September 6, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically at https://www.regulations.gov/

Re: File Code CMS-1770-P. 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:

The Association of Community Cancer Centers (ACCC) appreciates the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the calendar year (CY) 2023 Physician Fee Schedule (PFS) and Quality Payment Program (QPP) proposed rule, published in the Federal Register on Friday, July 29, 2022 (87 Fed. Reg. 45860).

ACCC is the leading education and advocacy organization for the multidisciplinary cancer care community including physicians, nurses, social workers, pharmacists, researchers, hospital executives, administrators, financial navigators, and other oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 30,000 cancer care professionals from over 1,700 private practices, hospital-based cancer programs, large healthcare systems, and major academic centers across the country, as well as members from 35 state oncology societies.

ACCC respectfully offers the following comments to CMS in response to the CY 2023 PFS proposed rule. In summary, we recommend that CMS:

- Finalize its proposal to extend the originating site, geographic location, audio-only, and telehealth service list flexibilities for 151 days after the end of the COVID-19 public health emergency;

- Add telephone E/M service codes 99441-99443 to Medicare Telehealth Services List on a Category 3 basis and consider covering these codes beyond CY 2023;
- Finalize its proposal to maintain its current definition of the substantive portion of a split (or shared) E/M visit as history, physical exam, medical decision-making, or more than half of the total time for CY 2023, but not implement its updated definition of the substantive portion as more than half of total time only in CY 2024;
- Expand Medicare Part A and B coverage to include medically necessary dental services prior to the initiation of chemotherapy or radiation therapy;
- Finalize its proposal to reduce the minimum age for colorectal cancer screening tests from 50 to 45 years and to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result with no cost-sharing;
- Consider inclusion of the *Improve Access to Genetic Counseling and Testing* improvement activity in the Merit-Based Incentive Payment System (MIPS) Improvement Activities Inventory for performance year 2023 or future years;
- Finalize its proposal to maintain the MIPS performance threshold at 75 points for the 2023 performance year/2025 payment year; and
- Delay the start date of the Advancing Cancer Care MIPS Value Pathway (MVP) until the 2024 performance year to allow time for necessary MVP refinement and provider implementation.

Physician Fee Schedule

Conversion Factor and Oncology Impact

As an overarching preface to our comments, ACCC would like to emphasize our concern with the CY 2023 PFS conversion factor (CF), which CMS estimates to be $33.0775.[1] When compared to the CY 2022 CF of $34.6062, the proposed 2023 CF represents a decrease in reimbursement for all services in the fee schedule of 4.42%. This decrease is the result of Medicare's statutory requirement for budget neutrality when accounting for changes in work relative value units (RVUs) and the expiration of the 3.0% boost to the CY 2022 CF, which was included in the Protecting Medicare and American Farmers from Sequester Cuts Act, passed in December 2021.

CMS has finalized substantial decreases to the CF since its CY 2021 PFS final rule, and Congress took action at the end of 2020 and 2021 to mitigate the impact of these cuts. At the same time, oncology programs and practices across the country have had to contend with considerable financial pressures, largely resulting from significant increases in the cost of clinical labor and supplies during the COVID-19 pandemic. When combined with the 2% Medicare sequestration that was reinstated on July 1, 2022, and the additional 4% Pay-As-You-Go (PAYGO) sequester resulting from the American Rescue Plan Act, set to go into effect on

[1] 87 Fed. Reg. 46385 (July 29, 2022).

January 1, 2023, we fear that the proposed reimbursement cuts to oncology care providers will be unsustainable for cancer programs and practices in the current economic environment.

While we are concerned about these reimbursement cuts for all oncology care providers, we are especially concerned about the even greater payment cuts proposed for non-facility oncology practices as a result of RVU changes. As shown in the specialty impact table from the proposed rule (Table 1), CMS estimates that non-facility-based oncology practices will experience a 2% *decrease* in total allowed charges in 2023 compared to a 1% *increase* for facility-based practices. These community-based cancer practices are vital to the oncology care provided in rural and underserved communities throughout the country. In the interest of maintaining equitable access to care and allowing independent practices to remain viable, CMS should not disproportionately reduce reimbursement for non-facility-based oncology practices.

Table 1: CY 2023 Estimated Impact on Total Allowed Charges by Specialty and Setting[2]

Specialty	Total: Non-Facility/Facility	Allowed Charges (mil)	Combined Impact
Hematology/Oncology	TOTAL	$1,707	-1%
	Non-facility	$1,130	-2%
	Facility	$577	1%
Radiation Oncology and Radiation Therapy Centers	TOTAL	$1,609	-1%
	Non-facility	$1,540	-1%
	Facility	$69	-1%

Furthermore, CMS is proposing to reduce payments for radiation oncology services for 2023 by approximately 4%. A recent analysis of Medicare reimbursement for radiation oncology services confirms that radiation oncology has faced year-over-year fee schedule payment reductions that are unsustainable. According to the analysis, Medicare reimbursement for radiation therapy declined by 27% between 2010 and 2019, when adjusted for inflation and utilization.[3] Additional payment cuts have continued since 2019, which is having a significant impact on the ability of community-based practices to provide state of the art care close to patients' homes. Since last year, radiation oncology practices are now reporting that their overhead costs have increased by 10-20% due to inflationary pressures.

ACCC fears that these reimbursement cuts also threaten the ability of cancer programs and practices to deliver comprehensive cancer care through the provision of supportive oncology care services, like those offered by social workers, dieticians, financial navigators, genetic counselors, case managers, oncology pharmacists, and other members of the multidisciplinary cancer care team. **We therefore strongly encourage CMS to work with Congress to achieve payment stability for oncology services and avert these significant pending cuts to reimbursement in 2023 to protect Medicare beneficiary access to high-quality cancer care.**

* * *

[2] Id. at 46390-94.
[3] Hogan, Jacob, Amit Roy, Patricia Karraker, Jordan R. Pollock, Zachary Griffin, Neha Vapiwala, Jeffrey D. Bradley et al. "Decreases in Radiation Oncology Medicare Reimbursement Over Time: Analysis by Billing Code." *International Journal of Radiation Oncology* Biology* Physics* (2022).

Payment for Medicare Telehealth Services

CMS proposal (87 Fed. Reg. 45885): CMS proposes to implement provisions of the Consolidated Appropriations Act of 2022 (CAA) that extended some of the flexibilities implemented during the COVID-19 public health emergency (PHE) for an additional 151 days after the end of the PHE. These flexibilities include allowing telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home, and allowing telehealth visits to be audio-only.

ACCC comment: ACCC appreciates the flexibilities CMS has implemented to expand access to telehealth throughout the COVID-19 PHE. ACCC cancer program and practice members have reported that patients and providers have benefited from increased telehealth access. These flexibilities have enabled immune-compromised patients with cancer to avoid delays in care, maintain access to high-quality cancer care with their existing care teams, and reduce potential exposure to COVID-19. ACCC supports CMS' proposal to extend the originating site, geographic location, audio-only, and telehealth service list flexibilities for 151 days after the end of the COVID-19 PHE.

At the same time, we urge CMS to strengthen its proposal by extending those expanded telehealth policies after the expiration of the PHE. While many of the requirements that govern Medicare telehealth services are statutory in nature and can only be revised through congressional action, CMS does have the authority to make certain permanent changes to telehealth reimbursement through proposed rulemaking. This includes promulgating alternative definitions of "interactive telecommunications" to allow for exceptions to HIPAA requirements on remote communications technologies and modifying prior interpretations of the statutory payment requirements for distant site providers. CMS should continue to explore how it can enact policies that allow robust and enduring access to Medicare telehealth services to the fullest extent of its statutory authority.

Telephone Evaluation and Management (E/M) Services

CMS proposal (87 Fed. Reg. 45890): In the CY 2021 Medicare PFS final rule, CMS created a new telehealth category, "Category 3", for certain codes included on the Medicare Telehealth Services List. Category 3 services are those that were added to the list during the PHE for which there is likely a clinical benefit when provided via telehealth, but for which there is not yet sufficient evidence available to add them to the list permanently. In its implementation of the CAA, CMS proposes to continue to cover services that were temporarily added to the Medicare Telehealth Services List during the PHE (but have not since been added on a Category 1, 2, or 3 basis) through the 151-day period after the end of the PHE. As previously finalized by the agency, services that have been added on a Category 3 basis will remain on the list through the end of CY 2023.

Telephone (audio-only) E/M services (CPT codes 99441-99443) have not been added to the Medicare Telehealth Services List on a Category 3 basis, and so coverage for these services is due to end after the 151-day period following the end of the PHE. For this reason, CMS has received requests to add these codes to the list on a Category 3 basis.

ACCC comment: ACCC strongly recommends that CMS add telephone E/M service codes 99441-99443 to Medicare Telehealth Services List on a Category 3 basis and consider covering these codes beyond CY 2023. While audio-only services may not match the clinical benefits of their interactive audio and video E/M counterparts (CPT codes 99212-99214), audio-only E/M services are still vital to patients with cancer that are unable to attend visits in person or are unable to engage in a video visit for any variety of reasons. Patients with poor broadband access, patients who lack access to the requisite equipment to accommodate video functionality, and patients with limited digital literacy or English proficiency all stand to benefit from continued access to telephone E/M services.

ACCC member programs and practices agree that interactive audio-video telehealth visits are the preferred modality to engage with a remote patient via telehealth, but it is not possible to complete this type of telehealth visit with all patients seeking to utilize telehealth services. In many cases, providers try to facilitate a video visit, but due to the instability of an internet connection, lack of technology capability, or other technical challenges, the visit ultimately becomes an audio-only one. Importantly, one ACCC cancer program reported that in looking at their data on telehealth utilization, they found that patients from underrepresented racial and ethnic groups were significantly more likely to rely on the use of audio-only telehealth visits than their White counterparts.

Therefore, ACCC is concerned that the elimination of coverage for telephone E/M services after 151 days following the end of the COVID-19 PHE will exacerbate existing disparities in access to high-quality cancer care. We further recommend that CMS fully consider the health equity implications of eliminating coverage for these codes prior to removing them from the Medicare Telehealth Services List at the end of 2023.

Split (or Shared) E/M Visits

CMS proposal (87 Fed. Reg. 46003): CMS proposes to maintain its 2022 definition of the "substantive portion" of a split (or shared) E/M service performed in a facility setting through CY 2023. A split (or shared) service refers to an E/M visit performed by both a physician and a non-physician practitioner (NPP) in the same group practice a facility setting where "incident to" billing is not available. This means clinicians who furnish a split (or shared) E/M visit will continue to have a choice of history, physical exam, medical decision-making (MDM), or more than half of the total practitioner time spent to define the substantive portion to determine which practitioner will bill the visit. CMS proposes to delay implementation of its updated definition of the substantive portion as more than half of the total time only until January 1, 2024.

ACCC comment: While ACCC generally supports CMS' proposals to update E/M coding to be consistent with the American Medical Association CPT Editorial Panel guideline revisions[4], we remain concerned with CMS' proposed policy changes for split (or shared) E/M visits. Changing the definition of the substantive portion of a split (or shared) E/M visit will be disruptive and counterproductive to the delivery of high-quality, team-based care in the facility setting, which represents an increasing proportion of oncology care year over year.

[4] 87 Fed. Reg. 45987 (July 29, 2022).

Patients with cancer benefit from the effective collaboration between physicians and NPPs across all care settings. ACCC supports policies that promote Medicare beneficiary access to the highest value, team-based care and that allow oncology care providers, including both physicians and NPPs, to perform at the top of their licenses. Defining the substantive portion of a split or shared E/M service based on the physician or NPP who performs more than 50 percent of the total time of the visit will disincentivize the continuation of these collaborative care relationships.

Moreover, this new definition fails to ensure appropriate compensation for physicians when they make a substantive contribution to team-based care and risks underutilizing NPPs to meet arbitrary billing guidelines. Especially at a time of ongoing oncology workforce shortages and excessively high levels of burnout across the multidisciplinary cancer care team, CMS should not implement policies that would disincentivize team-based care and interfere with the way care is delivered in the facility setting.

Therefore, ACCC agrees with CMS' proposal to maintain its current definition of the substantive portion of a split (or shared) E/M visit as history, physical exam, MDM, or more than half of the total time for CY 2023. However, we strongly oppose the adoption of the updated definition of the substantive portion as more than half of total time only in 2024 or any time thereafter. We urge CMS to revise its split or shared E/M visit policy to allow physicians and NPPs to bill split (or shared) visits based on either time or MDM to mitigate the negative impact that a time-only option would have on team-based oncology care.

Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services

CMS proposal (86 Fed. Reg. 46033): Section 1862(a)(12) of the Social Security Act excludes Medicare coverage of routine dental services. However, dental services are covered by Medicare in only a limited number of circumstances, including when treatment is medically necessary, the dental service requires hospitalization because of an individual's underlying medical condition and clinical status, or the dental service is an integral part of a covered primary procedure or service furnished by another physician treating the primary medical illness. Medicare Administrative Contractors determine whether an exception for dental coverage applies on a claim-by-claim basis, and CMS has received feedback that interpretation of these exceptions have been too restrictive.

To provide greater clarity on the issue of dental coverage, CMS proposes to clarify its interpretation and codify certain payment policies for medically necessary dental services. First, if a dental service is "inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services," it will be covered by Medicare Parts A and B, whether or not the dental service is provided in an inpatient or outpatient setting. CMS seeks comments on medical conditions where Medicare should pay for dental services, including patients being treated with chemotherapy and radiation therapy.

ACCC comment: ACCC appreciates the agency's request for information on Medicare payment for dental services, particularly in relation to chemotherapy and radiation therapy. We appreciate the clarification of when a dental service will be covered by Medicare Parts A and B, and we agree that the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is integral to the clinical success of the treatment.

ACCC recommends that Medicare cover dental exams for Medicare patients before beginning chemotherapy or radiation therapy. Standard care in many cancer centers includes a comprehensive oral exam prior to starting therapy.[5] The National Cancer Institute recommends that cancer patients receiving high-dose chemotherapy, stem cell transplants, or radiation therapy should have an oral care plan in place before treatment begins to mitigate the risk of oral complications.[6]

Dental care is essential and appropriate for patients with head and neck cancers. For any patient undergoing radiation therapy to the head and neck, it is important to receive a thorough initial dental evaluation, including dental x-rays, with special attention to any teeth that may require timely procedures, such as root canals and extractions, prior to radiation therapy. After radiation therapy, patients should receive ongoing dental evaluations for possible problems, such as caries, high risk extractions, or mandibular osteonecrosis.

ACCC also recommends covering dental exams and related preventative services before institution of bone directed therapy using bisphosphonates and denosumab. There is no effective treatment for bisphosphonate-induced osteonecrosis, yet preventative dental exams and management decreases risk of osteonecrosis of the jaw in patients receiving these therapies.[7] Research shows that osteonecrosis of the jaw is a preventable condition, and that care coordination and preventative services can result in improved outcomes and lower incidences of osteonecrosis of the jaw for patients with cancer that receive bisphosphonate therapy.[8]

Expansion of Coverage for Colorectal Cancer Screening

CMS proposal (86 Fed. Reg. 46081): CMS proposes to reduce the minimum age for certain colorectal cancer (CRC) screening tests from 50 to 45 years. The agency also proposes to expand the definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Under this revised definition, there would be no beneficiary cost sharing for the initial screening stool-based test nor the follow-on screening colonoscopy test.

ACCC comment: ACCC supports CMS' proposal to reduce the age limit and increase Medicare beneficiary access to non-invasive cancer screening tests and follow-up colonoscopies without any beneficiary cost sharing. This proposal aligns Medicare coverage with the May 18, 2021, recommendation of the U.S. Preventive Services Task Force to lower the age criteria for CRC

[5] Yong, Chee Weng, Andrew Robinson, and Catherine Hong. "Dental Evaluation Prior to Cancer Therapy." *Frontiers in Oral Health* 3 (2022).
[6] National Cancer Institute. Oral Complications of Chemotherapy and Head/Neck Radiation (PDQ®)–Health Professional Version. https://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oral-complications-hp-pdq. Updated July 14, 2021.
[7] Kalra, Sandeep, and Veena Jain. "Dental complications and management of patients on bisphosphonate therapy: A review article." *Journal of oral biology and craniofacial research* 3, no. 1 (2013): 25-30.
[8] Ripamonti, Carla I., M. Maniezzo, T. Campa, E. Fagnoni, C. Brunelli, G. Saibene, C. Bareggi, L. Ascani, and E. Cislaghi. "Decreased occurrence of osteonecrosis of the jaw after implementation of dental preventive measures in solid tumour patients with bone metastases treated with bisphosphonates. The experience of the National Cancer Institute of Milan." *Annals of Oncology* 20, no. 1 (2009): 137-145.

screening tests and to further evaluate abnormal results of stool-based assays with a follow-up colonoscopy as part of the evidence-based screening recommendation.[9]

ACCC members have reported an increase in patients presenting with later stage cancers due to missed screenings as a result of the COVID-19 pandemic. ACCC applauds the Administration's efforts via the Cancer Moonshot to get screenings back on track, and this update to Medicare payment policy is a necessary step toward achieving that goal by making CRC screenings more accessible and less cost prohibitive to Medicare beneficiaries. We encourage the agency to finalize this proposal.

Quality Payment Program

Proposed Changes to the MIPS Improvement Activities Inventory

CMS proposal (87 Fed. Reg. 46285): For the 2023 performance period, CMS proposes to add four new improvement activities (IAs), modify five existing IAs, and remove six previously adopted IAs from the Merit-Based Incentive Payment System (MIPS) Improvement Activities Inventory. All four of the newly proposed IAs are responsive to the Administration's goal of advancing health equity.

ACCC comment: ACCC appreciates CMS' leadership in creating new MIPS IAs that align with the Administration's goal of advancing health equity and reducing racial and ethnic disparities by increasing support for underserved communities. This is a key priority for ACCC, and we are pleased to see new IAs that reflect these initiatives. At the same time, we would also like to see CMS incorporate additional IAs, particularly the IA titled *Improve Access to Genetic Counseling and Testing*, which also aligns with the Administration's goal of promoting health equity.

In 2021, ACCC supported the National Society of Genetic Counselors (NSGC) in submitting this MIPS IA, which is intended to drive appropriate engagement between eligible clinicians and genetic counselors. It also seeks to improve Medicare beneficiaries' experience and health outcomes by integration of genetic counselors into clinical care teams and establishing protocols to increase access to genetic services in appropriate scenarios. Addressing barriers to genetic counseling and testing services in the treatment of cancer and improving Medicare beneficiary access to genetic counselors is an important legislative and regulatory priority for ACCC, and we would like to reaffirm our support for this IA.

The National Comprehensive Cancer Network has recommended genetic testing services for patients with many cancer types, emphasizing the important role of genetic counselors in improving the quality of cancer care and decreasing the overall cost of care. Improving access to genetic counseling services can lead to more effective, individualized cancer treatments. As personalized medicine and genetic markers are increasingly used to inform cancer treatment plans, access to genetic counseling and testing has become essential for Medicare beneficiaries.

[9] U.S. Preventive Services Task Force. Final Recommendation Statement: Colorectal Cancer Screening. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening. Published May 18, 2021.

ACCC therefore requests that CMS consider inclusion of the *Improve Access to Genetic Counseling and Testing* IA in the MIPS IA Inventory for performance year 2023 or future years. Alternatively, ACCC would request that, if CMS has determined that the genetic counseling IA overlaps with existing activities in the MIPS IA Inventory, that the proposed interventions be reflected in the current validation criteria to ensure that clinicians can earn credit for those IAs by promoting improved access to genetic counseling.

It is our belief that the genetic counseling IA aligns with the 2023 PFS, CMS' goals for value-based care, and overall vision for MIPS Value Pathways through the following:

- Meets all eight IA acceptance criteria. The genetic counseling IA is designed to be broadly applicable across multiple clinical areas serviced by Medicare clinicians and is informed by evidence-based interventions that have demonstrated significant improvement in beneficiary health outcomes. This IA includes low-burden interventions that can be easily documented, and that will streamline clinical workflow processes, so it is feasible to implement and validate, as well as drive collaboration between physicians and genetic counselors through the linkage to existing MIPS measures.
- Aligns with CMS' Framework for Health Equity and promotes health equity for vulnerable patients where genetic factors contribute to healthcare disparities. The genetic counseling IA includes practice improvements, such as development of standard protocols to trigger a referral for genetic counseling if a patient's family or medical history indicates a suspected genetic condition. These activities not only create workflow efficiencies and empower the workforce to increase capacity of practices to deliver quality care, but they can also reduce disparities in patients who receive genetic services and enhance health outcomes.
- Promotes comprehensive screening and early detection for CRC, which contributes to the reduction of racial and ethnic disparities among vulnerable at-risk populations. CRC rates affect non-White populations at disproportionally higher rates, and social drivers can exacerbate existing genetic susceptibility. Increasing access to genetic counselors can improve early identification of high-risk individuals and facilitate potentially life-saving cascade testing to family members. Interventions within the genetic counseling IA, such as establishment of universal testing protocols for appropriate clinical scenarios or standardized processes to improve identification of eligible patients for genetic services, would incentivize providers and practices to coordinate care with genetic counselors.
- Creates an incentive to improve appropriate access to care in the absence of quality measures that directly assess genetic counseling services and outcomes, and bolsters proposed indirectly relevant quality measures (e.g., MMR/MSI testing) by driving coordination between physicians and genetic counselors. Currently, there are no quality measures that directly assess genetic counseling services or outcomes across key patient care continuum domains. In the absence of such measures, the genetic counseling IA can create a critical incentive in the QPP for providers to improve access to genetic counseling services. The genetic counseling IA also aligns with and can support the proposed testing-related measure*: The Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma*. The genetic counseling IA supports the

goals of this measure by creating an incentive for specialists to optimize identification of patients eligible for biomarker testing and efficient follow-up on test results.

MIPS Performance Threshold

CMS proposal (87 Fed. Reg. 46321): In accordance with statute, CMS is required to establish the performance threshold for MIPS using either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. In the CY 2022 PFS final rule, CMS set the MIPS performance threshold at 75 points for the 2022 performance year/2024 payment year, which corresponds to the mean final score from the 2019 MIPS payment year. In the CY 2023 PFS proposed rule, CMS proposes to maintain the performance threshold at 75 points for the 2023 performance year/2025 payment year.

ACCC comment: We agree with CMS' proposal to establish a MIPS performance threshold of 75 points for the 2023 performance year. By not increasing the performance threshold for CY 2023, CMS will provide some level of stability for MIPS eligible clinicians during a year when many transitional policies are coming to an end, most notably the extreme and uncontrollable circumstances policies triggered by the COVID-19 PHE, which resulted in the reweighting of performance categories for many MIPS eligible clinicians across ACCC member cancer programs and practices over the last several years.

CMS expects that the mean final score for the 2023 performance period will be lower than the mean final scores from the 2018 through 2020 performance periods, largely due to these temporary policies. CMS should also consider the fact that absent congressional action before the end of the year, there will no longer be an additional MIPS payment adjustment for exceptional performance due to the expiration of the annual statutory allocation of $500 million for exceptional MIPS performance. Given the budget neutral design of the MIPS program, an increase in the performance threshold in the same year as the removal of bonus payments for exceptional performance would unfairly penalize MIPS participating clinicians and groups that are already expected to underperform previous performance periods.

Reporting under MIPS requires significant time and financial investment for cancer programs and practices. ACCC encourages CMS to bear in mind the above considerations when establishing MIPS reporting and scoring requirements in 2023 and beyond to ensure that oncology care providers can meaningfully participate in MIPS without fear of negative payment adjustments as they continue to experience significant inflationary and workforce pressures that are already threatening their financial viability.

MVP Strategy and Implementation Timeline

CMS proposal (87 Fed. Reg. 46264): In the CY 2022 rulemaking cycle, CMS laid out its MIPS Value Pathways (MVPs) Framework and a proposed implementation timeline for MIPS eligible clinicians to begin reporting MVPs. CMS finalized its proposal to open voluntary reporting via MVPs in the 2023 performance year and to require multispecialty groups that choose to report through an MVP to participate as subgroups beginning in the 2026 performance year. The agency also indicated its intent to sunset traditional MIPS after the 2027 performance year and for MVPs to become the only MIPS reporting option thereafter, although it did not yet finalize

this timing. In the CY 2023 PFS proposed rule, CMS does not propose any further changes to this implementation timeline but continues to solicit feedback on the transition and future alignment between MVPs and advanced alternative payment models (APMs).

ACCC comment: ACCC supports CMS' efforts to make MIPS more clinically relevant to specialty providers, reduce reporting burden, improve the cohesiveness of the four performance categories, and create a pathway to advanced APM participation. We also appreciate CMS' willingness to engage stakeholders in the development of new MVPs, ensuring that the MIPS program is collecting meaningful performance measures that will have a tangible impact on the provision of quality patient care.

However, to date CMS has proposed only 12 MVPs and does not yet have any evidence of clinician acceptance or uptake of MVPs in practice. We encourage CMS to fully evaluate the effectiveness of MVPs as an alternative approach to MIPS through the first several performance years and to identify the challenges and proposed solutions for clinicians reporting via MVPs prior to making any firm decisions on the MVP implementation timeline. Absent this real-world experience in the new MVP framework and enough MVPs for all medical specialties and subspecialties, we do not support CMS' proposal to require mandatory subgroup reporting for multispecialty groups in the 2026 performance period nor its proposal to sunset traditional MIPS.

Advancing Cancer Care MVP

CMS proposal (87 Fed. Reg. 46266): CMS proposes the introduction of its first oncology-specific MVP, Advancing Cancer Care, which would be available for reporting in the 2023 performance year. This MVP would include 11 MIPS quality measures and two Qualified Clinical Data Registry measures within the quality component, 13 IAs within the improvement activities component, the Total Per Capita Cost measure within the cost component, and two population health measures available for selection. CMS indicates that the cost measure was chosen because it captures the overall costs of care after establishing a primary care-type relationship, which includes care provided to patients by medical, hematological, and gynecological oncologists.

ACCC comment: ACCC appreciates CMS' effort to establish its first MVP specific to oncology services and allow cancer care providers a new opportunity to progress in their value-based transformation journeys. At the same time, we believe that the Advancing Cancer Care MVP could benefit from modification following the collection of feedback from the oncology stakeholder community. ACCC recommends that CMS refine this MVP and narrow its scope such that its purview is more specific to the practice of medical oncology only.

In its current design, the Advancing Cancer Care MVP is meant to include participation among medical oncologists, hematologists, and gynecological oncologists. The role of radiation oncology, however, seems to be limited to the quality measures and the Total Per Capita Cost measure, which would likely include radiation therapy when delivered as part of a patient's care regimen. The inclusion of these measures obligates participating providers to value therapies, including radiation therapy, that are outside of their scope of practice.

If a patient requires and can benefit from radiation therapy services, then the patient should be referred to a radiation oncologist for radiation therapy services. As designed, this MVP has the potential to disincentivize appropriate referrals. Additionally, even if appropriately referred, the designated specialists will not have control over the treatment planning or cost associated with the delivery of radiation therapy treatments, which can be substantial, and which places unfair pressure on both specialties. Therefore, we recommend that CMS engage with appropriate stakeholders to create alternative MVPs that are more clinically relevant to surgical and radiation oncology, respectively.

In addition to the need for feedback and further refinement of the Advancing Cancer Care MVP, we note that the implementation of a new reporting structure necessitates significant changes to clinical workflows and the IT systems that support them. Health IT vendors and technology partners need sufficient time to build and test new measure collection and reporting capabilities to satisfy the requirements of this new MVP, and we do not believe that a January 1, 2023, start date for this MVP gives clinicians nor their IT partners sufficient time to fully analyze and implement this new reporting structure.

Finally, many oncology programs and practices are currently assessing participation in the recently announced Enhancing Oncology Model (EOM), which is set to begin July 1, 2023. Given the considerable resources necessary to evaluate participation in both of these new value-based payment arrangements, we believe it will unfairly burden cancer care providers to implement this new MVP in the same calendar year as EOM. For all of these reasons, ACCC recommends that CMS delay the implementation of the Advancing Cancer Care MVP until the 2024 performance year.

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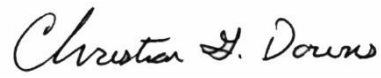
Thank you for this opportunity to share the oncology care provider perspective on the CY 2023 PFS and QPP proposed rule. As the association representing the multidisciplinary cancer care team, ACCC is uniquely suited to participate in this dialogue with CMS in its efforts to maintain a stable and equitable Medicare payment system. If you have any questions on our comments, please feel free to contact Matt Devino, Director of Cancer Care Delivery & Health Policy, at mdevino@accc-cancer.org or (301) 263-3510.

Respectfully Submitted,



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