

September 16, 2020

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Department of Health and Human Services

Attention: CMS-1734-P

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Submitted Electronically at www.regulations.gov

Re: Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy [CMS-1734-P]

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1734-P) proposed rule with comment period published in the Federal Register on August 18, 2020.

ASCO is a national organization representing nearly 45,000 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.

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Below are our comments on specific provisions of the Physician Fee Schedule (PFS) and the Quality Payment Program (QPP) as outlined in the 2021 proposed rule.

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I. Physician Fee Schedule Provisions

Budget Neutrality

ASCO urges CMS to work with Congress to implement positive updates to the Medicare conversion factor to offset the appropriate increases to office visits.

The 2021 proposed physician conversion factor (CF) is \$32.2605. When compared to the 2020 CF of \$36.0896, the proposed 2021 CF represents a decrease of \$3.83, or 10.6%. This negative adjustment, that impacts all services across the fee schedule, results from the budget neutrality adjustment to account for changes in work relative value units (RVUs). The change in work RVUs is driven largely, but not entirely, by updates to evaluation and management (E/M) services that were finalized in the CY 2020 PFS Final Rule and are effective January 1, 2021. ASCO supports the payment policy updates for E/M services and, along with other stakeholders, is urging HHS and Congress to work together to suspend budget neutrality in 2021.

When the COVID-19 pandemic began to impact the United States, oncologists had to quickly adapt their practices to mitigate the spread of the coronavirus. These necessary changes resulted in unforeseen and

unexpected financial consequences such as lost revenue from the delay and cancelation of procedures, cancer treatments and visits; increased infrastructure costs; and increased purchasing of personal protective equipment and supplies. As a result, many oncology practices are currently facing significant economic hardships. ASCO is concerned that the financial insecurity resulting from this public health emergency will only be worsened by the budget neutrality adjustments in CY2021. ASCO strongly supports the E/M payment policy changes CMS has finalized for 2021; however, we are concerned that the negative effects of a greatly reduced CF will create additional undue provider burden during an already stressful and trying time.

Evaluation and Management (E/M)

ASCO supports the E/M payment policy updates CMS will put into effect in 2021.

As finalized in the CY 2020 PFS final rule, in 2021 CMS will largely align its E/M visit coding and documentation policies with changes laid out by the American Medical Association CPT Editorial Panel for office and outpatient E/M visits, beginning January 1, 2021. CMS will move forward with implementing the changes finalized to E/M services in the 2020 final rule including increased work RVUs, code selection based on total time spent or medical decision making, addition of the GPC1X code for visit complexity, and the addition of a prolonged service code. ASCO thanks CMS for collaborating with stakeholders during this process and encourages CMS to continue to do so as the payment policy for the remaining E/M service categories are re-evaluated in the coming years.

Telehealth

CMS should make permanent coverage and reimbursement for audio-visual services and, when appropriate, audio-only services and continue to expand coverage for all modes of delivery of telemedicine.¹

On March 17, 2020, CMS announced the expansion of telehealth services on a temporary and emergency basis under the waiver authority added under section 1135(b)(8) of the Social Security Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. Starting on March 6, 2020, Medicare was authorized to pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in the patient's home. This included the authority to loosen restrictions and make regulatory changes to telehealth during the public health emergency (PHE) to increase access to telehealth for both beneficiaries and their physicians and practitioners. In response to these temporary policy updates, CMS is soliciting comments on several of telehealth provisions in this proposed rule including: coverage and reimbursement for audio-only services and the addition of services to the CMS telehealth list on a permanent and temporary basis.

Payment for Audio-Only Visits

Under waiver authority, in the first COVID-19 interim final rule (IFC) CMS established coverage and payment for audio-only services, which Medicare had previously not covered as a typical service. CMS recognized that the audio/visual technology required for telehealth services is not always available to all

¹ https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/Interim_Position_Statement_Telemedicine_2020.pdf

Medicare beneficiaries. And with the goal of reducing exposure risks to COVID-19, the agency believed there were circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate and set the payment consistent with the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) recommendation in the 2008 final rule. ASCO and other stakeholders informed CMS that audio-only were in greater demand than CMS had originally believed. Additionally, physicians had been successfully using audio-only to manage complex care. CMS acknowledged that the intensity and time commitment required to furnish an audio-only visit during the COVID-19 pandemic was not accurately captured by the valuation established in the first IFC; therefore, CMS increased the reimbursement rates for these services to equal the rate of in-person, established patient E/M services.

The agency is not proposing to continue covering and reimbursing for audio-only services beyond the PHE for the COVID-19 pandemic as a telehealth service; however, CMS does recognize that the need for audio-only interactions could remain as beneficiaries continue to try to avoid sources of potential infection.

ASCO is committed to supporting efforts that ensure oncologists have the resources they need to provide high-quality cancer care regardless of where that care is delivered; therefore, we believe CMS should cover and reimburse audio-only services. Analysis of data from ASCO practices shows that of all services provided through technology-based communications from mid-March through mid-June, audio-only visits make up 35%-50% of these technology-based visits; virtual check-ins made up less than 1%.² Cancer patients are heavily relying on audio-only E/M services and need CMS to ensure they have access to get the care they need.

CMS has acknowledged that many Medicare patients lack access to audio/visual communications. The lack of broadband and/or access to technology for both patients and physicians will not be limited to the time during the PHE; these populations could potentially benefit from audio-only services. We continually hear concerns from physicians who need to have lengthy and complicated conversations with their patients who do not have access to two-way, audio/visual communications. ASCO's Policy Statement on Cancer Disparities and Health Equity commits ASCO to "support and promote policies, systems, environments, and practices to address persistent barriers to equitable receipt of high-quality cancer care across the care continuum."³ CMS should work to promote health equity through encouraging the use of telemedicine in all care settings, including but not limited to rural and safety net providers. CMS should cover and reimburse audio-only services in order to prevent the unintentional exacerbation of health inequities.

Cancer patients, because they are often immuno-compromised, are an especially vulnerable subset of the Medicare population. Granting physicians flexibility to provide clinically appropriate and high-quality care to these beneficiaries through audio-only means can help keep these vulnerable patients in their homes, reducing unnecessary exposure to all illnesses, not just COVID-19. While we agree with the agency that telehealth platforms incorporating both audio/visual two-way communication—when available – is preferred, there are instances when this is not possible. This lack of access to technology, often impacting patients vulnerable to other disparities in care, will not be limited to the time during the

² <https://www.asco.org/sites/new-www.asco.org/files/content-files/practice-and-guidelines/documents/2020-PracticeNET-COVID19-Insights.pdf>

³ <https://ascopubs.org/doi/pdf/10.1200/jco.2008.21.1680>

PHE; therefore, we urge the agency to permanently cover and reimburse audio-only services beyond the PHE.

Requests to Add Services to the Medicare Telehealth Services List for CY 2021

ASCO supports the coverage and inclusion of additional services on the Medicare telehealth list, and we encourage CMS to continue soliciting stakeholder comments and feedback regarding potential future additions.

Through the rule-making process, CMS has the authority to add services to the list of covered Medicare telehealth services. The agency includes services on a Category 1, or permanent, basis when they determine that the services being added are similar to those on the existing list of covered Medicare telehealth services. CMS includes services on a Category 2, also permanent, basis when the agency determines that the services being added are not similar to Category 1 services but there is demonstrated clinical benefit to the patient and other requirements are met.

For CY 2021, CMS is proposing to add nine services on a permanent, Category 1 basis. The agency is also proposing to create an additional temporary category, Category 3, which includes services added to the Medicare telehealth list during the PHE for the COVID-19 pandemic that will remain on the list through the calendar year in which the PHE ends. Category 3 as proposed includes 13 services that were added during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria.

ASCO thanks CMS for soliciting stakeholder comment regarding the additional permanent and temporary services placed on the Medicare telehealth list. In our recently released interim position statement⁴, ASCO urges CMS to extend the expanded telemedicine policies after the expiration of the PHE; therefore, we support this proposal to permanently and temporarily add services to the telehealth list as this has the potential to increase access to services for cancer patients. Additionally, ASCO believes quality care is based on evidence, and we urge CMS to evaluate the safety, quality of care, and outcomes resulting from telehealth visits and to consider specialty input and insight when considering additions in future rulemaking.

Electronic Prescribing of Controlled Substances

ASCO supports delaying the e-prescribing of controlled substances requirement until January 1, 2022, allowing CMS sufficient time to address ASCO's and other stakeholders' comments.

Since Medicare Part D was signed into law in 2003, electronic prescribing (e-prescribing) has been optional for physicians and pharmacies for prescriptions made for covered Part D drugs. However, Part D sponsors offering drug plans have been required to have the electronic capabilities to support electronic prescribing. Section 2003 of the SUPPORT Act requires physicians to electronically prescribe a Schedule II, III, IV, or V controlled substance under Medicare Part D in accordance with an electronic

⁴ <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-Interim-Position-Statement-Telemedicine-FINAL.pdf>

prescription drug program beginning January 1, 2021. CMS states that although they believe e-prescribing is more efficient, it does take additional time and resources to implement as practices must have the electronic capabilities in addition to following DEA guidance requiring two-factor authentication. Additionally, CMS recognizes the challenges COVID-19 has placed on some prescribers to be prepared by January 1, 2021.

CMS is proposing to require all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 standard by January 1, 2022. CMS is requiring the NCPDP SCRIPT 2017071 standard as it is required in Medicare Part D; CMS believes that prescribers should use the same standard for e-prescribing controlled substances. To help inform CMS' implementation of section 2003, the agency recently issued a Request for Information to solicit stakeholder feedback on whether CMS should include exceptions to the electronic prescribing of controlled substances (EPCS) requirement and under what circumstances and whether CMS should impose penalties for noncompliance with the EPCS mandate. CMS will use this public feedback to draft separate rules to further implement this SUPPORT Act provision. CMS believes that delaying implementation until 2022 affords providers time to prepare while still stressing the importance of expediting implementation.

ASCO supports e-prescribing of controlled substances for prescribers 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 e-prescribing has for Medicare beneficiaries including reduced logistical burden and timely access to prescriptions; however, we also urge CMS to continue to recognize the unique situation cancer patients are in vis-a-vis controlled substances. ASCO is submitting comments in response to the July RFI, and we urge CMS to consider our input before implementation. Our recommendations are as follows:

- CMS should not impose penalties on prescribers if they do not adhere to e-prescribing requirements. Physicians need time to acquire and become familiar with using the technology; CMS should recognize that instances may occur when the beneficiary prefers a traditional prescription.
- CMS should consider the benefits and drawbacks of e-prescribing for underserved Medicare patients. ASCO supports safe and unburdened access to opioids for all cancer patients.
- Patient access to appropriate pain medication should be the greatest concern, and CMS should not impose any restrictions, penalties, or limitations that may interfere with beneficiary access.
- Prescribers who might not have optimized electronic health record (EHR) technology prior to COVID may have greater capacity to do so now, and CMS should analyze, discuss, and share e-prescribing data from the COVID-19 pandemic.

Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

We urge CMS to list the drugs approved through the 505(b)(2) pathway that would be mapped to a multiple source code and to state the financial impact this proposal would have on the Medicare program.

Separately paid Medicare Part B drugs fall into one of two categories: single source (brand drug sold by one manufacturer) or multiple source drugs (brand and generic). The payment limit under section 1847A of the Act for a single source drug is based on the pricing information for that one (brand) produced or distributed under the applicable FDA approval, while the payment allowance for multiple source drugs is based on the volume-weighted average ASPs of all drug products assigned to the HCPCS code. Drug products approved through the pathway established under section 505(b)(2) of the Food, Drug, and Cosmetic Act rely partly on safety and effectiveness information from studies not conducted by or for the applicant, nor is the application required to have the same labeling as the approved drug(s) that the application relied upon. Drugs approved through this pathway can be either single or multiple source drugs.

CMS is proposing to move certain drugs that went through this approval pathway from single-source codes to multi-source codes, which would affect reimbursement. CMS is proposing to continue assigning certain 505(b)(2) drug products to existing multiple source drug codes. To determine whether the product can be assigned to an existing multiple source drug code for the purpose of payment, CMS proposes the following criteria:

- The product's active ingredient(s), drug name and description
- The product's labeling information
- How a drug is ordered (prescribed) and used clinically

We appreciate CMS' efforts to lower drug prices for Medicare beneficiaries, and we understand the intent; however, we are concerned with the lack of transparency CMS has put forth in this proposal. For ASCO to submit meaningful and appropriate comments we need to understand the extent to which this proposal may or may not affect reimbursement for anti-cancer therapies. We are concerned that if the payment limit for a drug moves from single source to multiple source this could lower reimbursement resulting in financial implications for the physicians offering the therapy. If reimbursement is insufficient to cover the cost of the drug it will be difficult or impossible for physicians to treat cancer patients appropriately.

Physicians need to be adequately reimbursed for drugs to ensure that their patients have access to the most effective treatment. In the proposed rule, CMS states that two recently introduced section 505(b)(2) drug products are comparable to drug products in existing multiple source drug codes and currently have Medicare payment allowances that are approximately 10 times higher than that of the existing multiple source code. This is a significant difference in reimbursement and could seriously affect a physician's ability to procure the treatment if CMS does not adequately reimburse for the drug. In the event that these are therapies on which oncologists and their cancer patients rely, we would like to have all the necessary facts to provide informed comment on this proposal. CMS states that some drugs approved through the 505(b)(2) pathway meet the criteria for a single source code, and we would like to understand which drugs CMS determines do and do not meet these criteria, especially as the number of drugs approved through the 505(b)(2) pathway has nearly doubled since 2011.

In addition to our concerns regarding lack of transparency in this proposal, ASCO also expresses concern that this proposal could lead to additional prior authorization and utilization management hurdles for cancer patients. Utilization management policies often flow from assumptions regarding the availability of clinically equivalent oncology drugs within the same general class or category, which is one of the

three criteria CMS is proposing. However, in many cases oncology drugs do not have substitutes that are both equally effective and less expensive for a given patient. Given that drugs approved through the 505(b)(2) pathway use “safety and effectiveness information from studies not conducted by or for the applicant” we express our concern regarding the safety of this proposal on cancer patients. Policies that result in cancer patients receiving therapies that are not recommended by their oncologist can threaten both the outcomes for patients and the well-being of their families or caretakers.

National Coverage Determinations

ASCO expresses concern that if this proposal is finalized, CMS will set a precedent to facilitate removal of increasingly relevant and more widely used NCDs, which has the potential to reduce access patient to care.

CMS is seeking comments on the proposal to remove nine National Coverage Determinations (NCDs). CMS believes that these NCDs may no longer contain pertinent or clinically relevant information and are rarely used by beneficiaries. Services that were automatically covered under these NCDs will now be covered at the Medicare Administrative Contractor’s (MAC’s) discretion, and coverage of services that were previously barred by the NCD is also at the discretion of the MAC. CMS believes this will result in greater contractor flexibility and will better serve the needs of Medicare beneficiaries.

Although it seems a benign proposal to remove outdated NCDs with low volume, and we appreciate that CMS is proposing to use criterion established in 2013 to identify and remove NCDs that they believe no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries, ASCO is concerned that if this proposal is finalized as proposed, this may lead to the removal of additional NCDs with greater utilization or that are necessary for beneficiaries to receive coverage of services. We are concerned that this is a slippery slope and could easily pave the way for additional removal of NCDs upon which Medicare patients heavily rely, and thus eroding access to care. By giving MACs the discretion to cover a service currently included in these NCDs decreases transparency for both the patient and the physician and creates inconsistencies across the Medicare program. ASCO supports evidence-based medicine and believes that CMS is better positioned to monitor current evidence than individual MACs. In an effort to maintain transparency, integrity, and quality within the Medicare program we urge CMS to exercise caution and to carefully consider how removal of these NCDs may affect beneficiary access to care.

II. Quality Payment Program (QPP) Provisions

MIPS Value Pathways (MVPs)

ASCO supports CMS' proposal to delay the implementation of MIPS Value Pathways (MVPs) until 2022 or later.

In the 2020 Fee Schedule Final rule, CMS established that participation through MIPS Value Pathways (MVPs) would begin with the 2021 performance period. However, due to stakeholder concerns about this timeline and with clinicians working hard to address the spread of COVID-19 within their practices and communities, CMS will not be introducing any MVPs into the program for the 2021 performance period. ASCO supports this decision as clinicians are focused on caring for their patients during a pandemic and will not have the additional resources required to learn and implement what is essentially an overhaul of the MIPS program. We would further urge CMS to consider delaying MVP implementation beyond 2022 based on ASCO's earlier arguments—and those of other stakeholders-- that such an overhaul of the MIPS program should be phased in gradually in order for clinicians to familiarize themselves with the new requirements; these issues existed before the current pandemic and have only been exacerbated by it.

ASCO also supports the proposal to continue the traditional MIPS participation option as MVPs are gradually phased in. We believe this will give interested clinicians the ability to attempt earlier adoption of MVPs while also allowing those who are not yet prepared for such a change a longer timeframe for learning and adoption. Related to this phase-in, ASCO encourages CMS to consider a "pilot" year for the initial MVPs; under this scenario, practices willing to report on MVPs could be held harmless for effects of the MVP on scoring which may encourage participation and would allow CMS to collect valuable data on feasibility and initial performance. Finally, a pilot year could also provide real-life data to inform CMS' efforts around scoring alignment for MIPS and MVPs.

As CMS took a gradual implementation approach to MIPS in 2017 and 2018, CMS should also view the first two years of each new MVP as a transition period. It will take time to develop, refine, implement and educate physicians about the specific features of an MVP. Physicians may also be concerned that by adopting the new MVP approach, they will be at risk for a negative payment adjustment, especially given that it is still completely unclear how scoring for an MVP would work or if the same scoring thresholds would apply to MVPs and traditional MIPS. Rather than mandate that physicians or groups report certain MVPs, CMS should incentivize physicians to report MVPs. Possible incentives include more timely data and data analysis and reporting on a smaller set of patients during the transition to MVPs. Additionally, physicians should be incentivized to report on new quality measures and to report new MVPs to encourage the development of new, more meaningful reporting opportunities.

We urge CMS to hold physicians harmless from a penalty for the first two years of participation in a new MVP. This transition period should be rolling and begin when a new MVP is introduced into the program. Although several specialty societies are submitting an MVP proposal for 2021, most physicians will not have an MVP option in the near term. In addition, a transition period is critical for incentivizing

specialists who have been participating at a group level but would move to sub-group participation in an MVP, which is potentially more administratively burdensome than reporting as a group.

CMS should consider the expenses to adopt and administer an MVP for physicians in small practices who have been reporting via claims, as well as physicians in health systems and group practices that have been reporting via the CMS Web Interface. We urge CMS to consider incentives to participating in MVPs, such as aligning scoring of MVPs with MIPS alternative payment models (APMs) and across payment systems similar to the facility-based scoring methodology.

Finally, CMS should also incentivize specialty societies, who have devoted limited resources toward developing measures, QCDRs and alternative payment models, to propose MVPs. For example, CMS should provide specialty societies with more QPP and claims data to help them identify MVP opportunities and reduce the costs of developing them and proposing them to CMS.

APM Performance Pathway (APP)

ASCO supports CMS' proposal to make optional the new APM Performance Pathway (APP) for MIPS APMs, but is concerned about the mandatory nature of the APP for Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program (MSSP) and opposes the abrupt retirement of the CMS Web Interface ("GPRO") for group reporting of quality measures.

CMS is proposing a new APM Performance Pathway (APP) reporting option in 2021 to align with the MVP framework. As part of the APP introduction, CMS will be sunsetting the CMS Web Interface as a collection type beginning in the 2021 performance period. While this change will significantly reduce the number of measures required to be reported by ACOs participating in the Medicare Shared Savings Program, as well as groups and virtual groups that report through the CMS Web Interface, it will also require these groups to report on a larger pool of patients (70% of all patients versus the 248 Medicare patients included in the CMS Web Interface), include non-Medicare patients, and adopt new reporting mechanisms for quality reporting with which they may not be as familiar (i.e. QCDR/registry or EHR). APM entities do not necessarily share an EHR, especially ACOs. This factor is typically less of a problem if an entity is reporting on less than 250 patients; however, the requirement for reporting on 70% of a large ACO's patients would likely require synchronization of EHRs to capture the same measures and consolidate data.

We appreciate the agency's arguments for the sunsetting of the Web Interface, including the decrease in users over time and the expense of continuing the Web Interface for a decreasing number of users. However, the agency acknowledges that the loss of approximately 80% of current users in 2021 would be due to the agency's own proposed requirements that ACOs must begin reporting through the APP in 2021 and would thus be terminated from the interface due to the new policy, with no other option provided. In such a scenario, rather than an abrupt termination of the Web Interface, we would encourage CMS to continue this reporting mechanism for an additional year to allow for a transition period for those practices to prepare for a new reporting mechanism; we believe this flexibility to be especially important during a pandemic when resources are already stretched thin.

APM Scoring Standard

ASCO encourages CMS to allow for a transition year from the APM scoring standard to the MIPS scoring standard for MIPS APMs.

CMS is continuing to allow MIPS eligible clinicians (ECs) to participate in MIPS as individuals or as part of a group or virtual group and is expanding the use of the APM Entity submitter type to allow the use of all MIPS submission mechanisms.

In past years, MIPS ECs participating in MIPS APMs were required to participate in MIPS through their APM Entity for scoring under the APM Scoring Standard. CMS is proposing to end the APM Scoring Standard beginning with the 2021 performance period. Additionally, CMS is proposing to add the APM Entity as a submitter type which may report to MIPS on behalf of associated MIPS eligible clinicians.

The APM Entity would be defined by the Participation List or Affiliated Practitioner list of the applicable MIPS APM. The APM Entity would be able to report on the Quality and Improvement Activities performance categories. Quality measures could be selected and reported in the same manner and using the same options that are available to all other MIPS eligible clinicians, or could be reported through the APP. The Cost category would also be scored for APM Entities that do not report through the APP. When an APM Entity chooses to report to MIPS, CMS would generally calculate a Promoting Interoperability performance category score for the APM Entity group.

Lacking access to the granular data CMS has at its disposal it is difficult to know exactly the impact on practices—including one-sided risk Oncology Care Model (OCM) practices--that a change in scoring standards would have. We would therefore encourage CMS to allow for a transition year for practices to adapt to the new requirements.

Subgroup Reporting

ASCO supports the flexibility for practices to engage in optional “subgroup” reporting of measures and cautions that CMS must recognize the additional practice burden involved with subgroup reporting via incentives such as scoring incentives or lessened reporting burden elsewhere.

ASCO has previously supported the ability of participants within a practice to break out into “virtual groups” or “subgroups” for the purposes of selecting and reporting meaningful quality measures. In this proposed rule, CMS proposes this option for MVPs, which presumably would take effect during the performance year MVPs are introduced. We support this flexibility as long as it remains optional and would encourage CMS to extend this concept to the reporting of all MIPS measures, not just the MVP bundle.

Performance Threshold and Performance Category Weights

ASCO supports CMS' proposal to set the performance threshold at 50 points instead of the 60 points originally finalized given the difficult circumstances practices are facing during a pandemic. ASCO also supports the continued phase-in of performance category weights to the final weights required by statute in 2022.

CMS continues to incrementally adjust the performance threshold and performance category weights to meet the requirements established by the statute. Beginning with the sixth year of the program (2022 performance period), the performance threshold needs to be set at the mean or median of the final scores for all MIPS eligible clinicians for a prior period, and the quality and cost performance categories must be equally weighted at 30% each.

CMS proposes to set the performance threshold for 2021 at 50 points instead of the 60 points previously finalized, while keeping the exceptional threshold at 85 points. CMS proposes the following category weights for the 2021 performance period: quality performance category, 40%; cost performance category, 20%; promoting interoperability performance category, 25%; and improvement activities performance category, 15%. By law, the cost and quality performance categories must be equally weighted at 30% beginning in the 2022 performance period, so the weights CMS proposes allow for a final phase-in to the final 2022 weights.

Specific Performance Category Proposals

CMS should not finalize its proposal to apply the 7-point achievement cap to quality measures that are found to be "topped out" for two consecutive years if that finding is based on performance period data from 2021.

ASCO agrees with CMS that, due to the pandemic and ensuing reporting flexibilities allowed for 2019 data submission, it is likely that the agency may not have a representative sample of historic data for CY 2019 in order to create historic measure benchmarks for the 2021 performance period. Due to this concern, the agency is proposing to use performance period benchmarks for 2021 instead of possibly skewed historical benchmarks.

Paired with this proposal, CMS is proposing to apply a cap of 7 achievement points, for the 2021 performance period and beyond, to measures that are identified as topped out for 2 or more consecutive years including the 2021 MIPS performance period benchmarks. Taken together, these proposals would put clinicians at risk of inadvertently reporting on a measure that is subject to the 7-point cap, if that measure were found to be topped out in the 2021 performance period. Although clinicians could ascertain the topped-out status of a given measure for the 2018 performance period, he or she would have no way of knowing if that measure would become topped out for a "second" year in the 2021 performance period. We are concerned that this could lead to artificial lowering of scores beyond the clinician's control and may disincentivize the reporting of measures that would otherwise be considered for reporting. ASCO urges CMS not to finalize this proposal for the 2021 performance year.

ASCO supports the proposal to establish policies in relation to the Annual Call for Improvement Activities including an exception to the nomination timeframe during a public health emergency (PHE).

Prior to the PHE, CMS had established a process and timeline—the Annual Call for Activities—for the submission or nomination of new or updated improvement activities. During the PHE, CMS developed and implemented new improvement activities designed to reward and incentivize pandemic-related activities such as participation in Covid-19 clinical trials and Covid-19 clinical registries. These new activities were developed outside of the usual Call for Activities and are of benefit to patients and clinicians. Subsequently, CMS proposes to establish permanent policies in relation to the Annual Call for Activities including an exception to the nomination period timeframe during a public health emergency (PHE); ASCO supports this proposal as it affords the agency and interested stakeholders the opportunity to submit meaningful new improvement activities that reflect real-world events and are of value to patients and clinicians.

ASCO supports the agency’s proposal to retain the “Query of Prescription Drug Monitoring Program (PDMP)” measure as an optional measure in the promoting interoperability category and to award 10 bonus points for this measure.

Clinicians across the country have made great strides in their adoption of PDMPs despite a continuing lack of interoperability across many systems. ASCO continues to advocate for increased interoperability between and amongst electronic medical record systems and PDMPs and has also advocated for policies to ease the administrative burden associated with PDMP inquiries such as “batch-checking” and delegation, and we support the retention of this measure as optional in the QPP.

Cost Measures

CMS should discontinue in MIPS use of the cost measures discussed below until such time it can be shown that the measures are valid, reliable, and can be attributed appropriately.

ASCO continues to raise serious concerns regarding the use of the Medicare Spending per Beneficiary (MSPB) and Total per Capita Cost (TPCC) measures in MIPS. On June 26th, 2020, ASCO submitted comments to the National Quality Forum (NQF) outlining our concerns with these measures prior to the deliberations of the NQF Cost and Efficiency Technical Expert Panel (TEP). The TEP recently met and made preliminary recommendations: it voted not to support the revised MSPB measure for MIPS and could not reach consensus on the TPCC measure for MIPS.

In our follow-up comment letter sent to NQF on September 14th, 2020 (Appendix 2), ASCO strongly supported the decision not to endorse the MSPB measure and urged the Committee not to endorse the TPCC measure. Given that NQF has not endorsed these measures—yet NQF endorsement of measures is required for entities other than CMS—it would be inconsistent for CMS to continue to use these measures in MIPS, particularly in light of serious ongoing concerns regarding measure validation and attribution, and we urge CMS to remove them from the program.

Other Scoring Proposals (COVID-19 Flexibilities for PY 2020)

ASCO supports CMS' proposal to increase the maximum number of points available for the complex patient bonus for performance year 2020.

CMS is proposing to change the maximum number of points available for the complex patient bonus to account for the additional complexity of treating patients during the COVID-19 PHE. As proposed, clinicians, groups, virtual groups, and APM Entities could now earn up to 10 bonus points towards their final score for the 2020 performance year, double the originally finalized five points. CMS is proposing this increase for the 2020 performance period only.

ASCO supports this proposal and we hope that CMS will also consider applying it for performance year 2021, depending on circumstances, recognizing that such a policy would have to be retroactively applied as it is not discussed in the 2021 proposed rule.

ASCO supports the agency's proposal to allow individuals, groups, virtual groups, and APM entities to submit an application to reweight MIPS performance categories as a result of extreme and uncontrollable circumstances, such as the PHE resulting from the COVID-19 pandemic.

In the proposed rule, CMS is proposing to allow APM Entities to submit an application to reweight MIPS performance categories as a result of extreme and uncontrollable circumstances, such as the public health emergency resulting from the COVID-19 pandemic. If an application were approved, it would remain in force even if MIPS data was subsequently reported (this marks a departure from usual CMS policy). This policy would apply beginning with the 2020 performance period.

Following the release of the proposed rule, on August 17, 2020, CMS updated its QPP COVID-19 Response Fact Sheet⁵ to reflect additional flexibilities for non-APM practices. CMS announced that physicians will have the option to opt-out completely or partially from the 2020 MIPS program by completing a hardship exemption application that is associated with the COVID-19 Public Health Emergency (PHE). Practices may request reweighting of the cost and quality categories to zero (in which case they would be scored on promoting interoperability and improvement activities) or may request to opt out of all four performance categories and avoid a 2022 payment adjustment. For these non-APM practices, CMS policy that submission of MIPS data to CMS after a hardship exception approval would override the application approval would remain in effect and physicians would be scored on any data submitted.

ASCO strongly supports these proposals that will allow practices to obtain hardship exemptions given the current climate of extreme stress and uncertainty for practices and patients. Practices should not have to waste valuable time and resources attempting to comply with reporting requirements that they likely will not be able to meet for 2020; moreover, practices can ill afford to be penalized financially through no fault of their own at this time of great resource constraints when they are already struggling

⁵ <https://qpp-cm-prod-content.s3.amazonaws.com/uploads/966/QPP%20COVID-19%20Response%20Fact%20Sheet.pdf>

to keep their doors open. We thank CMS for providing this flexibility and urge the agency to work with clinicians and practices to decrease all reporting and regulatory burdens as much as is feasible.

ASCO supports the agency’s proposals for flexibilities for ACOs including the application of the “Extreme and Uncontrollable Circumstances” policy.

For performance year 2020, all ACOs are considered affected by the Public Health Emergency (PHE) for the COVID-19 pandemic, and the Shared Savings Program extreme and uncontrollable circumstances policy applies. In addition, for performance year 2020 only, CMS is proposing to waive the requirement for ACOs to field a Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey. Consequently, ACOs would receive automatic full credit for the patient experience of care measures.

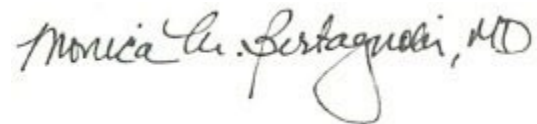
Corrections to Measure Specifications

During our review of *Table Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2023 MIPS Payment Year and Future Years*, we identified errors in two measures (D.29 and D.30) and note the correction to those errors in Appendix 1.

* * * * *

ASCO appreciates the opportunity to comment on the proposed rule. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology

Appendix 1

Table Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2023 MIPS Payment Year and Future Years: Identified Errors and Necessary Corrections

D.29 Oncology: Medical and Radiation – Pain Intensity Quantified; NQF 0384, 0384e/Quality# 143/eCQM CMS157v9: The rationale of “We propose to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.” should include denominator 1 and 2. Telehealth has been added as an eligible encounter for all collection types, therefore the rationale should read, “We propose to add telehealth encounters as denominator eligible for submission criteria 1 and 2 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.”

D.30 Oncology: Medical and Radiation – Plan of Care for Pain; NQF 0383/Quality# 144: Similar to D.29, the rationale of “We propose to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.” should include denominator 1 and 2. Telehealth has been added as an eligible encounter for all collection types, therefore the rationale should read, “We propose to add telehealth encounters as denominator eligible for submission criteria 1 and 2 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.”

Appendix 2

ASCO comments to the National Quality Forum

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to submit comments to the National Quality Forum (NQF) Cost and Efficiency Technical Advisory Panel. Following are our general comments on the Medicare Spending per Beneficiary (MSPB) and Total per Capita Cost (TPCC) measures.

ASCO is the national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members 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, including Medicare beneficiaries.

Given the growing number of episode-based cost measures, and continued work on their development, ASCO would encourage the NQF and CMS to consider whether the TPCC and MSPB measures still serve a purpose, as many of the beneficiaries captured in the episode-based measures will also be included in either or both the MSPB and TPCC measures. With the measures as proposed, a beneficiary could potentially be attributed to multiple providers within and across multiple measures. First, this could magnify the impact on cost measures of any individual beneficiary and second, could complicate any true differences in cost and value. CMS developed these measures specifically for use in the Merit-based Incentive Payment System (MIPS) and we believe that the measure and attribution should demonstrate that its use in MIPS will not just yield reliable and valid results, but most importantly, enable end users to make meaningful distinctions in the costs associated with the care provided to these patients.

3574: Medicare Spending Per Beneficiary (MSPB) Clinician

ASCO appreciates the Committee's thoughtful review and we strongly support the current recommendation to not endorse this measure. We agree with the concerns on the reliability and validity of the measure, which are consistent with our pre-evaluation comments. Further information and testing must be provided to demonstrate that its use in MIPS will yield reliable and valid results and enable end users to make meaningful distinctions on the costs associated with the care provided to these patients. Outside of an ACO setting or other risk-sharing arrangement that covers all care provided to a population, the measures attribute costs to providers for care they did not provide and who have limited control over many of those costs. The measures do not provide insight into which treatments are most effective in providing high quality, low cost care. Episode-based cost measures are a better approach to evaluating value.

3575: Total Per Capita Cost (TPCC)

The American Society of Clinical Oncology (ASCO) appreciates the Committee's thoughtful review and we urge the Committee to not endorse this measure. In addition to the concerns on the measure's validity outlined in the report, we believe that information on reliability results below the 25th

percentile, the measure's correlation to quality, and a discussion on the attribution methodology are needed prior to endorsing this measure.

The summary in the body of the report and Appendix A did not include any discussion on the attribution methodology, which we believe is a significant threat to the validity of the measure. While the TPCC eliminates the problem of attributing costs that occurred before the clinician ever saw the patient, which the AMA supports, the current approach could attribute the measure to practices that billed only 34.8% of the total E&M claims for a beneficiary and for clinicians it is only 28.9% of the total E&M claims billed. We believe that these percentages are lower than desirable and validate the concerns that the AMA expressed to CMS during development and testing of this measure. The attribution methodology assumes that a primary care relationship exists if two things happen within three days or three months, and not otherwise, leading to problems as identified in the following examples:

- A cancer survivor receives a twelve-month follow-up exam from their oncologist, along with a two-dimensional echocardiogram with doppler flow study to screen for cardiotoxicity. The oncologist is attributed the beneficiary's costs for a twelve-month period, despite no other management of the patient.
- A newly diagnosed cancer patient requests a second opinion from an oncologist other than their primary clinician. The oncologist conducts an evaluation and management service which happens to take place within +/- 3 days of other designated primary care services. The oncologist performing the second opinion confirms the primary clinician's treatment plan and the patient returns to their primary clinician for continued management and treatment. The consulting oncologist is attributed the beneficiary's costs for a twelve-month period, despite never having managed the beneficiary's care.
- A nurse practitioner is employed by a cancer practice to assist in management of cancer patients receiving chemotherapy and/or radiation therapy. The nurse practitioner does not qualify for an exemption from the measure given that a physician's NPI, rather than theirs, is used to bill for the chemotherapy services.
- An oncologist whose TIN includes in-office chemotherapy services is attributed a patient who receives chemotherapy services within 90 days after an E&M primary care service, but outside of +/- 3 days of the E&M primary care service. An equivalent hospital-based oncologist is not attributed a similar case, as the chemotherapy services are billed by the hospital TIN.
- An oncologist whose TIN includes in-office chemotherapy services qualifies for an exemption from the measure due to their NPI-TIN being used to bill for chemotherapy services. An equivalent hospital-based oncologist does not qualify for an exemption, as the chemotherapy services are billed by the hospital TIN.

In each of these examples, an oncologist will not know if they qualify for the TPCC measure, as the exemption is applied retrospectively based on a measurement of candidate events for which the oncologist bills for chemotherapy or radiation therapy services. We feel it is inappropriate for a clinician to be included in a measure for which they are unaware of which beneficiaries they may be attributed, or whether they will receive an exemption. We have previously recommended that all medical and radiation oncologists be excluded from the TPCC measure.

ASCO believes that the concerns outlined by the Committee during the initial review along with the fatal flaws in the attribution methodology should result in the measure not achieving a recommendation for endorsement. We appreciate the Committee's consideration of our comments.