ASCO®
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

June 28, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1752–P
P.O. Box 8013
Baltimore, MD 21244–1850

Submitted Electronically at www.regulations.gov

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program (CMS-1752-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 fiscal year 2022 Hospital Inpatient Prospective Payment System proposed rule published in the Federal Register on April 12, 2021.

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.

Below we offer our comments on select proposals in the rule.

* * * * * * * * *

ASCO supports CMS' proposal to maintain the rate-setting methodology finalized in the 2021 proposed rule to exclude clinical trial cases and cases with standard pharmacy charges less than $373,000 from rate-setting for Medicare Severity Diagnosis Related Group (MS-DRG) 18 as these cases do not reflect the actual hospital costs for providing chimeric antigen receptor T-cell immunotherapies (CAR-T) therapy.

As CMS stated in the 2021 final rule, data analysis indicates that the average costs of CAR T-cell therapy cases identified as clinical trial cases are 17 percent of the average costs of CAR T-cell therapy cases determined to be non-clinical

trial cases. Clinical trial claims do not accurately reflect the cost of CAR-T therapy because submitting institutions are not responsible for covering the cost of the therapy in clinical trials, unlike non-clinical trial cases. Should CMS include clinical trial cases or cases with pharmacy charges less than $373,000 without adjusting the relative weight, the resulting reimbursement rate for the MS-DRG would be insufficient to cover the cost of providing the therapy, jeopardizing patient access.

ASCO applauds CMS for recognizing the value that CAR-T therapies offer cancer patients by previously establishing a new MS-DRG for CAR-T therapy, and we urge CMS to maintain access to these cutting-edge therapies through appropriate reimbursement. ASCO supports the delivery of CAR-T therapy in all manufacturer-approved, high-quality health care settings where patients can be safely and effectively treated with this very complex and demanding treatment regimen, including all care required for adverse events and follow-up care.

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 PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) program beginning with the FY 2024 program year as proposed, and to re-introduce the *Oncology: Pain Intensity Quantified – (NQF #0384)* measure into the program.

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. As CMS states in the proposed rule, the Plan of Care for Pain measure "provides important data for patients and hospitals in making decisions about care and informing quality improvement efforts." 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.[1] 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%).[2] 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.

CMS stated reason for the proposal to remove the Plan of Care for Pain measure is because it is not feasible to report without data from the Pain Intensity Quantified measure. ASCO recommends that CMS reinstate the Oncology: Pain Intensity Quantified – (NQF #0384) measure in 2022, rendering implementation of the Oncology: Plan of Care for Pain – (NQF #0383) measure feasible for reporting. The numerator and denominator of the two pain measures are linked with the intent of being reported

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

[2] 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

together, and elimination of the pain intensity quantified measure makes reporting plan of care for pain problematic.

The Intensity Quantified (NQF #0384) measure was removed from the program beginning in FY 2021 because the measure was topped out. While ASCO does understand the rationale for removing measures that consistently perform well, we would like to highlight that 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 will continue to offer actionable performance data to clinicians to ensure the delivery of high-quality cancer care and should not be removed from the program.

As CMS states in later sections of this proposed rule, the agency aims to update and align quality measures across the different reporting programs. We would like to emphasize that both the Pain Intensity Quantified and Care Plan for Pain measures are currently reported in the Merit-based Incentive Payment System (MIPS)[3], the Oncology Care Model (OCM)[4], and the Radiation Oncology (RO) Model[5]. To further CMS' goal of aligning quality measures across all reporting programs, we recommend the inclusion of the two pain measures in the PCHQR program.

Finally, the National Quality Forum (NQF) endorsed both pain measures less than one year ago. CMS noted in the RO Model proposed rule that the Plan of Care for Pain measure was undergoing review for National Quality Forum (NQF) endorsement. While CMS expected changes to the measure specifications, it did not believe these changes would alter the fundamental basis of the measure, nor did it believe they would impact the measure's appropriateness for inclusion in the RO Model. The NQF endorsed both the Pain Intensity Quantified and the Plan of Care for Pain measure in July of 2020[6] and the measure is included in the RO Model. To underscore the fundamental role of pain management in high-quality cancer care and maintain consistency across programs we would encourage CMS to maintain the Plan of Care for Pain – (NQF #0383) measure in the PCHQR program along with the Pain Intensity Quantified (NQF #0384) measure.

Digital Quality Request for Information (RFI)
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

[3] #143 Oncology: Medical and Radiation – Pain Intensity Quantified
#144 Oncology: Medical and Radiation - Plan of Care for Pain
[4] OCM-4a Oncology: Medical and Radiation – Pain Intensity Quantified (NQF 0384)
OCM-4b Oncology: Medical and Radiation – Plan of Care for Pain (NQF 0383)
[5] https://www.govinfo.gov/content/pkg/FR-2020-09-29/pdf/2020-20907.pdf
[6] Oncology: Medical and Radiation – Pain Intensity Quantified (NQF 0384)
Oncology: Medical and Radiation – Plan of Care for Pain (NQF 0383)

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.*
    - *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 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.*
    - *ASCO is concerned with CMS' proposal of an ecosystem with all of these data sources when the calculation of existing quality measures using basic transactional data from source EHRs has not been shown to be consistent or reproducible.*

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.*
- 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 RFI

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[7] 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 algorithms 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 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

[7] 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.

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.[8] 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.[9] 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.[10,11] 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.

* * * * * * * * *

We appreciate the opportunity to comment on the 2022 Hospital Inpatient Prospective Payment System 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

---

[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.
[9] Ibid.
[10] 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.
[11] 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.