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September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted Electronically at www.regulations.gov

Re: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements. [CMS-1751-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 Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1751-P) proposed rule with comment period published in the Federal Register on July 23, 20201

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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ASCO recognizes the changes CMS is continuing to make to improve payment policies for Medicare services and appreciates CMS' willingness to engage stakeholders in discussions of proposed changes to both the Physician Fee Schedule (PFS) and Quality Payment Program (QPP) policies. ASCO supports some of the proposed updates and has concerns regarding others CMS has proposed for calendar year (CY) 2022. A summary of our comments is below:

Physician Fee Schedule

- ASCO strongly urges CMS work with Congress to address the looming cuts to reimbursement resulting from the reduced conversion factor, the expiration of the Medicare sequestration moratorium, and the statutory sequestration set to take effect in January of 2022.
- ASCO supports CMS' proposal to update labor prices and encourages CMS to update practice expense inputs on a more frequent basis; however, we strongly urge CMS to delay implementation of the updated labor prices until CMS can work with ASCO to establish rates for RN/OCN clinical labor and until Congress can address a permanent legislative fix to budget neutrality.
- ASCO supports CMS' proposal to extend coverage of Category 3 telehealth services through the end of CY 2023; however, we strongly urge CMS to add office/outpatient services for telephone evaluation and management to the category 3 list.
- ASCO strongly supports CMS' proposal to permanently adopt coding and payment for audio-only virtual check-in code G2252 and to continue to expand coverage for all modes of delivery of telemedicine.
- ASCO supports regulatory updates to waive co-insurance and simultaneously to increase the Medicare payment, keeping providers whole, for screening colonoscopies and sigmoidoscopies when they become a diagnostic procedure.
- ASCO supports delaying the e-prescribing of controlled substances compliance requirement until January 1, 2023.
    - ASCO supports CMS' proposal to waive e-prescribing requirements for a prescription issued when the practitioner and dispensing pharmacy are the same entity.
    - ASCO supports CMS' proposal to waive e-prescribing requirements in cases of recognized emergencies and extraordinary circumstances such as natural disasters, environmental hazards, or a pandemic, and in cases of prescribers facing extraordinary circumstances preventing them from electronically prescribing a controlled substance such as lack of broadband.
- ASCO urges that CMS 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.
- ASCO supports CMS' proposal to delay enforcement of the AUC program, offering practitioners and practices relief from financial and administrative burdens.

Digital Quality Request for Information

- ASCO offers perspective on CMS' four-stage plan to transition CMS' quality measurement enterprise to fully digital by 2025.

Health Equity Request for Information

- ASCO offers perspective on how CMS can improve data collection and measurement to help advance health equity in the Medicare program.

Quality Payment Program

- ASCO does not support CMS' proposal to sunset traditional MIPS in favor of the newly created MVPs in 2028. There is no statutory requirement for MVPs, and CMS should not implement MVPs until there has been successful uptake and use of MVPs by clinicians. Only by examining clinicians' use of MVPs can CMS make an informed proposal on the eventual sunsetting of traditional MIPS.
- As the steward of the Oncology: Plan of Care for Pain (NQF #0383) measure, ASCO strongly urges CMS not to remove this measure from the MIPS program beginning with the 2022 performance year as proposed.
- ASCO offers comments on proposals in each of the four performance categories, quality, cost, promoting interoperability, and improvement activities.

We offer our full perspective and comments on provisions in the CY 2022 Medicare Physician Fee Schedule and the Quality Payment Program in greater detail in the balance of this letter.

Physician Fee Schedule

Reimbursement Impact on Oncology

In 2022, oncology practitioners are expected to absorb alarming decreases in reimbursement because of four primary factors: the 3.75% decrease to the PFS conversion factor (CF), the reinstatement of Medicare sequestration, statutory sequestration, and decreases in Relative Value Units (RVU) for oncology services. As a result of these 4 factors, we estimate that on average, Medical Oncology will experience a 10.2% decrease and Radiation Oncology will face a 12.95% decrease in reimbursement in 2022.

ASCO strongly urges CMS to work with Congress to address the looming cuts to reimbursement resulting from the reduced conversion factor, the expiration of the Medicare sequestration moratorium, and the statutory sequestration set to take effect in January of 2022.

The proposed CY 2022 PFS conversion factor is $33.58, a decrease of $1.31 (-3.75%) from the CY 2021 PFS conversion factor of $34.89. Signed into law on December 27, 2020, the Consolidated Appropriations Act (CAA) of 2021 funded a 3.75% positive payment adjustment which helped mitigate some of the scheduled reductions to the CY 2021 CF. The 3.75% decrease largely reflects the end of the additional money funneled into the PFS for 2021. As this update was only funded for CY 2021, Congress will need to act to extend it beyond 2021.
In addition to the reduction in the CF, physicians are facing other payment cuts that can only be averted with Congressional action. These payment reductions include expiration of the moratorium on Medicare sequestration at the end of CY 2021 and statutory sequestration cuts required by Pay-As-You-Go (PAYGO) legislation, which were triggered by the significant additional spending in the American Rescue Plan enacted in March 2021. Together, these cuts represent a 6% decrease in reimbursement in 2022.

These payment reductions come at a time when physician practices, hospitals that employ physicians and other stakeholders are facing uncertainty about the future of pandemic recovery, whether and what flexibilities for telehealth services will continue beyond the public health emergency, and challenges brought on by other regulatory burdens. ASCO is concerned that the financial insecurity resulting from this public health emergency will only be worsened by the budget neutrality adjustments in CY2022 and the congressionally mandated reductions in reimbursement. For oncologists to maintain healthy practices and 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 2022.

Labor Price Updates

The remaining factor contributing to decreases in RVUs for oncology services is the update of 20-year-old clinical labor expense inputs and a resulting budget neutrality adjustment that CMS estimates will further the reimbursement cuts by 2% for medical oncology and 5% for radiation oncology, severely jeopardizing patient access to cancer care.

ASCO supports CMS' proposal to update labor prices and encourages CMS to update them on a more frequent basis; however, we strongly urge CMS to delay implementation of the updated labor prices until CMS can work with ASCO to establish rates for RN/OCN clinical labor and until Congress can enact a permanent legislative fix to budget neutrality.

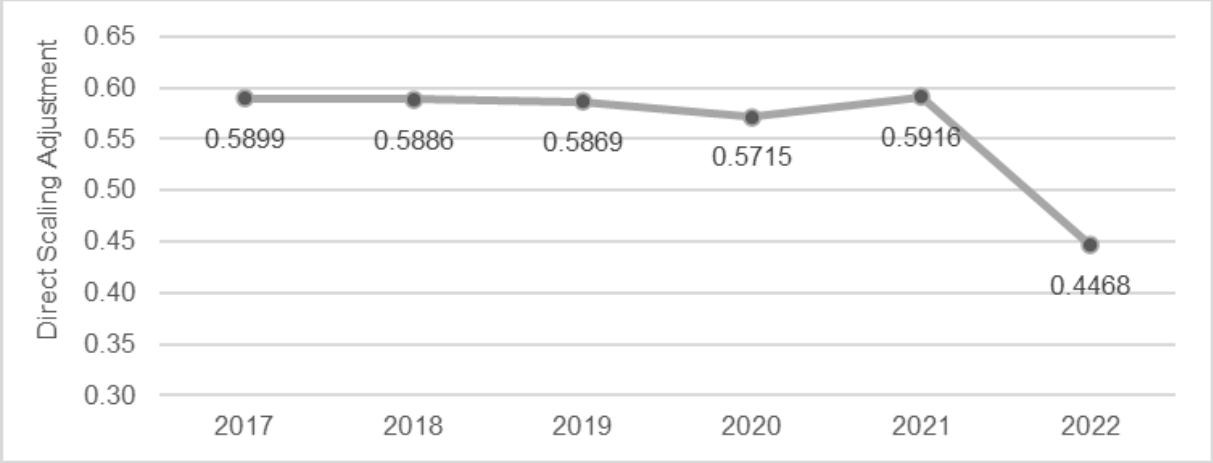
We agree with CMS that clinical labor prices should be updated and that in many cases the Bureau of Labor Statistics (BLS) data may be the most appropriate data upon which to set the rate for certain clinical labor types; however, we ask CMS to delay implementation of labor price updates until CMS and ASCO can work together to establish an appropriate rate for RN/OCN clinical labor as we have previously done. The BLS does not include RN/OCN wage data, and ASCO is concerned that CMS' methodology for estimating RN/OCN price inputs does not result in an accurate reflection of this cost. The RN/OCN price inputs set by CMS are based on proprietary data. As such, ASCO is not able to verify its accuracy and appropriateness. As proposed, RN/OCN price is tied to the nuclear medicine technologist clinical labor type, which was not the case prior to this update and is not an appropriate crosswalk. We also have concerns with the way CMS is proposing to "blend" labor rates. Finally, we do not believe that CMS is capturing important differences in wages between certified and non-certified oncology nurses.

We have worked successfully with CMS in the past to establish accurate RN/OCN rates, and we believe this remains the best approach. We strongly urge CMS to delay implementation of the labor price update until ASCO and other stakeholders can work with the Agency to establish accurate methodology and labor price inputs for current RN/OCN labor.

While we agree that in theory it is suitable to update labor prices so that all direct inputs (supply, equipment, and labor) are updated in the same timeframe, we have grave concerns that despite an increase in labor rates, the resulting outcome is a decrease in RVUs and reimbursement putting access to cancer care at risk. If labor updates are finalized as proposed, the scaling factor will see the largest decrease it has in five years (see figure 1), and direct labor rates for all other inputs are to be decreased by 24%. The direct scaling factor leads to unfair absolute cuts in RVUs despite the increase in clinical

labor rates. We strongly urge CMS to update the direct practice expense inputs on a more regular basis avoiding such drastic and extreme shifts in the scaling factor and resulting changes to RVUs.

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



Even more urgently, we call on CMS to work with Congress to address the root problem, a budget neutrality requirement that decreases PE RVUs in order to accommodate appropriate increases in clinical labor rates. ASCO strongly urges CMS to work with Congress to make permanent legislative fixes to MACRA and budget neutrality so that increases are reflected in RVUs when appropriate and to maintain the intended relativity within the PFS. Currently, no additional funds are earmarked for the PFS for the next five years. Instead, these funds are used for MIPS bonuses. However, MIPS practitioners have not received bonuses substantial enough—even before the COVID-19 PHE—to offset decreases in the PFS. Practitioners are reporting simply to avoid a penalty. We understand that CMS does not have the authority to adjust statutory requirements for MIPS scoring. As such, we strongly recommend that CMS and Congress come together to address budget neutrality and increase funding for the fee schedule.

Telehealth Services List

In the CY 2021 Final Rule CMS provided coverage through the end of the PHE for over 100 services that had been added to the Medicare Telehealth List on an interim basis (i.e., category 3). In this rule, CMS is proposing to extend coverage to these services through the end of CY 2023 and is soliciting comments on additional codes to be included as category 3 with Medicare coverage through the end of CY 2023.

ASCO supports CMS' proposal to extend coverage of Category 3 telehealth services through the end of CY 2023; however, we strongly urge CMS to add office/outpatient services for telephone evaluation and management to the category 3 list.

ASCO thanks CMS for soliciting stakeholder comment regarding the extension of category 3 services temporarily placed on the Medicare telehealth list. While we support coverage of these services through

the end of 2023, we strongly encourage CMS to add office and outpatient telephone evaluation and management (E&M) codes 99441-99443 to this list of category 3 services.

Like CMS, 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, including office/outpatient telephone E&M services. We also support CMS for considering specialty input and insight when making further additions to the telehealth services list. In our recently released interim position statement[1], we state that we support reimbursement for audio-only services when appropriate. Should CMS refuse to add telephone E&M services to the category 3 list, cancer patients, practitioners, and policy makers will lose this opportunity to better understand impact of telephone E&M utilization and its health outcomes. The lack of data will also obviate stakeholder's ability to offer potentially meaningful and insightful comments regarding the continuation of coverage and reimbursement for audio-only E&M. We ask that CMS include audio-only E&M services on the telehealth list on a temporary basis through the end of 2023.

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 hear concerns regularly from physicians who routinely have time-intensive conversations about complex medical issues with 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."[2] CMS should promote health equity by encouraging the use of telemedicine in all care settings, including rural and safety net providers. CMS should cover and reimburse audio-only services 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 continue far beyond the PHE; therefore, we urge the agency to add telephone E&M as a category 3 telehealth service.

Virtual Check-In Code

In its CY 2021 PFS Proposed rule, CMS established, on an interim basis, code G2252 for an extended virtual check-in (11-20 minutes), which could be furnished using any form of synchronous

[1] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-Interim-Position-Statement-Telemedicine.pdf
[2] https://ascopubs.org/doi/10.1200/JCO.20.00642

communication technology, including audio-only. CMS established a payment rate of 0.50 work RVUs. CMS is proposing to permanently adopt coding and payment for code G2252.

ASCO strongly supports CMS' proposal to permanently adopt coding and payment for audio-only virtual check-in code G2252 and to continue to expand coverage for all modes of delivery of telemedicine.[3]

Colorectal Cancer Screening Tests

Following a statutory change in the Consolidated Appropriations Act of 2021, CMS is proposing regulatory changes that will reduce the financial burden of colorectal cancer screening to beneficiaries. Screening colonoscopies and sigmoidoscopies that detect a lesion and lead to tissue removal, will be treated as screening rather diagnostic procedures and subject to special screening payment provisions. CMS will phase in a reduction in beneficiary co-insurance requirements between 2022 and 2030, at which point beneficiary co-insurance will be zero. Effective January 1, 2022, CMS proposes to increase the Medicare payment percentage while the beneficiary coinsurance percentage decreases. **ASCO supports these regulatory updates to waive co-insurance and simultaneously increase the Medicare payment, keeping providers whole, for screening colonoscopies and sigmoidoscopies when they become a diagnostic procedure.**

Electronic Prescribing of Controlled Substances (EPCS)

The SUPPORT Act required that Medicare Part D prescriptions for controlled substances be prescribed electronically starting on January 1, 2021. In previous rules, CMS pushed back the deadline for EPCS compliance until January 1, 2022. The Agency is now proposing a start date of January 1, 2023. CMS also proposes that the threshold prescribers would need to meet for compliance is 70 percent of their controlled substances being e-prescribed in a calendar year and outlines exceptions and waivers from the e-prescribing requirement.

ASCO supports delaying the e-prescribing of controlled substances compliance requirement until January 1, 2023.

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 of e-prescribing for Medicare beneficiaries, including reduced logistical burden and timely access to prescriptions. However, we also urge CMS to continue to recognize the unique situation practices and patients face during the COVID-19 pandemic. As CMS has delayed many other deadlines providing necessary administrative relief to practitioners, we urge CMS to stay the course and delay this compliance requirement until 2023 also.

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

Costs associated with updating systems may also be prohibitive for some small practices that may not have electronic health records. 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 during the COVID-19 pandemic. Patient access to appropriate pain medication is critical and CMS should not impose any restrictions, penalties, or limitations on providers that may interfere with patient access.

ASCO supports CMS' proposal to waive e-prescribing requirements for a prescription issued when the practitioner and dispensing pharmacy are the same entity. ASCO supports waivers for practices with in-office dispensing, avoiding redundancies in e-prescribing that may prove inefficient for patients. Additionally, CMS should recognize that instances may occur when the beneficiary prefers a traditional prescription. For cancer patients who may benefit from receiving prescriptions from their physicians, the likelihood of adherence and quality improvement increases, and this process should not be interrupted. CMS should be assured that reporting associated with prescribing of controlled substances can still occur in these instances. ASCO encourages CMS to finalize the waiver for practices with pharmacies, affording prescribing flexibilities to practices with in-office dispensing.

ASCO supports CMS' proposal to waive e-prescribing requirements in cases of recognized emergencies and extraordinary circumstances such as natural disasters, environmental hazards, or a pandemic, and in cases of prescribers facing extraordinary circumstances preventing them from electronically prescribing a controlled substance such as lack of broadband. 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. Practitioners facing external factors preventing the e-prescribing of controlled substances should not prevent them from providing necessary and quality care to some of Medicare's most vulnerable cancer patients. While CMS states that the attestation form for a waiver would be made available on a CMS-supported website, we urge CMS to consider those without broadband and to offer alternative methods for submitting a waiver request such as phone or fax.

Medicare Part B Payment for Drugs Approved through the Pathway Established under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act

In the 2021 PFS, CMS proposed to move certain drugs approved through the pathway established under section 505(b)(2) of the Food, Drug, and Cosmetic Act pathway from single-source codes to multi-source codes, which would affect reimbursement. CMS also proposed to continue assigning certain 505(b)(2) drug products to existing multiple source drug codes. CMS proposed criteria to determine whether the product could be assigned to an existing multiple source drug code for the purpose of payment. ASCO submitted comments in response to the 2021 proposal asking CMS for additional information on the affected drugs and the financial impact of this proposal.

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

We appreciate CMS' efforts to lower drug prices for Medicare beneficiaries, and we understand the intent of this proposal; however, offering the decision framework alone does not help us discern the impact this proposal could have on oncology physicians and patients. As we stated in our comments on the 2021 PFS proposed rule, for us to submit meaningful and appropriate comments we need to understand the extent to which this proposal affects access and 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 must be adequately reimbursed for drugs to ensure that their patients have access to the most effective treatment. In the 2021 proposed rule, CMS stated that two 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 necessary treatment if CMS does not adequately reimburse for the drug. These may be therapies on which oncologists and their cancer patients rely. As such, we would like to have all the necessary facts, especially as the number of drugs approved through the 505(b)(2) pathway has nearly doubled since 2011.

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 are concerned about the safety of this proposal—and potential harm to clinical outcomes—for patients with cancer. For ASCO to submit meaningful comments, we ask that CMS list the drugs approved through the 505(b)(2) pathway and the resulting financial impact this proposal would have on the Medicare program.

Appropriate Use Criteria

CMS proposes to delay enforcement of the Appropriate Use Criteria (AUC) program by at least one year until the later of January 1, 2023, or the January 1 that follows the end of the public health emergency. The AUC program requires ordering physicians to consult appropriate use criteria using a clinical decision support mechanism prior to ordering advanced imaging services for Medicare beneficiaries and furnishing physicians to report this information on the claim. Currently, CMS is scheduled to begin denying claims that do not report AUC information on January 1, 2022.

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

The proposed delay recognizes the significant disruptions caused by the COVID-19 pandemic and will allow more time for the education and operations testing period, which is critical given CMS' finding that only 9-10 percent of 2020 diagnostic imaging claims would have met the AUC reporting requirements if enforcement had been in effect.

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' gradual implementation of the AUC program, which allows practices to ready their EHR and other health information technology systems for consultation with appropriate use criteria. Establishing an AUC compatible EHR system can be very costly for practices. This extra cost can be prohibitive during pandemic-free years and is especially burdensome during the COVID-19 PHE. By extending the educational and operational testing period in 2022, CMS is providing additional opportunity for practitioners to better prepare for the full implementation of the AUC program.

Digital Quality Request for Information

CMS aims to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025 while also updating and aligning quality measures across the different reporting programs. The RFI accompanying the proposed rule seeks comment on a four-stage plan to transition CMS' quality measurement enterprise to fully digital by 2025.

CMS proposes a common definition for digital quality measures (dQMs) as follows:

> "a software that processes digital data to produce a measure score or measure scores."

Based on this definition, data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (e.g., medical devices and wearable devices), patient portals or applications (e.g., for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources defined by the Secretary.

CMS is considering whether to require Fast Healthcare Interoperable Resources (FHIR®) as the common standard. Under its four-part plan, CMS would then:

1. Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based application program interfaces (APIs)
2. Redesign its quality measures to be self-contained tools (meaning the agency can retrieve data; calculate measure score(s), and produce reports)
3. Better support data aggregation
4. Work to align measure requirements across reporting programs and the private sector, where appropriate

Digital Quality Measurement Questions and ASCO Responses

Definition of Digital Quality Measures.

- Do you have feedback on the dQM definition?
    - *ASCO has concerns regarding the term "software" and would like CMS to clarify the intended definition of software and the implications for measure developers. Software development is a different skill set than measure development and technical specifications. Computer readable documentation or computer executable (e.g., MAT exports) may be a more appropriate term. In envisioning dQMs as self-contained tools,*

ASCO seeks clarification on CMS' expectations on measure developers to identify or partner with HIT vendors creating FHIR APIs, and the potential added burden this may pose for medical specialty societies.

- *The overarching concern is the significantly increased cost of measure development to medical specialty societies. This cost has the potential to become increasingly burdensome to the point that many medical specialty societies may stop developing measures*.

- Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.
  - *Although the list of data sources listed in the definition may be too broad to be realistic, ASCO agrees the list of data sources to be included with dQMs is appropriate; however, FHIR is not yet mature enough to integrate all of these data sources within one measure. The use of FHIR as the transmission standard would be workable, but we would call out the need for specialty-specific implementation guides (IGs). It's not enough to say "use FHIR." We ask CMS to consider what the requirements will be for the third-party intermediaries for the ability to aggregate all these data sources. Will CMS be the data aggregator and calculate the measure score from these data sources, or will this responsibility be on the third-party intermediaries?*
  - *This also significantly increases the burden of the measure developers for testing. It is already a challenge to test eCQMs from one data source (EHRs), and testing measures that have data from multiple data sources may be impossible, and even if possible, too expensive to obtain data for testing. ASCO is concerned about the effect the aggregation of multiple data sources in a dQM paradigm could have on measure stewards' ability to demonstrate measure validity and reliability.*
  - *ASCO is concerned that the requirement for all measures to be digital could restrict the options for what measures are developed and stray too far from the clinical quality of measures and more towards data capture and availability. CMS notes that a common portfolio of dQMs would mean required data elements would be limited to standardized, interoperable data elements to the fullest extent possible. ASCO is concerned this may effectively limit de novo measure development in accordance with a limited set of data elements that are standardized and interoperable, which could in turn significantly narrow the scope of oncology measures that can be implemented in payment programs. Certain areas of oncology treatment are advancing rapidly, and the standardization and interoperability of data elements may lag behind emerging evidence and impede the deployment of new measures that assess performance gaps in newer areas of care delivery.*
  - *ASCO is concerned with CMS' proposal of an ecosystem with all of these data sources when the calculation of existing quality measures using data from source EHRs still uncovers gaps in data which hinder quality measure calculations.*

Use of FHIR for Current eCQMs.

- Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers?

  - *We agree that FHIR can reduce burdens but will require adequate IGs for all oncology use cases (or extensions to existing IGs).*
- What could we include in a CMS FHIR Reporting IG to reduce burden on providers and vendors?
  - *We recommend starting with the Minimal Common Oncology Data Elements (mCODE®) STU v2 IG from HL7 when finalized post-ballot in 2021. This may require additional extensions to the IG depending on the measures.*

Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

- Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements?
  - *Yes, but operationalizing this will be challenging.*
- Are there specific FHIR Implementation Guides suggested for consideration?
  - *HL7 FHIR IG*
- How important is a data standardization approach that also supports inclusion of patient-generated health data (PGHD) and other currently non-standardized data?
  - *We would ask CMS to consider how PGHD will be accessed and how the protected health information (PHI)/consent issues will be handled.*
  - *ASCO supports the collection of PGHD for clinical care but deems its use in CMS quality measurement programs too experimental.*
- What are possible approaches for testing data quality and validity?
  - *The challenge is access to the various data sources. CMS should provide a standardized actual patient data set for testing.*
- What functionalities should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?
  - *Oncology data elements do not lend themselves easily to standardization and maintenance of interoperable, computer-readable, and up-to-date data dictionaries. Another challenge is the lack of a mandate to implement data capture standards within EHRs. Data in structured EHR fields varies widely among implementations because data capture standards have not been widely adopted by EHR systems and practices. We remain concerned with how CMS will operationalize this.*
- How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?
  - *There is a higher risk of decreasing engagement due to cost and specialized expertise needed for digital measure development.* Depending on where the burden of responsibility lies in creating or identifying FHIR APIs, this approach could marginalize medical specialty societies who may be challenged to find increasingly sophisticated technical staff or partner with HIT vendors to create dQMs
- Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

    - *Will data aggregation from multiple sources jeopardize data integrity? Would there be a "system of record" for each source? For example, would there be multiple overlapping EHR data feeds or would attribution be required for each data source type?*
- How can CMS best facilitate and enable aggregation?
    - *CMS will have to play a role in facilitating aggregation, as the various participants will be reluctant to freely share data. There are already significant issues with data blocking and EHRs.*

While ASCO believes that access to near real-time quality measure scores would benefit an oncology practice, we do have reservations that purely digital quality measurement is possible, even by 2025, without the wholesale requirement of the use of data standards developed for oncology, such as mCODE. mCODE is a focused set of data elements developed by a collaboration of oncology experts; data elements were selected based on their broad applicability to cancer patients and survivors and to support a variety of cancer care and research applications across a variety of cancer types. As a Health Level 7 (HL7) Standard for Trial Use (STU) these elements were refined with broad input and review through the HL7 ballot; they are currently being tested through a variety of implementation use cases managed through the CodeX™ HL7 FHIR Accelerator™.

Health Equity Request for Information

CMS solicits comments on how the agency can improve data collection and measurement to help advance health equity in the Medicare program and requests that stakeholders provide additional information about how the agency can improve reporting and application of health disparity data related to social risk factors and race and ethnicity. Health equity and cancer disparities have long been a focus in ASCO's programs and policy work, and we look forward to working closely with CMS to ensure equitable access to high quality cancer care.

ASCO's recently published Cancer Disparities and Health Equity Policy Statement[4] summarizes past efforts and offers numerous recommendations to the broader cancer care community. These recommendations include the promotion of policies and systems to address persistent barriers to equitable care, such as equitable payment reforms, alternative payment models, and financial assistance programs. The policy statement also highlights persistent shortcomings in the clinical cancer research enterprise, as well as structural barriers to equitable care, and proposes solutions to address these obstacles to cancer health equity.

Risk assessment tools flag when a patient is at increased risk for developing cancer compared to the average person. The inclusion of race and ethnicity in these models may result in earlier or more frequent screening, but it does not affect the standard recommendation for screening. For example, breast cancer screening for most patients is recommended on an age-basis. If a risk assessment tool

[4] Patel, M. I., Lopez, A. M., Blackstock, W., Reeder-Hayes, K., Moushey, E. A., Phillips, J., & Tap, W. (2020). Cancer disparities and health equity: A policy statement from the American Society of Clinical Oncology. Journal of Clinical Oncology, 38(29), 3439-3448.

determines race increases patient risk for breast cancer, then a provider may recommend breast cancer screening earlier than the age-based standard.

ASCO is encouraged that research efforts to improve the calibration and accuracy of cancer risk assessment tools are ongoing. Experts continue to expand the number of risk factors that are incorporated into risk tools and recognize the importance of ongoing validation in various racial and ethnic populations to improve generalizability. As these efforts continue, it is imperative that racial and ethnic minorities are included in this work, to ensure that the tools are accurate in assessing risk for all populations. ASCO is committed to ensuring all individuals have access to high quality cancer care, including timely and appropriate screening, based on the patient's needs.

ASCO recognizes that patient data are often incomplete, inaccurate, or overly simplified and usually do not consider many social and community factors.[5] Moreover, cancer disparities research is limited by a lack of comprehensive, consistent data on factors that impact disparities in cancer care and patient outcomes, including a patient's social status and demographics, community and lifestyle factors, and biology and genetics. Widespread variation in data collection methodologies has also compromised the utility of select data sets for disparities research. In a joint statement regarding the future of cancer disparities research, ASCO joined the American Association for Cancer Research (AACR), the American Cancer Society (ACS), and the National Cancer Institute (NCI) in recommending the that a standard set of race and ethnicity data as well as sociodemographic measures, agreed upon by the cancer health disparity community, be included in clinical registries.[6] Further, it is recommended that to the extent possible, the most granular measures be selected, and in the case of race and ethnicity, questions address ancestry, immigration status and enclave effects. Measures of the built environment should be included, or patient address should be collected and geocoded, to assess neighborhood and structural effects on health, and so that physical and other contextual effects can be considered.

ASCO supports the collection of demographic elements and use of relevant data for quality improvement. Measures of race, ethnicity, sexual orientation, and gender identity should be self-reported and collected in all clinical settings.[7,8] Including relevant data reporting in all forms, especially the electronic medical record, will allow for patients to accurately record their medical history and individual characteristics that may impact their care.

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[5] Polite, Blase N., et al. "Charting the future of cancer health disparities research: a position statement from the American Association for Cancer Research, the American Cancer Society, the American Society of Clinical Oncology, and the National Cancer Institute." Cancer research 77.17 (2017): 4548-4555.
[6] Ibid.
[7] Griggs, Jennifer, et al. "American Society of Clinical Oncology position statement: strategies for reducing cancer health disparities among sexual and gender minority populations." Obstetrical & Gynecological Survey 72.10 (2017): 598-599.
[8] Polite, Blase N., et al. "Charting the future of cancer health disparities research: a position statement from the American Association for Cancer Research, the American Cancer Society, the American Society of Clinical Oncology, and the National Cancer Institute." Cancer research 77.17 (2017): 4548-4555.

Quality Payment Program

As practices prepare for 2022, they are facing Medicare reimbursement cuts of over 10%: 2% due to the reinstitution of the longstanding sequester, 4% from statutory PAYGO, and 3.75% from the loss of the update to the fee schedule for 2021. We are therefore extremely concerned by CMS' analysis that the overall proportion of clinicians receiving a positive or neutral payment adjustment in MIPS would decrease from 91.7% to 67.5% with implementation of the proposed policies. Practices large and small are still struggling with the COVID-19 pandemic, especially with the delta variant on the rise. As noted, oncology practices can expect to face cuts next year of over 10%, regardless of their performance in MIPS. Increasing the proportion of clinicians receiving a negative payment adjustment in MIPS in addition to the combination of existing statutory cuts and budget neutrality adjustments will be untenable for many practices, especially those that are small and/or rural.

CMS must continue to implement flexibilities during and for some time after the end of the public health emergency to allow practices to survive and make it through the pandemic to ensure patient access to care across the country, including rural and underserved areas. Therefore, we urge CMS to use these flexibilities and to automatically apply the Extreme and Uncontrollable Hardship Exception for the 2021 MIPS performance period, holding physicians harmless from a potential 9% penalty during an ongoing pandemic and in the face of double-digit cuts coming from outside of the MIPS program.

MIPS Value Pathways (MVPs)

ASCO does not support CMS' proposal to sunset traditional MIPS in favor of the newly created MVPs in 2028. There is no statutory requirement for MVPs, and CMS should not implement MVPs until there has been successful uptake and use of MVPs by clinicians. Only by examining clinicians' use of MVPs can CMS make an informed proposal on the eventual sunsetting of traditional MIPS.

Currently, CMS is proposing seven new MVPs for use beginning in performance year 2023. We believe that MVPs should be numerous and robust before CMS begins requiring their use, which again argues against CMS setting a premature deadline for sunsetting MIPS. Due in part to statutory requirements under which CMS must proceed, the MVPs as currently proposed can be characterized as essentially a collection of existing MIPS elements from the existing performance categories, but with additional requirements such as public health "quality" measures. The fact that the overall performance category weighting and scoring for the MVPs would remain identical to the scoring of performance categories in traditional MIPS also speaks to this reality.

There is an opportunity for CMS to work with stakeholders and medical specialty societies to create MVPs that reflect more "out of the box" thinking. For example, ASCO has long championed the use of evidence-based, high quality clinical pathways, and believes there is an opportunity to create meaningful MVPs aligned with such pathways if CMS would provide more flexibility in its requirements for measure testing and allow for a pilot period for new MVPs. We note that CMS has this flexibility for measure testing requirements, as some of the CMS-sponsored measures currently in widespread use in the program are not endorsed by the National Quality Forum (NQF) and indeed were sent back to the developer for additional work.

ASCO is also concerned by the approach CMS is taking in insisting that MVPs include population health administrative claims measures, especially as "foundational" to MVPs. These measures may more accurately be described as cost measures,[9] but CMS is proposing to include them for scoring in the quality category, thereby exposing physicians to attributed cost measures that may or may not reflect the care they provided. We believe much more work is needed here before these measures should be mandatory in MVPs.

Finally, ASCO has long supported the availability of subgroup reporting and is pleased that CMS is proposing to make available that opportunity for practices reporting MVPs in 2023 and 2024. However, we cannot yet support CMS' proposal to make subgroup reporting mandatory in 2025 until practices and the agency have more experience with the reporting of MVPs and the outcome of attempts to address any issues identified during the initial reporting periods.

Quality Measures: Removal of "Oncology: Plan of Care for Pain (NQF #0383)

As the steward of the Oncology: Plan of Care for Pain (NQF #0383) measure, ASCO strongly urges CMS not to remove this measure from the MIPS program beginning with the 2022 performance year as proposed. ASCO believes that the management of all pain, not just moderate to severe pain, is an integral part of high-quality cancer care and should be measured and treated. Pain is one of the most common symptoms associated with cancer, and inadequate cancer pain management is widely prevalent, harmful to the patient, and costly.

A meta-analysis revealed that pain was reported in 59% of patients undergoing cancer treatment, in 64% of patients with advanced disease, and in 33% of patients after curative treatment.[10] An analysis of registry data for chronic pain cancer patients found average pain intensity reported as mild (24.6% of patients), moderate (41.5%), and severe (33.9%).[11] In addition, pain is one of the symptoms patients fear most. Unrelieved pain of any degree denies patients comfort and greatly affects their activities, motivation, interactions with family and friends, and overall quality of life. There is mounting evidence in oncology that quality of life and survival are linked to early and effective palliative care, including pain management. Although improvements have been observed, undertreatment of pain remains an issue in a significant subset of patients with cancer. ASCO is concerned that the removal of this measure will undermine the critical nature of pain management in cancer care, which if ignored and undervalued will lead to worsened cancer patient health outcomes.

[9] The two available measures for 2023 include "Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups" (finalized in CY 2021 PFS final rule) and "Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions" (proposed).

[10] National Comprehensive Cancer Network (NCCN). (2020). NCCN Clinical Practice Guidelines in Oncology. Adult Cancer Pain Version 1.2020. Retrieved from http://www.nccn.org

[11] Moryl, N., Dave, V., Glare, P., Bokhari, A., Malhotra, V. T., Gulati, A., … Inturrisi, C. E. (2018). Patient-Reported Outcomes and Opioid Use by Outpatient Cancer Patients. The Journal of Pain: official journal of the American Pain Society, 19(3), 278–290. doi:10.1016/j.jpain.2017.11.001

As CMS has stated numerous times, the agency aims to update and align quality measures across the different reporting programs. However, earlier this year, CMS finalized the removal of the Plan of Care for Pain measure from the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) program, using the rationale that the Plan of Care for Pain measure was not feasible to report without data from the Pain Intensity Quantified (NQF #0384) measure, which was earlier removed from the PCHQR program (2021) because the measure was topped out. In contrast, CMS states that the rationale for the removal of the Plan of Care for Pain measure from MIPS is because this measure 1) "does not align with the Meaningful Measures Initiative as it splits a clinical process into individual quality measures" and 2) is limited to those patients that were screened positive for pain and CMS believes as a stand-alone measure it is not a true reflection of the quality of care being given, but only reflects care to a subpopulation of oncology patients with documented pain.

In our comments on the Inpatient Hospital Rule regarding the proposal to remove the Plan of Care for Pain measure, we pointed out that, while ASCO does understand the rationale for removing measures that consistently perform well, this measure is only topped out when it is manually reported, not when it is extracted directly from electronic health records or from administrative claims. These two measures—both of which were endorsed by the National Quality Forum (NQF) less than a year ago--together will continue to offer actionable performance data to clinicians to ensure the delivery of high-quality cancer care and therefore the Plan of Care for Pain measure should not be removed from the program. The numerator and denominator of the two pain measures are linked with the intent of being reported together, and elimination of the Plan of Care for Pain measure makes reporting the Pain Intensity Quantified measure problematic.

Finally, we would like to emphasize that the Plan of Care for Pain measure is currently included in the Radiation Oncology (RO) Model and both the Pain Intensity Quantified and Care Plan for Pain measures are currently reported in the Oncology Care Model (OCM). To further CMS' goal of aligning quality measures across all reporting programs, we recommend the continued inclusion of the two pain measures in the MIPS program.

General MIPS Proposals

Performance benchmarks. **ASCO supports CMS' proposal to use performance period benchmarks—as opposed to baseline period historic data—for the 2022 performance period.** Given the upheaval in medical practice due to the pandemic and CMS' much-appreciated flexibilities in reporting for the 2020 performance year, 2020 performance data cannot be considered a "representative" sample of historic data.

Performance Threshold. CMS is proposing to set the performance threshold at 75 points for the 2022 performance year. Given the disruption to practices starting with reporting of 2019 data through to today and for the foreseeable future with the pandemic and ongoing public health emergency, **ASCO urges CMS to consider maintaining the current threshold for the 2022 performance year, rather than moving ahead with increasing the threshold every year as though the program were proceeding in normal times**.

Small practice exceptions and reweighting. **We support CMS' proposal to no longer require an application from small practices for the small practice hardship exception and reweighting of performance categories.** As noted above, however, we believe that an automatic exception should be applied to all practices, regardless of size.

GPRO web interface sunset in 2023. **ASCO supports CMS' proposal to delay the sunsetting of the GPRO web interface until 2023, and thanks the agency for responding to our concerns regarding the elimination of the web interface in our previous comment letter**. Especially in light of the continuing pandemic, physicians and practices will need additional time to transition to alternative reporting mechanisms. We encourage CMS to reassess this policy in 2022 based on the status of the pandemic and practice readiness at that time.

Quality Measures

Removal of 3-point floor for quality measure scoring. Currently, quality measures that lack a benchmark are awarded a minimum of 3 points during MIPS scoring. CMS is proposing to remove this 3-point floor and to score a reported measure without a benchmark at zero points. Given that CMS is proposing to use performance period benchmarks, it would be impossible for a practice to know in advance that the measure(s) it is reporting on lacks a benchmark, so this policy would unfairly penalize physicians and practices who in good faith report clinically relevant quality measures. **We do support CMS' proposal to maintain the 3-point floor for small practices but urge CMS to expand that policy to all practices, regardless of size.**

New quality measure 5-point floor. **We support CMS' proposal to institute a 2-year, 5-point floor for new measures without a benchmark.** We have raised concerns previously that practices may avoid reporting on new measures that otherwise could be applicable to them due to a concern that they could be penalized with a score of zero for that measure if no benchmark can subsequently be set for that new measure. We are pleased that CMS is seeking to provide practices the opportunity to report on new measures via the assurance of this 5-point floor and would ask that CMS consider higher point floors for measures that are high priority or outcome measures.

Additional outcome measure(s) bonus point removal. **ASCO does not support the proposal to remove bonus points for reporting additional outcome measures beyond those required.** Bonus points serve as an incentive for the increased effort that these measures often require to be reported, and physicians should be rewarded for these efforts.

End-to-end electronic reporting bonus point removal. **ASCO does not support CMS' proposal to remove bonus points for end-to-end electronic reporting.** Practices generally need to invest in their health information technology and often redesign workflows in order to achieve end-to-end reporting and should continue to be recognized for these efforts.

Cost Measures

Proposal to include Part D drug costs in cost measures. **ASCO does not support the inclusion of Part D**

prescription drug costs in MIPS cost measures. We have long argued that holding physicians accountable for the price of drugs when they have no role in setting drug prices serves only to unfairly place the physician in the middle of a situation over which they have no control. We reiterate here that it is appropriate to hold physicians accountable for their use of drugs, e.g., via high quality clinical pathways, but making physicians accountable for the price of drugs set at launch by the manufacturer is profoundly misguided. While our prior objections have largely pertained to Part B drugs, the logic underpinning this position on Part D drugs remains the same.

Proposed process for cost measure development by stakeholders. **ASCO urges CMS to develop cost measures with input from national special societies and other interested stakeholders.** For those specialty societies that are interested in developing cost measures for use within an MVP, we agree with the American Medical Association (AMA) that CMS should provide them with claims data and funding to assist those societies in developing meaningful and appropriate cost measures.

Promoting Interoperability

Encounter start date of January 1, 2016. Beginning with the EHR reporting period in 2022, CMS is proposing to require that patient health information with an encounter start date of January 1, 2016, be made immediately available. ASCO supports patient ease of access to their medical records and information and agrees that in general the date of the encounter should not be a rate-limiting step in patient access. However, we would caution CMS to consider that some physician practices and/or health systems have "digitized" older medical records, and that this process often consists of digital imaging and/or PDF-type formats. It can be next to impossible to search for specific information in these types of "digitized" formats, which makes identification of specific information very difficult and does not allow for protection of certain information required by some state and federal laws. **We urge CMS to allow flexibility in these situations by allowing additional time for identification of requested information and to not penalize physicians who cannot meet the "immediacy" requirement due to technological limitations.**

Public health and clinical data exchange objective. CMS is proposing that physicians who do not meet the full objectives of the "Public Health and Clinical Data Exchange" objective receive a zero score for the entire PI category. While we understand the importance of this objective, we do not support penalizing physicians with a score of zero for an entire performance category based on the unsuccessful completion of one measure. Given the weight of the PI category in MIPS, this would significantly affect a clinician's MIPS score and greatly increase the risk of a negative adjustment, for just one measure. **ASCO urges CMS to simply not award points for this measure if a physician does not meet the objective and continue to score other PI measures as it normally would.**

Improvement Activities (IAs)

CMS is proposing to modify the IA "Consultation of the Prescription Drug Monitoring Program (PDMP)." This IA currently requires physicians to attest to reviewing 75% of their patients' history in the PDMP before prescribing a controlled substance (schedule II) when an opioid prescription lasts longer than three days. CMS is proposing to modify this IA by requiring a check of 100% of patients, with exceptions

for patients receiving palliative or hospice care. We are concerned that CMS does not elaborate on these exceptions nor does the agency detail how clinicians should document that such exceptions were appropriately followed. Depending on an oncology care professional's sub-specialty and patient mix, it is possible that many of a particular practitioner's patients would be eligible for the palliative care exception. **We urge CMS to issue specific guidance on how exceptions should be recorded and documented.**

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We appreciate the opportunity to comment on the 2022 Medicare Physician Fee Schedule 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,

Howard A. Burris III, MD, FACP, FASCO
Chair of the Board
Association for Clinical Oncology