September 11, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Submitted Electronically at www.regulations.gov

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 (CMS–1784–P)

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the 2024 Medicare Physician Fee Schedule and Quality Payment Program proposed rule (CMS–1784–P) that was published in the Federal Register on July 13, 2023.

ASCO is a national organization representing nearly than 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

We are pleased to offer our comments on select provisions below:

Physician Fee Schedule

- Conversion Factor
- Specialty Level Impact
- Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)
- Medicare Economic Index
- Telehealth
- Evaluation and Management
- Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services
- Request for Information (RFI): Drugs and Biologicals which are Not Usually Self- Administered by the Patient, and Complex Drug Administration Coding
- Medicare Part B Payment for Preventive Vaccine Administration Services
- Appropriate Use Criteria
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan
- Removing CEHRT Use Threshold Requirements and Requiring Reporting of the MIPS Promoting Interoperability Performance Category

Quality Payment Program

- Performance Threshold
- Establishing the Performance Threshold
- Complex Patient Bonus for Subgroups
- Targeted Review for Subgroups
- Require the Administration of the CAHPS for MIPS Survey in the Spanish Translation
- Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures
- New Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years
- Improvement Activities
- QP Determination
- Advanced APM CEHRT Requirement

Conclusion

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ASCO
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

Physician Fee Schedule

Conversion Factor

ASCO continues to urge CMS to work with Congress to implement positive updates to the Medicare physician conversion factor (CF), to address the flaws of the budget neutral system, and to end continuous, year after year, cycles of decreased payments, with the goal of supporting and sustaining beneficiary access to quality cancer care and physician practice health.

In the Consolidated Appropriations Act, 2023 (CAA, 2023), Congress provided a temporary 2.5% CF update for 2023 and a one-year temporary increase of 1.25% for 2024. The 2024 proposed rule also includes a -2.17% budget neutrality adjustment, 90% of which can be attributed to the implementation of the new Evaluation and Management (E/M) add on complexity code G2211created by CMS.[1] The combination of the negative 2.17% budget neutrality adjustment with the decrease in Congressional funds decreases the CF by 3.36% to $32.7476 in the 2024 proposed Medicare Physician Fee Schedule (MPFS). By contrast, in 1992 the CF was $31.0010. In the past 32 years, the CF has increased by only $1.75, or 5.36%. Meanwhile, overall inflation has risen 118%[2]. The physician CF has not kept up with inflation, increasing interest rates, or other drivers increasing practice costs over the past few years.

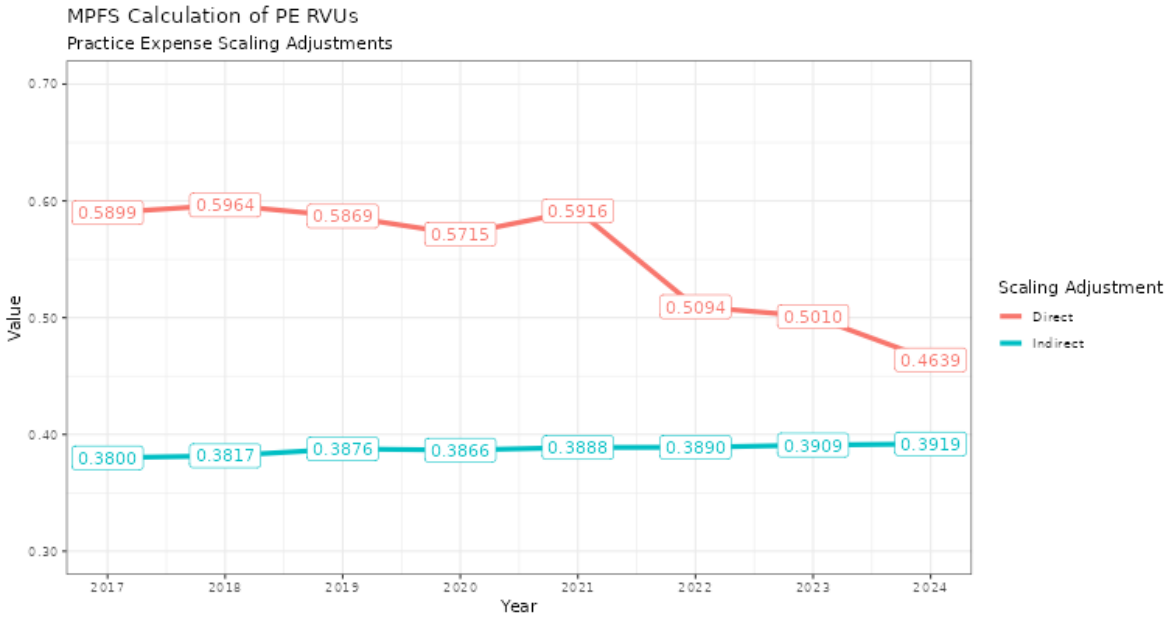
ASCO continues to urge CMS to work with Congress on reforms to the Medicare physician fee schedule, including passage of legislation that would provide annual inflationary update based on the Medicare Economic Index (MEI) to the MPFS, such as the Strengthening Medicare for Patients and Providers Act (H.R. 2474) introduced by Rep. Raul Ruiz.

An additional piece of the MPFS puzzle continuing to drive lower reimbursement for physician practices is a second budget neutrality mechanism titled the "direct scaling adjustment" which converts actual labor, supply, and equipment expenses to adjusted values. If specific direct practice expenses increase or decrease, contraposed changes to the direct scaling adjustment keep the total number of direct practice expense relative value units (peRVUs) equal to the prior year. Table 1 highlights the decrease in the scaling adjustment by over 22% in the last 6 years. The decrease in the direct scaling adjustment drives reduction for reimbursement in peRVUs, relative value units (RVUs) which are essential to successful practice operation and sustainability.

CMS is proposing to pay less than half, 46 cents per one dollar, for the direct expenses of providing care in an office setting. The continued decreases in reimbursement for running a community oncology practice threatens the ability to keep smaller practice doors open, which in turn can result in care that is delayed—or does not happen at all. Read the full *ASCO Practice Impact Analysis of the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2024* here.

[1] https://old-prod.asco.org/sites/new-www.asco.org/files/2024-MPFS-Proposed-Rule-Exec-Summary-Analysis.pdf?cid=DM14574&bid=297032845
[2] https://data.bls.gov/cgi-bin/cpicalc.pl?cost1=1&year1=199207&year2=202307

Table 1. Direct Scaling Adjustment Used to Determine Direct Practice Expense RVUs, by Calendar Year



Specialty Level Impact

The results of our analysis, which factor in all proposed policy changes included in the 2024 proposed rule and the temporary 1.25% increase to the CF as required by the CAA, 2023, are quite different than CMS' analysis which shows a 2% increase to Hematology/Oncology and a 2% decrease to Radiation Oncology.

Oncology practices are expected to receive the following decreases in reimbursement due to the MPFS proposed rule, to include changes in RVUs and a 3.4% decrease to the MPFS conversion factor:

- Hematology/Oncology: 0.2% decrease to Medicare allowable rates
- Radiation Oncology: 3.6% decrease to Medicare allowable rates
- Gynecologic Oncology: 0.7% decrease to Medicare allowable rates
- Surgical Oncology: 2.9% decrease to Medicare allowable rates

Differences among specialty-specific impacts is largely the result of increases in RVUs for outpatient cognitive services and labor-intensive services, countered by various budget neutrality mechanisms that decrease reimbursement for other expenses. Read the full *ASCO Practice Impact Analysis of the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2024* here.

These payment reductions come at a time when physician practices, hospitals that employ physicians, and other stakeholders face rising inflation, staffing shortages, and increased administrative burden. The

financial insecurity these challenges are causing will only be worsened by the budget neutrality adjustments in calendar year (CY) 2024, the Congressionally mandated reductions in reimbursement, and the loss of the "exceptional performance" bonus in the MIPS track of the QPP and the APM bonus. Additionally, preliminary reports indicate that over half of physicians in the MIPS track of the QPP may face negative penalties with the reinstitution of full reporting post-pandemic. **For oncologists to sustain their ability to provide patient access to high-quality and equitable cancer care, it is imperative that CMS work with Congress to address these cuts to reimbursement in 2024.**

Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

Community Health Integration

CMS is proposing to create two new G codes describing community health integration (CHI) services performed by certified or trained auxiliary personnel, which may include a community health worker (CHW), incident to the professional services and under the general supervision of the billing practitioner. CHI services could be furnished monthly (if medically necessary) following a required initiating E/M visit in which the practitioner identifies the presence of social determinants of health (SDOH) needs significantly limiting the practitioner's ability to diagnose or treat the problem addressed in the visit.

To improve health equity and the overall care of cancer patients, ASCO recommends that CMS finalize its proposal to establish two codes for community health integration.

In our 2023 proposed rule comments, ASCO recommended that CMS promote the availability of social support service programs and resources, especially as the Administration continues to prioritize and address health equity and the social determinants of health. Achieving cancer health equity requires broad approaches that address the social, economic, and environmental factors that influence health.[3] Evidence shows that incorporating community health workers can improve patient experiences with care, reduce acute care use at the end of life, and lower total health care costs net implementation.[4,5,6]

ASCO thanks CMS for incorporating stakeholder feedback and for recognizing unmet social needs can interfere with a clinician's ability to diagnose and treat patients. Acknowledging, through billing and coding opportunities, the resources required to connect patients with community services is a

[3] Allyn Moushey, M. S. W., M. P. H. Jonathan Phillips, and M. D. William Tap. "Cancer Disparities and Health Equity: A Policy Statement From the American Society of Clinical Oncology." (2020).
[4] Patel, Manali I., et al. "Association of a lay health worker intervention with symptom burden, survival, health care use, and total costs among Medicare enrollees with cancer." JAMA network open 3.3 (2020): e201023-e201023.
[5] Patel, Manali I., et al. "Effect of a lay health worker intervention on goals-of-care documentation and on health care use, costs, and satisfaction among patients with cancer: a randomized clinical trial." JAMA oncology 4.10 (2018): 1359-1366.
[6] Patel, Manali I., et al. "Effect of a community health worker intervention on acute care use, advance care planning, and patient-reported outcomes among adults with advanced stages of cancer: A randomized clinical trial." JAMA oncology 8.8 (2022): 1139-1148.

meaningful step toward improving health equity, promoting whole person care, and supporting clinicians' ability to care for patients.

Social Determinants of Health Risk Assessment

CMS is proposing coding and reimbursement for a SDOH risk assessment, which includes a review of the individual's SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions. The code would be furnished by the practitioner on the same date they furnish an E/M visit, could be done via telehealth, and must be a standardized, evidence based SDOH risk assessment tool. The code may be billed no more than once every six months.

ASCO supports CMS' proposal to establish code GXXX5, and we urge CMS to clarify that code GXXX5 may be billed with CHI codes.

We strongly support understanding and addressing the SDOH of patients with cancer; however, administrative burdens accompany more robust SDOH data collection. Physicians or other staff collecting the SDOH information may need training on how to best collect SDOH information, why it is important to do so, and appropriate strategies for initiating such conversations with their patients. Gathering SDOH information may require significant additional time to capture and then code into the patient's electronic health record (EHR), which could necessitate additional staff time and resources. Because patient's social needs and SDOH are always changing, SDOH screening should happen more than once, which also demands more time, staff, and resources to stay current. We agree with CMS that the resources involved in these activities are not appropriately reflected in current coding and payment policies; therefore, we support implementation of this code.

ASCO believes that it would be appropriate for clinicians to bill the CHI code GXXX1 with the SDOH code GXXX5 during the same visit. To bill the CHI codes, the billing practitioner "would assess and identify SDOH needs", which would be best accomplished through an evidence based SDOH assessment tool required in CMS' SDOH code description of GXXX5. In the rule CMS states "standardized, evidence-based tools can more effectively and consistently identify unmet SDOH needs".

Physicians must be able to act upon identified areas of unmet social needs immediately and without delay. We agree with CMS that an SDOH risk assessment without appropriate follow-up for identified needs would serve little purpose and likely place more burden on the patient to have to schedule a follow-up visit for connection to social services.

We urge the agency to clarify in the final rule that codes GXXX1 for CHI and GXXX5 *may* be billed during the same visit. We do not believe this should be *required* as a condition of payment for the SDOH code. A patient may not be willing to be connected to community resources for various social, personal, and logistical reasons, or it may take time for the patient to feel comfortable engaging in this manner. Patients and their physicians should have the flexibility to decide the patient's care without payer interference.

Principal Illness Navigation Services

CMS is proposing coding and reimbursement for principal illness navigation (PIN) services which help people who are diagnosed with high-risk conditions, like cancer, identify and connect with appropriate clinical and support resources.

ASCO supports CMS' proposal to reimburse care navigation services for patients with cancer, and we ask the Agency to provide additional billing and coding details.

ASCO supports the expansion and promotion of patient navigator programs as they have the potential to increase participation and retention of minority patients in clinical trials[7] and have been shown to improve access to cancer care and improve outcomes, especially in populations with health disparities[8,9]. Establishment of a patient navigator program could be a tremendous opportunity to remove obstacles for underserved populations who may not independently seek to enroll in clinical trials. Covering these services aligns with our shared goal of addressing social determinants of health and promoting health equity and supports the White House's Cancer Moonshot Initiative. We thank CMS for recognizing the work and resources associated with providing cancer patients navigation services by proposing Medicare billing and coding.

CMS proposes practitioners could bill separately for other care management services during the same month as PIN services if time and effort are not counted more than once, requirements to bill the other care management services are met, and the services are medically reasonable and necessary. ASCO is concerned about the overlap of activities included in the code descriptions for PIN services, principal care management, chronic care management, and complex chronic care management codes. Each of these code sets has an element of education, care coordination, management of care transitions, connection to social services, and treatment plan. To avoid billing and coding confusion and to prevent inadvertent coding errors, we ask CMS to clarify billing and coding expectations and provide clinical examples of when both PIN and care management services would be appropriately billed during the same month.

We also ask the Agency to clarify in the final rule that PIN services could be billed during the same month as CHI services and the SDOH risk assessment code. As CMS mentions in the rule, not all individuals who may benefit from PIN services will have unmet SDOH needs, but it will be necessary to

[7] Ghebre RG, Jones LA, Wenzel JA, Martin MY, Durant RW, Ford JG. State-of-the-science of patient navigation as a strategy for enhancing minority clinical trial accrual. Cancer 2014; 120: Suppl 7: 1122-30.
[8] Niharika Dixit, Hope Rugo, and Nancy J. Burke. Navigating a Path to Equity in Cancer Care: The Role of Patient Navigation. American Society of Clinical Oncology Educational Book 2021 :41, 3-10
[9] Kathryn M. McKenney, Noelle G. Martinez, Lynn M. Yee, Patient navigation across the spectrum of women's health care in the United States, American Journal of Obstetrics and Gynecology, Volume 218, Issue 3, 2018, Pages 280-286, ISSN 0002-9378, https://doi.org/10.1016/j.ajog.2017.08.009.

screen for SDOH to make that determination. As patient needs vary, we believe that it would be appropriate for a practitioner to bill both CHI and PIN for the same beneficiary in the same month.

ASCO supports the use of navigation services for patients with cancer, and we would like to collaborate with the Agency to promote incorporating these codes into physician practices. However, we ask CMS not to implement onerous and burdensome documentation requirements for billing PIN services. We believe the goal of the White House is to encourage incorporating patient navigators into a patient's care plan, and we urge CMS to be mindful of documentation requirements that could inadvertently undermine code uptake.

Medicare Economic Index

CMS proposes to continue to delay implementation of the 2017-based Medicare Economic Index (MEI) that was finalized in CY 2023. CMS cites the AMA's ongoing data collection effort to update the Physician Practice Information Survey (PPIS) and the significant redistributive impacts that MEI updates would have on PFS payments. CMS further notes that in CY 2023, it proposed to update the MEI based on 2017 Census Bureau data, which the agency believed was the most appropriate and recent data available. In the CY 2024 proposed rule, CMS notes that 2022 data will be available later this year and that the agency will monitor that data and any other data that become available related to physician services' input expenses and will propose any changes to the MEI, if appropriate, in future rulemaking.

ASCO supports CMS' proposal to delay implementation of the 2017-based MEI. ASCO strongly recommends that once new data is implemented it is done over a multi-year transition period to mitigate any negative impact on individual practices or specialties.

ASCO supports the concept that payment rates should be based on the most current and accurate data, and we do not believe the 2017 data – which is already outdated – is worth the effort and the additional disruption it would cause to the fee schedule.

Since 2019, CMS has been updating direct practice expense (PE) data which has caused swings in PE RVUs due to budget neutrality rules. Supply and equipment PE data was updated in a transitional manner from 2019-2022. CMS also initiated a four-year transition to updated clinical labor data in 2022 that will run through 2025. Due to the budget neutral nature of the payment system, these updates have also contributed to the ongoing year-to-year instability in the MPFS.

ASCO urges CMS to consider the timing of the updated MEI data in conjunction with other major data updates to the PFS. For example, the indirect PE update will have a significant impact on oncology and other practices. When considering these updates and their timing, the agency should take a holistic approach and consider the overall impact of all the various policy changes in MPFS cycle that could impact a practice.

Telehealth

Alignment of CAA 2023 Extension of Medicare Telehealth Flexibilities

CMS proposes to align MPFS payment policies with the extension of Medicare telehealth flexibilities in the CAA, 2023. This effectively means the major telehealth flexibilities in place during the public health emergency (PHE) would remain in place through December 31, 2024. **ASCO supports CMS' proposal to extend the originating site, geographic location, and audio-only flexibilities through the end of 2024. ASCO supports continued telehealth flexibility by maintaining the existing codes on the Medicare Telehealth Services through 2024 to align with these flexibilities also.** Please see the *American Society of Clinical Oncology: Interim Position Statement Telemedicine in Cancer Care* for additional information and evidence-based telehealth policy recommendations.[10]

Medicare Telehealth Services List

CMS proposes to change the structure of the telehealth list to eliminate Categories 1–3 and convert to a "permanent" and "provisional" approach. During the PHE, CMS used its authority to add codes to the list on a temporary basis; however, its authority to do so expired with the end of the PHE. CMS is proposing new steps for adding, removing, or changing the status of services on the list on a permanent basis.

ASCO overall supports the intent of CMS' proposal to streamline the process for adding new codes to the Medicare Telehealth List, and we ask the Agency not to create standards for the addition of codes beyond what is necessary and that could potentially jeopardize patient access to telehealth.

The existing structure, particularly the current Category 2 review process, creates an extremely high bar for new codes to be added to the list. As part of a Category 2 request, Requestors must "*submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient. The evidence submitted should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings and a list and copies of published peer-reviewed articles relevant to the service when furnished via telehealth*." We believe that CMS does not need to evaluate whether providing a service via telehealth adds clinical value above the medical necessity of the service itself. Telehealth is simply a means by which health care providers deliver services—an extremely useful tool that providers can employ to expand access to care. If a physician provides a specific high-quality service to a patient, we should expect it to be as effective and add as much clinical value regardless of whether it was delivered in-person or via telehealth.

The current Category 2 criterion also seems to require a requestor to make the case that delivering a service via telehealth provides even more clinical value than conducting the service in-person. While we

[10] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-Interim-Position-Statement-Telemedicine-FINAL.pdf

appreciate that CMS' proposal clarifies that a requestor would only need to show that the service has an equivalent clinical benefit regardless of whether it is delivered via telehealth or in-person, we question the need to conduct this lower-level review. If a service is covered by Medicare and can be delivered via telehealth (i.e., it meets the first three proposed criteria), then we believe that the code for that service should be permanently added to the Medicare Telehealth List. **We therefore ask that CMS provide additional clarity and ensure that the new policy does not create barriers to the use of telehealth.**

Facility Versus Non-Facility Payment Rates

Through the end of 2024, CMS will pay telehealth services at the same rate as they would be paid if they were delivered in-person. In the proposed rule, CMS proposes to reimburse telehealth services delivered to patients at their homes at the non-facility payment rate. These services would be billed under the place of service (POS) code 10. However, for all other telehealth services, CMS proposes to pay the lower facility-based rate. Clinicians would be required to use POS 02 for these telehealth services.

ASCO, along with other stakeholders, has several questions on whether the new coding policy is permanent and how it applies to reimbursement. Specifically, the rule seems to focus on the need to ensure payment for behavioral health and mental health telemedicine services at the higher rate but does not address the need to ensure equity in payment rates for other types of services and the potential patient access implications. **ASCO supports continuing to pay for all telehealth services provided to patients in their homes at the non-facility payment rate for 2024. CMS should ensure broad coverage and adequate reimbursement for all telemedicine services through service parity and payment parity.**

Home Address

CMS suspended plans to require physicians who provide telehealth services from their home to report their home address on their Medicare enrollment through the end of 2023. CMS stated that it would address this policy in future rulemaking[11].

ASCO is extremely disappointed that CMS omitted an extension of this policy through 2024 in the proposed rule, and we strongly urge CMS to finalize policy in the 2024 Physician Fee Schedule final rule which would not require clinicians to report their home address on Medicare enrollment forms. When CMS released early rounds of PHE unwinding guidance, we received a significant amount of concern from our members regarding this provision and concerns regarding privacy. Clinician's privacy should be safeguarded, and we urge CMS to finalize policy in the 2024 Physician Fee Schedule final rule.

[11] AMA telehealth policy, coding & payment | American Medical Association (ama-assn.org)

Evaluation and Management

G2211

CMS is proposing to move forward with implementing G2211, a new add-on code for complexity, for separate payment for office and outpatient (O/O) evaluation and management (E/M) visits starting January 1, 2024. CMS clarifies that G2211 would not be payable when the O/O E/M visit is reported with payment modifier -25, which denotes a separately billable E/M service provided by the same practitioner furnished on the same day of a procedure or other service. CMS also revises its previous utilization assumption to reflect that practitioners are not likely to report G2211 with every O/O E/M visit they report. CMS now estimates that G2211 will be billed with 38% of all O/O E/M visits initially and, when fully adopted after several years, G2211 will be billed with 54% of all O/O E/M visits.

ASCO supports implementation of the new code for complexity, G2211; however, we urge CMS to provide additional billing and coding guidance and a clear definition of "complex" so clinicians know when it would be appropriate to bill the new add-on code for complexity. We also ask CMS to revise the utilization assumption for this code.

In its proposal, CMS does not provide enough information to let clinicians know when it may be appropriate to bill the add-on code along with an O/O E/M code. This lack of clarity may result in clinicians, through no fault of their own, inappropriately billing for the new code.

Clinicians typically select a level of an O/O E/M code based on the complexity of the patient encounter. Thus, if a clinician already selects the O/O E/M code that best reflects the medical decision-making or time spent for the service, the question becomes how to use the new code in conjunction with a O/O E/M code for complex cases. CMS' utilization projections include an assumption that the add-on code would be billed along with lower-level O/O E/M visits. However, the medical decision-making (MDM) or time associated with the G code could potentially be captured by simply billing a higher-level code. For example, the time associated with the G code, 11 minutes, corresponds to the difference between a lower-level established O/O E/M visit (99213) and a higher-level established O/O E/M visit (99214). In this situation, a clinician could either bill the lower-level O/O E/M visit with G2211 or the higher-level O/O E/M code and no add-on code. Both options have an equal amount of time associated with them and therefore seem to be available to clinicians in this situation. However, it is unclear which option would be the most appropriate to use.

Given the possible confusion about when to bill for the add-on code and the equivalency between billing a lower-level O/O E/M visit with G2211 and a higher-level O/O E/M code without the add-on code, ASCO questions whether the CMS utilization assumptions are accurate. While CMS has significantly reduced its utilization assumptions from what they were initially, they still are significantly higher than the actual utilization of other similar codes, such as chronic care management (found on 2.3% of total claims) and transitional care management services (found on 9.3% of eligible claims). Without greater guidance and

clarity with respect to the likely utilization of the code, we are concerned it may further distort billing under the fee schedule.

Additionally, because oncologists often bill a modifier 25 with E/M services, we believe that CMS has overestimated utilization assumptions within the oncology specialty.

Split/Shared Visits

CMS proposes to continue to allow providers to use the history, physical exam, medical decision making (MDM) or more than half of the total time spent with a patient to determine the substantive portion of the split/shared E/M in CY 2024. CMS could consider whether a revision of the definition of "substantive portion", in or beyond CY 2024, is needed through future rulemaking.

CMS should propose an alternative policy in the CY 2024 Medicare Physician Payment Schedule Final Rule that allows physicians or APPs to bill split or shared visits based on either time or medical decision-making, following the 2023 changes to E/M services, to mitigate the negative impact that the time-only option will likely have on patient care.

In the interest of supporting high-value, high-quality care, ASCO supports policies that promote full access to the most effective team-based care. ASCO recognizes that it would be inappropriate to permit a physician to bill for a visit if they do not substantially participate in the visit. However, CMS's policy to require split/shared visits to be billed based only on time fails to ensure appropriate compensation for physicians when they make a substantive contribution to team-based care for a patient. E/M code selection and levels of service continue to be based on MDM or time spent. Therefore, prohibiting the determination of the substantive portion of a split/shared E/M visit by any method other than the majority of total time is unnecessarily restrictive and detrimental.

ASCO recommends the following in accordance with the American Society of Clinical Oncology Position Statement: Medicare Policy on Billing for Split/Shared Evaluation and Management Visits[12]:

- CMS should propose an alternative policy in the CY 2023 Medicare Physician Payment Schedule Final Rule that allows physicians or APPs to bill split or shared visits based on either time or medical decision-making, following the 2023 changes to E/M services, to mitigate the negative impact that the time-only option will likely have on patient care.
- CMS should work with specialties to ensure a smooth transition to updated billing practices and adequate and appropriate reimbursement. This policy, as it stands, will require education and significant changes to day-to-day workflow.
- CMS should work with stakeholders to ensure that resources are allocated in a manner that: emphasizes team-based, evidence-supported care; reimburses physicians at adequate rates; and

[12] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-ASCO-Split-Shared-Billing.pdf

implements future reforms in a way that reduces administrative burdens encountered by patients, physicians, and other health care professionals.

Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

CMS proposes to allow payment, under Parts A and B, for dental examinations, diagnostic services, and treatment services prior to and during the following cancer treatments: chemotherapy, CAR-T cell therapy, and antiresorptive and/or antiangiogenic drug therapy. This policy does not trigger any budget neutrality adjustments to the CF. **ASCO strongly supports this proposal and urges CMS to finalize as proposed.**

ASCO recommends covering dental exams and related preventative services before institution of bone directed therapy using bisphosphonates and denosumab. We urge CMS to finalize this policy as proposed. There is no effective treatment for bisphosphonate-induced osteonecrosis, but preventative dental exams and management decrease risk of osteonecrosis of the jaw in cancer patients receiving these therapies.[13] Research shows that osteonecrosis of the jaw is a preventable condition, and that care coordination and preventative services can result in improved outcomes and in lower incidence of osteonecrosis of the jaw for cancer patients receiving bisphosphonate therapy.[14] We thank CMS for including ASCO guidelines as the rationale for coverage in the proposed rule. ASCO guidelines state that cancer patients should receive an oral care assessment (including a comprehensive dental, periodontal, and oral radiographic exam, when feasible) prior to initiating the administration of high-dose bone modifying agents (antiresorptive therapy) when used in the treatment of cancer to reduce complications and manage modifiable risk factors[15].

ASCO recommends that Medicare cover dental exams for diagnosis and treatment for Medicare patients before beginning chemotherapy or CAR-T therapies. We urge CMS to finalize this policy as proposed. Standard care in many cancer centers includes a comprehensive oral exam prior to starting therapy.[16] 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

[13] Kalra S, Jain V. Dental complications and management of patients on bisphosphonate therapy: A review article. J Oral Biol Craniofac Res. 2013 Jan-Apr;3(1):25-30. doi: 10.1016/j.jobcr.2012.11.001. Epub 2012 Nov 22. PMID: 25737876; PMCID: PMC3942225.
[14] Ripamonti CI, Maniezzo M, Campa T, Fagnoni E, Brunelli C, Saibene G, Bareggi C, Ascani L, Cislaghi E. 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. Ann Oncol. 2009 Jan;20(1):137-45. doi: 10.1093/annonc/mdn526. Epub 2008 Jul 22. PMID: 18647964.
[15] rom N, Shapiro CL, Peterson DE, et al. Medication-Related Osteonecrosis of the Jaw: MASCC/ISOO/ASCO Clinical Practice Guideline. J Clin Oncol. 2019 Sep 1;37(25):2270-90. doi:
[16] Yong CW, Robinson A, Hong C. Dental Evaluation Prior to Cancer Therapy. Front Oral Health. 2022 Apr 18;3:876941. doi: 10.3389/froh.2022.876941. PMID: 35510226; PMCID: PMC9058061.

treatment begins to mitigate the risk of oral complications.[17] Proceeding with chemotherapy prior to dental treatment services when a known oral or dental infection present is not standard of care. CAR T-cell medical services cause a patient to be immunosuppressed and an untreated oral or dental infection could complicate or compromise the clinical outcome of the CAR T-cell medical service. For these reasons we strongly support CMS' proposal and urge finalization of the proposed policy.

Request for Information (RFI): Drugs and Biologicals which are Not Usually Self- Administered by the Patient, and Complex Drug Administration Coding

CMS is soliciting comments on payment for non-chemotherapeutic complex drug administration services, in response to concerns that non-chemotherapeutic complex drug administration payment is inadequate due to existing coding and Medicare billing guidelines.

ASCO believes the current definitions and coding structures for drug administration services are appropriate and adequate to code for chemotherapy and non-complex drug administration services but recognizes that payer coverage and reimbursement of these codes is often inconsistent.

Drug administration services are currently divided into three sections of codes: Hydration (codes 96360-96361), Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (codes 96365-96379), and Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration (codes 96401-96549). The nature of the substance or drug administered, the route of drug administration, and the primary reason for the patient encounter all play a role in the selection of the codes for description of a given outpatient drug administration service. Instructions in the preamble language of the given section of the CPT manual are quite explicit in this regard.

A CPT Assistant article from February of 2009[18] highlights the intent of the drug administration codes. "The CPT codebook does not designate whether a specific drug or agent is reportable using this series of codes, but rather gives guidance as to the type of preparation, staff, risk, monitoring, and interventions that are typical of these drugs. Coverage determinations for specific drugs and agents are made by each third-party payer, as are drug/agent classifications."

ASCO understands discrepancies occur between the code or service a physician bills and whether a payer will reimburse for the service. The current coding structure is sufficient to bill physician administered drugs, whether complex or not, and payers may need to implement current coverage policy and reimburse clinicians appropriately when they bill complex drug administration services. Payers should cover and reimburse complex drug administration codes when used with non-chemotherapy drugs when the clinician appropriately documents medical necessity, as with any other service.

[17] https://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oral-complications-hp-pdq
[18] Reyes, Dan and Janette Meggs, editors. "Coding Update: Infusion/Injection Services." *CPT Assistant*, vol. 19, no. 2, Feb. 2009, pp. 17-21.

Medicare Part B Payment for Preventive Vaccine Administration Services

CMS proposes to maintain an additional payment for in-home COVID-19 vaccine administration described by HCPCS code M0201 under the Part B preventative vaccine benefit, and to extend the additional payment for the other three preventative vaccines included in the Part B preventative vaccine benefit: pneumococcal, influenza, and hepatitis B. CMS proposes this policy in light of data demonstrating that the in-home additional payment for HCPCS code M0201 improved healthcare access to vaccines for often-underserved Medicare populations, including persons who are dually eligible, of advanced age, and have common chronic conditions. **For these reasons, we support CMS' proposal to increase Medicare beneficiary access to all Part B vaccinations, including COVID-19, by extending payment for in-home vaccinations.**

Appropriate Use Criteria

CMS proposes to take more permanent action on the AUC program by indefinitely pausing it to allow the agency to re-evaluate the program and consider next steps, if any. The primary driver of the decision is the acknowledgment that CMS has too many operational challenges in implementing the real-time claims-based reporting requirement.

ASCO supports CMS' proposal to indefinitely delay the AUC program, offering practitioners and practices relief from financial and administrative burdens.

Diagnostic imaging is a critical component in the diagnosis and treatment of cancer, and ASCO supports using evidence-based criteria to reduce undesirable variations in care. We also support CMS' proposal to delay implementation of the AUC program. Establishing an AUC compatible EHR system can be very costly and burdensome for practices; therefore, we urge the Agency for at least one year's notice before planning to implement so proper preparation can be done before reinstating the program. We also urge the Agency to consider how future AUC programs may impact beneficiary access to care.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan

ASCO strongly supports CMS' proposal to continue not imposing financial penalties to clinicians that do not comply with the Electronic Prescribing for Controlled Substances and will only issue notices of non-compliance.

ASCO supports e-prescribing of controlled substances as it can improve workflow efficiencies, aid in the deterrence and detection of prescription fraud and irregularities, allow for timely and accurate data collection and may result in reduced provider burden. ASCO also recognizes the benefits of e-prescribing for Medicare beneficiaries which may include reduced logistical burden and timely access to prescriptions.

The costs associated with establishing and/or updating electronic health record systems may be prohibitive for small or under resourced practices. Penalties should not be imposed while providers are

working to implement technology that would allow them to comply, especially as many of these practices are facing financial burden due to inflation as well as staffing shortages.

Patient access to appropriate pain medication is critical for patients with cancer, and CMS should not impose restrictions, penalties, or other limitations that may interfere with beneficiary access; CMS should instead work with practices to support compliance efforts.

Removing CEHRT Use Threshold Requirements and Requiring Reporting of the MIPS Promoting Interoperability Performance Category

For performance years beginning on or after January 1, 2024, unless otherwise excluded, all Merit-based Incentive Payment System (MIPS) eligible clinicians, Qualifying alternative payment model (APM) Participants (QPs), and Partial Qualifying APM Participants (Partial QPs) participating in the Accountable Care Organization (ACO), regardless of track, would be required to report the MIPS Promoting Interoperability (PI) performance category measures and requirements to MIPS and earn a MIPS performance category score for the MIPS Promoting Interoperability performance category.

ASCO does not support this proposal as QPs and Partial QPs are statutorily excluded from MIPS and because this proposal will increase administrative burden.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) statute expressly states that the term MIPS eligible professional does not include an eligible professional who is a qualifying APM participant or a partial qualifying APM participant. We do not believe that CMS has the authority to require these individuals to report the MIPS PI category.

Currently, Advanced APMs/ACOs attest to certified electronic health record technology (CEHRT) use, which is far less burdensome than reporting MIPS PI measures. If CMS finalizes this proposal, APMs and ACOs would have to report on a new (to them) category and will need to ensure that reporting systems are established and functional only 2 months after finalization of policy. We do not agree that requiring APMs/ACOs to report MIPS PI measures will "alleviate burden" and strongly urge CMS not to finalize this proposal.

Quality Payment Program

Performance Threshold

ASCO strongly opposes increasing the performance threshold from 75 points in performance year 2023 to 82 points in performance year 2024. We strongly urge CMS not to move forward with this proposal.

Per its Regulatory Impact Analysis, CMS estimates that more than half of MIPS eligible clinicians would receive a negative payment adjustment (up to -9 percent) for the CY 2024 performance period.

Finalizing this policy further disadvantages small practices as CMS estimates that 60 percent of such practices would receive a penalty. This, in addition to the CF cut, creates an even more unsustainable payment environment for physicians who must participate in MIPS as it becomes increasingly difficult to obtain QP status (see QP Determination section below).

In addition, oncologists incur greater costs due to the nature of their specialty, and studies have shown that oncologists are more likely to be disproportionally penalized by MIPS because of the cost measures.[19] Increasing the performance threshold makes it even more challenging for oncologists to avoid a payment penalty.

CMS should recognize that during the COVID-19 PHE many participants exercised hardship exemptions and have not fully participated in MIPS for some time. Increasing the threshold and making the program more difficult as clinicians are returning to MIPS sets up a significant challenge.

On top of the threshold increase, CMS adds greater complexity to MIPS by continuing to increase the data completeness requirements and expanding the reporting period for the promoting interoperability program. Lastly, the rule 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.

Establishing the Performance Threshold

Beginning with CY 2024 performance period/2026 MIPS payment year, CMS proposes to use three performance periods as the "prior period" to establish a performance threshold.

ASCO supports the option of using three performance periods as the "prior period" to establish a performance threshold for MIPS as this will minimize outliers and provide more consistency and stability for MIPS-eligible clinicians. However, it is not appropriate to use 2017-2019 data to establish the 2024 performance threshold.

2017—the first year MIPS was implemented--was a transition year for the MIPS program, and clinicians had flexibility in the quantity of data they submitted. In 2019, CMS implemented the extreme and uncontrollable circumstances policy exception for the 2019 performance year / 2021 payment year, allowing clinicians to forego submitting 2019 data to MIPS. This likely led to an inflated benchmark and an increase in providers that would reach high performance levels due to self-selection of high performers. Lastly, the cost category was not scored during the 2017-2019 performance periods. For these reasons, the mean final scores from 2017-2019 do not accurately reflect the current MIPS program policies and requirements and it would be highly inappropriate to use this data to set current performance thresholds.

[19] Patel, V. R., Cwalina, T. B., Nortj, N., Mullangi, S., Parikh, R. B., Shih, Y.-C. T., Gupta, A., & Hussaini, S. M. Q. (2023). Incorporating Cost Measures Into the Merit-Based Incentive Payment System: Implications for Oncologists. *JCO Oncology Practice*, *19*(7), 473–483. https://doi.org/10.1200/op.22.00858.

Complex Patient Bonus for Subgroups

ASCO supports CMS's proposal to add the affiliated group's complex patient bonus to the final score of a subgroup. This would fairly recognize and compensate both the affiliated group and subgroup for treating medically complex and socially at-risk groups of patients.

Targeted Review for Subgroups

ASCO supports CMS's proposal to allow subgroups to submit a request for a targeted review beginning with the 2023 performance period. MIPS eligible clinicians and groups have this opportunity, and since subgroup reporting will be mandatory it is appropriate that CMS would finalize this proposal.

Require the Administration of the CAHPS for MIPS Survey in the Spanish Translation

ASCO supports CMS' proposal to require groups, virtual groups, subgroups, and APM Entities to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, would administer the Spanish translation to Spanish-preferring patients using the procedures detailed in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Quality Assurance Guidelines.

As the rule notes, this requirement and recommendation to utilize other translations of the CAHPS for MIPS Survey align with CMS's efforts to provide culturally and linguistically appropriate services and ultimately help advance health equity and eliminate disparities, while obtaining more survey feedback that will feed into the quality improvement loop. ASCO also agrees with CMS that groups, virtual groups, subgroups, and APM Entities should administer the CAHPS for MIPS Survey in other available translations (Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese).

Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

ASCO agrees with CMS's proposal to eliminate the automatic 10 percent ICD-10 coding change factor that triggers measure suppression and truncation, and instead assess the impact of coding changes on a case-by-case basis.

As the proposed rule notes, CMS has found that a 10 percent change to ICD-10 codes does not always reflect a meaningful change to the measure intent and measure components. ASCO supports the US Oncology Network's request that measure suppression be a last resort as providers and practices may make plans to target quality initiatives at the beginning of the year, and work towards achieving performance across key measures. If measures are suppressed at the end of the year, this could discourage and undermine the work of the care team to achieve high performance in a particular area of patient care. If the measure intent remains the same and scoring impact is minimal, providers should be able to report the quality measures.

ASCO agrees with assessing each collection type separately for a given measure with regards to taking appropriate action resulting from coding impacts.

New Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years

ASCO supports the inclusion of the *Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood* measure.

ASCO supports the inclusion of this Consensus-Based Entity's (CBE) endorsed patient-reported outcome measure. Palliative care, i.e., optimizing the quality of life and reducing suffering among people with chronic and terminal illness, is essential as the number of Americans suffering with at least one chronic disease continues to grow. Per the Geriatrics and Palliative Care, Fall 2021 Cycle: CDP Technical Report, the Standing Committee passed the measure for supporting evidence and gaps in care, and the Scientific Methods Panel scored it as a reliable and valid measure. ASCO agrees with the measure steward and CMS's assessment that the intent of the measure is to demonstrate effective patient-provider communication.

While ASCO recognizes that gains in patient activation are important, we have concerns with inclusion of *Gains in Patient Activation Measure (PAM®) Scores at 12 Months* within the MIPS program.

First, the specification only uses one qualifying encounter for clinician attribution. We recommend the measure steward include a requirement for at least two qualifying visits to illustrate a patient-clinician relationship and enhance the accuracy, fairness, and reliability of the measurement process. It helps ensure that healthcare quality assessments provide a more comprehensive and meaningful evaluation of the care delivered to patients. This approach has several important benefits:

- Increased Reliability: By requiring two or more qualifying visits, the likelihood that a single outlier visit or unusual circumstance skews the measurement is reduced. An example might be situations in which a patient gets a second opinion from a provider and sees him/her only once. Healthcare quality measures aim to provide a consistent and reliable assessment of care quality, and using multiple visits helps smooth out variations.
- Patient Variability: Patient health can vary from one visit to the next because of changes in medical circumstances, lifestyle changes, or medication adjustments. Using two or more visits can help account for this natural variability and provide a more accurate assessment of the patient's overall health and care.
- Enhanced Accountability: Requiring multiple visits can hold healthcare providers accountable for the quality of care over time rather than just during a single encounter. This encourages consistent, high-quality care throughout the patient's healthcare journey.
- Stability Over Time: When healthcare organizations are assessed for quality over time, using multiple visits ensures that the measurement is more stable and reflects their true performance, rather than being overly influenced by short-term fluctuations.

- Clinical Validity: Many clinical quality measures are based on clinical guidelines and evidence-based practices. Using two or more visits aligns more closely with the clinical reality of managing and treating patients over time, ensuring that the measurement reflects the best practices in healthcare.

We also have concerns that the current measure specification is disease agnostic and includes all chronic conditions (with a few called out specifically in the exceptions). Measuring chronic conditions individually in clinical quality measures is essential for providing effective, patient-centered care, improving healthcare outcomes, and facilitating research and quality improvement efforts. It recognizes the unique challenges and needs associated with each chronic condition and ensures that healthcare resources and interventions are appropriately allocated and targeted.

Lastly, this measure is limited to one tool (PAM®) and will therefore not have broad applicability to oncology practices that have integrated other instruments into their practice (e.g., Patient Activation in Self-Management for Cancer (PAS-MC), Oncology Patient Activation Measure (OPAM), Communication and Attitudinal Self-Efficacy Scale for Cancer (CASE-Cancer), Cancer Patient Activation Measure (CPAM), etc.).

For the reasons cited above, we also oppose adding this measure to the Advancing Cancer Care MVP and the Oncology/Hematology specialty set.

Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

TBD: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: ASCO reiterates its comments above regarding this measure. Additionally, we believe adding a third screening measure to the MVP may lead to patient and care team screening fatigue and less meaningful, actionable results. Instead of adding another screening tool with the proposed PAM measure, ASCO encourages CMS to focus on improving the existing patient survey measures to be more oncology-specific and outcome-focused. We also encourage CMS to be transparent in their plans for moving MVPs forward. Will there be a maximum number of quality measures permitted in each MVP? ASCO appreciates that clinicians can choose the measures that are most meaningful for their practice, thus a varied range of cancer measures in the Advancing Cancer Care MVP is ideal. However, if CMS will be setting limits to the number of quality measures, if added, *Gains in Patient Activation Measure (PAM®) Scores at 12 Months* would be the third patient reported survey measure and may be duplicative.

The CAHPS for MIPS Clinician/Group Survey: In lieu of the PAM survey tool/measure, ASCO believes it would be appropriate to also include *NQF #2651 CAHPS® Hospice Survey* and *NQF #005 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 also important to note that we consider the CAHPS survey to count as one measure with multiple options.

Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors. ASCO strongly supports the inclusion of this measure to the Advancing Cancer Care MVP. This measure is currently part of the traditional MIPS reporting pathway and, as the measure narrative notes, when diarrhea and colitis are immune-related, they can be life-threatening if not addressed in a timely manner. The intent of this measure is to promote appropriate interventions for managing immune-related diarrhea and colitis, and the measure is supported by several clinical practice guidelines that address this measure's quality action of holding immunotherapy and administering corticosteroids or immunosuppressant for grade 2 or above diarrhea and/or grade 2 or above colitis. A performance gap in this area exists as well, for example one study found that only 49% of health care professionals are comfortable with recognizing and managing immune related adverse events.[20] ASCO's *Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy* guideline can be found here.

PIMSH13: Mutation Testing for Stage IV Lung Cancer Completed Prior to Start of Targeted Therapy: ASCO supports the inclusion of this measure; it was developed in partnership between the US Oncology Network and McKesson to foster appropriate biomarker testing and use of available targeted treatments.

Q487: Screening for Social Drivers of Health: This measure utilizes screening tools to assess areas of patient needs resulting from various social drivers. ASCO and others (e.g., The US Oncology Network) have encouraged CMS to improve upon this measure by monitoring 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.

ASCO requests that CMS update Q453: *Percentage of Patients Who Died from Cancer Receiving **Chemotherapy** in the Last 14 Days of Life* (lower score – better) to read *Percentage of Patients Who Died from Cancer Receiving **Systemic Cancer-Directed Therapy** in the Last 14 Days of Life* (lower score – better), to reflect the updated CY 2023 specifications.

Improvement Activities

ASCO strongly supports and thanks CMS for the inclusion of *IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program*. As ASCO noted in its comments last year, the ASCO Quality Training Program is an example of an activity that meets the requirements of this IA.

[20] Pai S, Blaisdell D, Brodie R*, et al*. Defining current gaps in quality measures for cancer immunotherapy: consensus report from the Society for Immunotherapy of Cancer (SITC) 2019 Quality Summit *Journal for ImmunoTherapy of Cancer* 2020;8:e000112. doi: 10.1136/jitc-2019-000112.

QP Determination

CMS is proposing to make QP determinations at the individual eligible clinician level only, instead of at the APM Entity level. ASCO has significant concerns with this proposal and with CMS' justification for changing how the QP determination is made. Making all the QP determinations at the individual level would make it extremely difficult for oncologists to meet the QP thresholds, which is required to avoid MIPS reporting and instead report under an Advanced Alternative Payment Model (APM).

The QP thresholds are determined by law. The Consolidated Appropriations Act, 2023, extended the QP thresholds of 50% for the payment amount method and 35% for the patient count method through performance year 2023 (payment year 2025). However, starting in performance year 2024 (payment year 2026), the QP thresholds are set to increase to 75% for the payment amount method and 50% for the patient count method. According to the most recent data CMS released, the average payment threshold score for MSSP was 46.42 and 53 for the Oncology Care Model. The average patient threshold scores were 45.18 for MSSP and 21 for OCM. [21] Even under the prior year's thresholds, clinicians would fall short of reaching the target thresholds for QP status.

With CMS's proposed change it would be exceedingly difficult for individual clinicians to meet these high thresholds, especially oncologists who see patients in different healthcare settings. Many oncologists treat patients within multiple health care systems, some of which are part of an Advanced APM and others that are not. All Medicare patients that the clinician sees, regardless of health system, would be included in the denominator; however, only those patients in the health system that is part of the APM would be included in the numerator. Calculating the QP status at the individual level does not accurately capture this oncologist's performance and would make it very difficult or impossible to reach the high QP thresholds.

ASCO does not support CMS' proposal to make QP determinations at the individual level alone. We recommend that CMS determine QP status at both the APM entity level and the individual level and designate the clinician as a qualifying participant based on qualification in either category.

CMS is proposing changes to longstanding policy by making QP determinations at the individual level instead of the APM entity level because of what they call a free-rider scenario – when an individual who would not meet the QP threshold individually reaps the financial benefits of the APM entity that does achieve QP status. While we know that these scenarios do occur, CMS needs to understand that specialists are committed to achieving quality care for their patients, and they are meaningfully engaged in ACOs. They participate in governance of the ACO, participate in shared electronic health records, and implement data collection strategies to reduce total cost of care. They may not reach QP status as an individual because of how policy is implemented, but they are contributing to the success of the ACO. If CMS determines QP status at the individual level and does not recognize the work they do by including

[21] Advanced Alternative Payment Model (APM) Incentive Payments for 2023.

them in the APM entity QP status, specialists will receive no incentive for the increased work and time they spend improving the ACO.

Because of the narrow scope of EOM, no future increased enrollment in EOM and the general lack of specialty specific models, clinicians have no APM opportunities to add to their denominator through other specialty models. Based on old data from the Oncology Care Model, even those few participants in EOM will likely not meet the thresholds on an individual level.[22]

Since CMS has the discretion to make QP determinations at the individual level instead of the APM entity level, then we believe they also have the discretion to establish other means of ensuring meaningful participation in a qualifying APM at 42 CFR 425.306.

Even with the suggestion above, there is a likelihood that many specialists will be unable to meet the statutory thresholds. One core reason is the MSSP exclusivity rule which prevents clinicians with certain primary specialty designations, including medical oncology, hematology/oncology, gynecology/oncology, from participating in more than one MSSP (42 CFR 425.306 and 42 CFR 425.402).

ASCO recommends that CMS allow specialists caught in step 2 of 42 CFR 425.306 the flexibility to participate in more than one ACO, which would increase the numerator and therefore the likelihood of reaching the QP threshold. Only some medical specialties, including oncology, are restricted in such a way, while others have the opportunity to participate in more than one ACO.

Instead of calculating QP status at the individual level and pushing specialists out of APMs, CMS should incorporate the recommendations included above to encourage specialist participation in advanced AMPs and achieve the goals of the Quality Payment Program.

Advanced APM CEHRT Requirement

CMS is proposing to remove the 75% threshold and have the Advanced APM require the use of the certified electronic health record technology (CEHRT) for QP performance periods beginning in 2024.

ASCO supports CMS' proposal for the definition of CEHRT to vary based on unique model characteristics. We urge the agency to incorporate a transition period allowing 75% OR attesting to CERHT use before complete elimination of the 75% threshold.

ASCO supports allowing for a more flexible interpretation of CEHRT requirements to allow them to be more reflective of the unique nature of specific models, clinical conditions, and patient populations. This flexibility is necessary to accommodate the unique needs of practices participating in these models and the patients they serve. We also recommend that that CMS be flexible when moving away from the 75% threshold. The goal is to have everyone participate so we ask that CMS implement this change in a

[22] Advanced Alternative Payment Model (APM) Incentive Payments for 2023.

manner that promotes CEHRT adoption and does not penalize practices or prevent them from participating in an APM.

Conclusion

ASCO commends the Agency on the many proposals in this rule supporting the holistic care of cancer patients. Access to navigation services has been shown to improve care delivery during and after cancer treatment, and as CMS acknowledges, dental services are a necessary component of cancer treatment. ASCO is committed to addressing and improving health equity. We believe CMS is beginning to make critical changes that will foster physicians' ability to address patients' SDOH needs, which have been shown to improve patient clinical outcomes. We would like to collaborate with the Agency during the implementation process of these proposals to ensure patient, clinician, and practice success.

Despite the commendable policy changes, ASCO is concerned with the current and future landscape of physician reimbursement if changes are not made to support physicians. A 5% increase to the conversion factor in the last 22 years is unacceptable, and only made more problematic by the challenges faced by oncologists in the Quality Payment Program. Current and proposed policies are further preventing physicians from successful participation in APMs – increased administrative burden, the absence of an APM incentive payment in 2024, and challenges attaining QP status are all forcing physicians away from APMs and into the MIPS program.

However, the MIPS program is not a safe space for physicians either. If CMS moves forward with the proposal to increase the performance threshold, more than half of physicians will earn a penalty in 2024, and small practices will bear a disproportionate share. ASCO has long invested in self-evaluation and quality improvement, but many aspects of the current Quality Payment Program add to administrative burden and cost of practice--and do not reflect accurately on the quality of care offered by oncology clinicians.

Offering services that are critical to successful cancer patient outcomes should not come at the expense and devaluation of other, also necessary services. We acknowledge Congressional action is needed to address budget neutrality, and we strongly urge CMS to work with us and Congress to adopt physician payment reform legislation. We urge CMS to use its regulatory authority to adopt the recommendations in this letter to support physicians and physician practices across the county.

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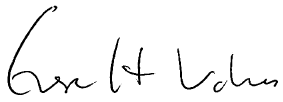
ASCO
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

We appreciate the opportunity to comment on the 2024 Medicare Physician Fee Schedule and Quality Payment Program proposed rule. Please contact Gina Hoxie (gina.hoxie@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



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