dose container or single-use package drug. CMS is also proposing, effective January 1, 2023, to require providers to bill either the JW modifier to identify any discarded amounts or the JZ modifier to attest that there were no discarded amounts for all single-dose containers or single-use drugs. While The Network supports the implementation of this policy to discourage drug waste, we caution that reporting of the new JZ modifier will be an additional step for providers and believe CMS may be underestimating the burden. Further, we ask CMS to provide transparency into how the manufacturer refunds will be used within the Medicare program and how Medicare beneficiaries may benefit from them.

Colorectal Cancer Screening

CMS is proposing to reduce the minimum age for certain colorectal cancer screenings tests from 50 to 45 years and provide coverage for follow-on colonoscopies after a Medicare-covered non-invasive stool-based colorectal cancer screening test returns a positive result. Both tests would be paid at 100% with no beneficiary cost sharing. The Network supports this proposal and agrees it will improve access to screenings and increase the likelihood of earlier diagnosis and more effective treatment for colorectal cancer.

Medicare Potentially Underutilized Services RFI

CMS is seeking feedback on Medicare services that have high value but may be underutilized and ways to address potential barriers to accessing those services, particularly amongst underserved communities. Specifically, CMS is looking for ways to mitigate these obstacles through examining conditions of payment or payment rates or by prioritizing beneficiary and provider education investments.

- **Complex/Chronic Care Management (CCM) and Principal Care Management (PCM)**: We appreciate CMS' recognition of the important role care management plays in helping patients with complex conditions, such as cancer. While CMS has recently increased reimbursement for CCM and PCM, one hurdle preventing greater adoption of these programs is the complexity of recording time and possibility of claims denials due to other providers billing the service for the same beneficiaries. We encourage CMS to provide greater clarification regarding patient attribution and believe this will help these programs gain traction.
- **Cancer screenings**: The rate of cancer screenings dropped considerably during the pandemic and still has not returned to pre-pandemic levels. We are seeing more patients present with late-stage cancers due to the delay in screenings. It is critical that CMS increase education and promotion of cancer screenings, including finding innovative ways to incentivize beneficiaries to obtain them, with an emphasis on underserved populations.

Rebasing and Revising Medicare Economic Index (MEI)

CMS is proposing to rebase and revise the MEI. The proposed methodology is intended to better reflect current market conditions for physicians; namely the trend toward larger, physician-owned practices and movement from physician-

owned practices toward hospital-owned practices. However, CMS is proposing to delay implementation of the rebased and revised MEI to allow time for further public comment.

As community-based providers, we find the increase in hospital-owned physician practices to be concerning and agree it may be prudent to update the MEI to reflect this trend. While we appreciate CMS' recognition of the need for public review and comment of the proposal before moving forward with finalization, we believe more transparency into the process is needed so we can provide fully informed feedback. CMS provides the specialty-specific impacts of the proposed changes to the MEI if implemented in full in CY 2023 as well as the impact in Year 1 if implemented over 4-years, which demonstrates considerable impact across specialties and highlights the need for further examination. For example, CMS estimates full implementation of the proposal to result in a +3% impact to non-facility hematology/ oncology but the Year 1 impact would be -1%. A +6% impact is estimated for radiation oncology and radiation therapy centers. We ask CMS to make the contractor reports it may have commissioned to inform its work available for stakeholder review and then provide another opportunity for comment once we have reviewed the data. We believe it would be helpful to better understand how Census Bureau Service Annual Survey, Bureau of Labor Statistics, and other data was used to determine the compensation and benefits categories.

CY 2023 Quality Payment Program (QPP) Proposed Rule

Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs RFI

CMS is proposing to further revise its future definition of digital quality measure (dQM) as a self-contained measure specification and code package that uses one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. Potential data sources for dQMs may include: administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), health information exchanges (HIEs) or registries, and other sources.

The Network agrees that, in theory, a multitude of data sources is appropriate and would allow for more granular quality measures. However, it is unclear who would be able to leverage dQMs from a development standpoint. We caution that the list of data sources may be too broad to be realistic, and FHIR is not yet mature enough to integrate all these data sources within one measure. Moreover, it is unclear who would be able to leverage the dQMs to receive the data sources and produce performance results. Currently, registry and qualified clinical data registry (QCDR) vendors struggle to aggregate data sources from multiple EHRs, and the reality of integrating a broader set of data seems unrealistic until there are more standardized code sets, especially for specialty areas. In addition, it is likely that dQMs will significantly increase the cost of measure development to the point where it will stifle innovation. It is also unclear how measure developers would approach measure testing when there are so many data sources at play. Testing measures that have data from multiple sources may be impossible and cost prohibitive for many measure developers.

The Network expresses concern that the requirement for all measures to be digital may restrict the options for which measures are developed. Practice Insights, in collaboration with The US Oncology Network, has been a CMS-approved QCDR for past 6 years supporting innovative, oncology-specific quality measure development for MIPS and other value-based care programs. We are uniquely positioned because we have direct integration with an oncology-specific EHR; however, we recognize that clinical data used for many specialty-specific quality measures may not be readily available in standard code sets or discrete data fields for automated data extraction. Oncology is a complex area with rapidly evolving testing and treatment options. Typically, oncology-specific measures are developed as registry measure specifications to account for the granularity of data sourced from the EHR that may not be accounted for in a standardized code set. CMS notes that a common portfolio of dQMs would limit required data elements to standardized, interoperable data elements. This approach may significantly impact the ability to develop meaningful and targeted oncology-specific measures since standardization and interoperability of data elements may lag behind.

More broadly, The Network recognizes the value of standardized, interoperable health data and supports the timely transition to and adoption of FHIR-based health information technology to increase access to real-time quality and cost data. We also support the alignment of quality measure selection and measure specifications across reporting programs, federal and state agencies, and the private sector.

The Network has long emphasized Medicare providers should be assessed upon specialty-specific performance measures and strongly supports specialty-specific measurement functionality within FHIR-based APIs. We also encourage CMS to consider ways to minimize the clinician quality reporting burden, such as providing a hardship exemption for providers transitioning to new EHR systems mid-year or allowing for partial-year reporting of quality measures. Finally, we have concerns with the appropriate role of data aggregation in quality measurement both now and in the future. While reducing fragmentation of data is a noble goal, the extent to which third-party data is consolidated with provider-supplied data and used to measure quality performance deserves heightened scrutiny. The Network asks CMS to provide future opportunities for public comment before mandating the use of dQMs.

MIPS Value Pathways (MVP) and APM Participant Reporting RFI

In the CY 2022 PFS final rule, CMS finalized seven MVPs that will be available for reporting beginning with the CY 2023 performance period/ 2025 MIPS payment year. CMS is now proposing five additional MVPs, including the Advancing Cancer Care MVP. The MVP framework is intended to reduce complexity and burden, move towards more meaningful measurement, capture the patient voice, and move to higher value care. In the CY 2023 proposed rule, CMS is exploring opportunities to advance health equity, better promote higher value care and APM participation, and is seeking feedback on how to best facilitate specialty clinician reporting of quality performance measures that reflect the specialty services provided.

CMS is seeking further input on the direction of the MVP framework and its intersection with APMs, beginning with how to ensure MVP reporting serves as a bridge to APM participation. The Network believes it is critical to align quality measures and improvement activities with the specialty MVPs and corresponding APMs established by CMMI. Practices are hesitant to engage in risk-bearing APMs without experience executing quality improvement initiatives, similar to those defined by the MIPS Improvement Activities and APM enhanced services, so MVPs could serve as a steppingstone if the quality measures and improvement activities align with those of a similar APM.

CMS also asks how to best limit burden and develop scoring policies for APM participants in multispecialty groups who choose to participate in MVPs and report specialty care performance data. While The Network supports the availability of subgroup reporting for practices reporting MVPs, we do not support CMS' proposal to *require* multispecialty groups to form subgroups to report MVPs, beginning with the 2026 performance year. The ability to report as a group or decide which clinicians will be included in a subgroup supports the ideals of team-based care. These are often comprised of multi-disciplinary clinicians that manage patients' care cohesively, so mandating subgroups be formed based exclusively on specialty runs counter to the tenets of team-based care. Further, The Network disagrees with CMS' approach to scoring subgroups. Currently, the proposed rule indicates that subgroups would receive a subgroup quality score, but the cost and promoting interoperability categories would be scored based on the affiliated (parent) group. Additionally, the Network discourages CMS from developing a process for a composite score for groups that participate in both the APP and MVP subgroups because the scoring methodology is already complex and introducing a composite score would make it difficult for participants to monitor performance correctly throughout the measurement period.

In order to encourage clinician and practice adoption of MVPs, CMS should consider additional incentives for clinicians, such as bonus points for participation, lower performance thresholds to avoid a downward adjustment, or guaranteed held harmless from downward adjustment. Without sufficient participation during the transition phase when MVPs are optional, it will be difficult for CMS to gain a sense of impact for clinicians and receive meaningful feedback from participants on how MVPs may encourage/ discourage future participation in APMs.

Finally, we note that during the CY 2022 PFS rulemaking, CMS indicated consideration of the end of performance year 2027 as a potential sunset date; however, in the CY 2023 PFS proposed rule, CMS states that while it intends for MVPs to become the only method to participate in MIPS in future years, it has not yet finalized the timing for the sunset of traditional MIPS. The Network urges CMS not to sunset traditional MIPS until there has been successful uptake and use of MVPs by clinicians. This demonstration will better inform CMS as to the appropriateness of sunsetting the traditional MIPS program.

Development of New MVPs

The Network supports CMS' proposal to modify the process to evaluate MVP submissions. We support greater transparency of MVPs under development so that QCDR vendors, specialty societies, and technology vendors may have

a better opportunity to collaborate. This would help promote measure development that is feasible and improve patient care. We support a minimum 30-day comment period for candidate MVPs prior to their inclusion in proposed rulemaking. We recommend that any feedback on MVPs be communicated to the MVP steward in advance of rulemaking to allow for the opportunity to modify the MVP, advise on the feedback received, and to continue providing guidance to CMS as the experts in the MVP specialty area.

Additionally, The Network strongly encourages CMS to create a standard annual timeline for release of new MVPs and maintenance of existing MVPs. This is critical to the ability for vendors to support new MVPs; otherwise, it will be challenging for vendors to quickly adapt and integrate new MVPs, given the complexity of measure development. Specifically, The Network recommends that when CMS proposes new MVPs, it should consider making implementation of these new MVPs optional for vendors to support in Year 1. This would allow health IT partners and vendors sufficient time to build and test the new MVP reporting platform and associated new measures within their qualified registry (QR)/ QCDRs. For example, and discussed in further detail below, the Advancing Cancer Care MVP has been included in the CY 2023 PFS proposed rule for implementation in 2023. This would only allow developers five months to build the system to go live on January 1, 2023, and that still requires the developer to make the assumption that CMS will finalize the ACC MVP as proposed. If the developer waits for the CY 2023 PFS final rule, they will have even less time to prepare. Making the first year optional would also allow QR/ QCDRs to include their intent to support an MVP in their annual Self-Nomination applications and allow sufficient time to educate their clients on the MVP(s) that will be supported.

Advancing Cancer Care 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. While we were pleased to see CMS propose the Advancing Cancer Care MVP, we have several concerns regarding the proposal and strongly encourage CMS to postpone its release until 2024 so practices and vendors can be better prepared and positioned to successfully participate in these programs.

First, we are concerned about the short runway (5 months) for implementation for the 2023 MIPS program year. We believe the short notice will place unnecessary burden on QCDR/QR vendors that may want to support the MVP, but do not have the resources to complete the required development in order to make the MVP available at the beginning of the 2023 MIPS program year. Moreover, if CMS decides to require QCDR/QRs to support MVPs applicable to their clients, this will not be sufficient notice to guarantee accurate development of the MVP within vendor systems. Postponing the release of the Advancing Cancer Care MVP until 2024 would give vendors more time to prepare so they can better support oncologists with implementation. If CMS does move forward with the Advancing Cancer Care MVP for 2023, then we strongly encourage the agency to make the implementation of MVPs optional for vendors to support in Year 1.

In addition to the logistical challenges regarding the proposed timing of the Advancing Cancer Care MVP, The Network is concerned that participation in the MVP conflicts with the concurrent release of the Enhancing Oncology Model (EOM). Practices are in the process of determining whether they will participate in the EOM and will not know if their applications have been accepted until mid-2023. Oncologists may be slow to engage in the MVP as they determine whether they will participate in the EOM and releasing the MVP prior to the start of EOM creates an undue burden for practices.

If CMS decides to finalize the Advancing Cancer Care MVP (whether optional or required), The Network has several recommendations. First, we recommend that the Advancing Cancer Care MVP focus on medical oncology. We encourage CMS to create separate MVPs for surgical oncology and radiation oncology and identify measures that are more applicable to these specialties for those alternate MVPs. Currently, all quality measures except one are specific to medical oncology. The Network recommends CMS remove the MIPS462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy measure because it uses radiation oncology data. All measures in the MVP, except Q462, can be reported by medical oncologists who use iKnowMed, whereas radiation oncologists use Aria or Mosaiq. Therefore, it will create an undue burden on a medical oncology registry to collect radiation oncology data, in addition to medical oncology data. If CMS feels strongly that this measure be included in the proposed MVP, then we would recommend that QR/QCDRs be given the discretion to determine which measures are most applicable and feasible for them to support for their clients.

Regarding the Quality category, in addition to the broadly applicable CAHPS for MIPs Clinician/Group Survey, we believe it would be appropriate to 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 Oncology Care Model (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.

We also recommend that CMS include PIMSH4 Patient-Reported Pain Improvement. This is a patient reported outcome (PRO) that is critical to oncology care, leading to more favorable patient care, as well as lowering costs associated with unmanaged pain that often leads to avoidable ED visits and hospitalizations. CMS, ASCO and The Network agreed on the inclusion of this measure during our prior discussions. CMS stated, "CMS agrees with the inclusion pending approval for future performance periods and all criteria met for inclusion of QCDR within an MVP." As an oncology-specific PRO measure, this should be a top measure for inclusion in the MVP. Furthermore, the measure has undergone full testing with results reviewed and approved by CMS for the 2023 MIPS program year. The measure also has an established 2022 CMS National Benchmark.

We recommend that CMS include PIMSH1 Advance Care Planning in Metastatic Cancer Patients. CMS, ASCO and The Network also agreed on the inclusion of this measure during our prior discussions. CMS stated, "CMS included this measure as an alternative to MIPS047 as it is specific to cancer patients and includes a timeframe for completion to ensure that the care is personalized and aligned with the patient goals. This quality measure ensures an advance care plan is discussed within 6 months of metastatic diagnosis and would align with the intent of the MVP." This measure has also undergone full testing with results reviewed and approved by CMS for the 2023 MIPS program year. The measure also has an established 2022 CMS National Benchmark.

We also recommend including PIMSH12: COVID Vaccinations. Although this measure was not part of the original Network MVP application, the measure has been fully implemented for the 2022 MIPS program year. The Network provided CMS with the measure testing results and they have been reviewed and approved by CMS for the 2023 MIPS program year. Note, for 2023 this measure will be enhanced to look specifically at vaccination rates for cancer patients who have received the full CDC-recommended booster series for immunocompromised patients. The Network encourages CMS to consider this measure for inclusion in the MVP, given that compliance with COVID vaccinations is critical for cancer patients who are immunocompromised.

Last, for the Improvement Activities category, we recommend that CMS include IA_PSPA_28 Completion of an Accredited Safety or Quality Improvement Program in the list of Improvement Activities (IA). During prior discussions with the CMS team, ASCO and The Network shared the importance of this IA. In addition, ASCO's Quality Training Program would be an excellent example of an activity that would meet the requirements of this IA. CMS has included IA_PSPA_28 in the Rheumatology's MVP, so there is precedent for its inclusion in an MVP.

MIPS Performance Category Scoring, Measures, and Activities

Quality Performance Category
CMS is seeking comment on the potential future inclusion of two new measures in the APP measure set: MUC21-136: Screening for Social Drivers of Health and MUC21-134: Screen Positive Rate for Social Drivers of Health. The Network agrees with the need to collect social determinants of health (SDOH) data and begin incorporating SDOH into quality measurement; however, MUC21-136 and MUC21-134 appear to be somewhat limited as process measures without a clear outcome or targeted intervention component. For example, MUC21-136 Screening for Social Drivers of Health will require screening a patient for SDOH, but there is no requirement to take action or follow-up on findings from the screening. By comparison, MIPS 134 Depression Screening requires a follow-up plan to be documented if the screening is found to be positive. We recommend that CMS consider a more comprehensive measure that requires a plan of action or targeted intervention to meet the patients' needs.

Similarly, MUC21-134 Screen Positive Rate for Social Drivers of Health has no requirement to take action based on the positive screen. Moreover, it is unclear how this would be scored; clinicians should not be penalized for a high-performance rate if their patient population has a high positivity rate for SDOH. We encourage CMS to clarify how these screenings can translate into meaningful action to drive improvements in patient care.

For the reasons described above, The Network does not support of the addition of MUC21-136: Screening for Social Drivers of Health to the APM Performance Pathway, the foundational layer of the MVP, or the general MIPS program at this time. The Network believes that the most actionable way to incorporate SDOH and assess improvements for at-risk populations is to stratify quality measures by identified social needs. For example, is there a correlation between MIPS1: Diabetes and Controlling HbA1c and patients with food insecurity? By stratifying the performance rates, clinicians could assess improvement in patient care as a result of interventions to improve food insecurity issues. From a MIPS program performance perspective, clinicians could be incentivized to make improvements year over year for a targeted patient population (i.e., an improvement bonus for achieving higher performance during a subsequent year, similar to the bonuses that have historically been awarded).

Quality Data Submission Criteria
CMS is proposing to amend the definition of the term "high priority measure" to include health equity measures. CMS believes including quality measures pertaining to health equity as high priority measures will incentivize the adoption of health equity measures by MIPS- eligible clinicians. The Network supports this proposal.

Health Equity RFI
To facilitate efforts to reduce health inequities, CMS is considering the development of broadly applicable health equity measures for potential use within traditional MIPS and MVPs and seeking feedback to better understand the type and structure of health equity measures that would be appropriate for the implementation.

In order to address SDOH screening needs and support action to improve the quality of care provided to populations with health inequities, The Network encourages CMS to create a SDOH screening measure that requires the clinician/practice take action on positive findings. This could include:

- Discussed needs and support with the patient; no additional resources or referrals needed at this time
- Resources to support the patient's needs identified and referral completed
- Resources to support the patient's needs unavailable at this time; will continue to follow up with the patient to devise a support plan

The Network believes better collection of patient SDOH risks will lead to the ability to risk-stratify other MIPS measures that assess patient outcomes or care delivery processes. The Network also recommends CMS provide clinicians with a list of supported SDOH screening tools, similar to the list of screening tools provided for MIPS 134 Depression Screening. It is important that patients are screened consistently to ensure the most relevant SDOH concerns are addressed. The Network supports both the collection and use of self-reported patient characteristics and assessing patient-clinician communication. Similar to ACP discussions, SDOH assessment should be an ongoing conversation, evaluation, and reassessment over time.

Additionally, The Network encourages the incentivization of providers to leverage ICD-10 Z-Codes enabling the capture of measurable data useful in closing care gaps within vulnerable demographics. Z-Codes will provide actionable data which can be linked to electronic patient reported outcomes (ePROs) providing opportunities to show improvement in quality of care, which will help address social drivers of health and reduce health inequities. Furthermore, incentivizing the capture of Z-Codes will enable Diagnosis-Related Group (DRG) weighting leading to additional financial support for providers serving low-income and at-risk populations managing multiple chronic conditions.

Third Party Intermediaries

QCDR Measure Self-Nomination Requirements
CMS is proposing to require QCDRs to publicly post measure specifications no later than 15 calendar days following CMS' posting of approved QCDR measure specifications on a CMS website; that QCDRs need to confirm that the measure specifications they post align with the measure specifications posted by CMS. The Network supports allowing QCDRs 15 calendar days to publicly post measure specifications; however, we believe QCDRs should only be required to publicly post the current MIPS program year once the PFS final rule has been released and the previous MIPS program year has ended.

QCDR Measure Approval Criteria
The Network supports CMS' proposal to delay the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year. During CY 2023, we encourage

CMS to provide greater transparency around quality measure testing requirements so that measure developers are held to the same standards. For example, during QCDR vendor support calls, CMS could provide a walk-through of a desired QCDR measure testing document with examples of appropriate tests that were conducted so that vendors understand the level of complexity and thoroughness expected by CMS to meet measure testing standards. Additionally, The Network supports CMS' proposal to require all QCDR measures to be fully tested before inclusion in an MVP.

Advanced APM QP Thresholds and Partial QP Thresholds

In the CY 2023 PFS proposed rule, CMS reviews the statutory eligibility and incentive structure for clinicians participating in Advanced APMs to achieve APM Qualifying Participant (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 eligible 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% of payments or 35% of patients; this will increase to 75% of payments or 50% of patients for performance years beginning with 2023. The current threshold for partial QP status is 40% of payments or 25% of patients; this will increase to 50% of payments or 35% of patients for performance years beginning with 2023. 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, representing approximately 25% of physicians in the OCM, a voluntary, 6-year pilot program from the Centers for Medicare and Medicaid Innovation (CMMI). We welcomed CMS' recent announcement of the EOM and are encouraged by what is known so far about the new program. However, based on the recently released 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% of payments / 35% of patients) thresholds, and achieving future thresholds of 75% of payments/ 50% of patients may be even more challenging. According to CMS, for OCM participants, the average payment threshold score was 53% (just barely meeting the 50% threshold), and the average patient threshold score was 21% (far below the 35% threshold). Compared to the OCM, EOM will only enroll patients who are receiving systemic chemotherapy for 1 of 7 types of cancers, inevitably reducing the number of episodes and payments. This will make the existing targets more challenging to achieve and the higher thresholds more daunting.

Additionally, after performance year 2022 (payment year 2024), there is no further statutory authority for a 5% APM Incentive Payment for eligible clinicians who become QPs for a year. In performance year 2023 (payment year 2025), the statute does not provide an incentive for eligible clinicians who become QPs. Beginning in performance year 2024 (payment year 2026), the update to the QP conversion factor for QP-eligible clinicians is 0.75%, and the update to the general conversion factor is 0.25%.

The EOM will require participating practices to accept 2-sided risk on Day 1 and will also reduce the upfront payment amount to fund enhanced services. In summary, practices are being asked to do more with less at the same time that the reward for participating is lower, given the sunsetting 5% lump sum bonus and the much lower 0.75% Medicare payment adjustment. These factors may act as a deterrent to participation, especially for practices who did not participate in OCM and hence have not made the initial investments in software or staffing that are necessary for successful participation in a model like the EOM. The Network urges CMS to work with Congress to extend the existing QP threshold scores and the 5% Advanced APM bonus to continue incentivizing participation in Advanced APMs.

Potential Transition to Individual QP Determinations Only RFI

As discussed above, for most eligible clinicians participating in Advanced APMs, QP determinations are made at the APM entity level. CMS seeks feedback on transitioning away from an APM entity level QP determination and instead calculating threshold scores and making QP determinations at the individual eligible clinician level. The Network encourages CMS to retain the APM entity-level approach to determine QP status and consider assessing individual clinicians for QP status only when the APM entity as a whole does not meet the QP thresholds. This approach is in line with rewarding the entity for its collective commitment to APM participation. However, The Network does agree with CMS that the current structure does not reward individual clinicians who are highly committed to APM participation, but who ultimately do not achieve QP status because of less engaged clinicians that may bring down the overall entity's collective QP threshold score.

Conclusion

On behalf of The US Oncology Network, thank you for the opportunity to provide comments on Proposed Rule CMS-1770-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,

Mark T. Fleming, MD
Chair, National Policy Board
The US Oncology Network