June 17, 2022

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

Submitted Electronically at www.regulations.gov

Re: Medicare 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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation (CMS–1771–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 2023 Hospital Inpatient Prospective Payment System proposed rule published in the Federal Register on April 18, 2022.

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.

We are pleased to offer our comments in response to select proposals and requests for information (RFI) below.

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Chimeric Antigen Receptor T-Cell (CAR-T) Reimbursement

ASCO supported the establishment in fiscal year (FY) 2021 of a new Medicare Severity-Diagnosis Related Group (MS-DRG) for CAR-T therapies giving providers the reimbursement certainty they need to offer the therapy; however, we would like to express our continued concerns that the
reimbursement rate for MS-DRG 018 is insufficient to cover the cost of the therapy and related services. Current reimbursement rates leave providers with financial losses and could result in restricted access to this life-saving therapy.

Under the proposed methodology, if a hospital submits quality data and is a meaningful EHR user with a wage index greater than one, the unadjusted payment amount for CAR-T services will be approximately $299,460 in FY 2023. This is considerably less than the cost of the drug alone, which ranges from $373,000 to $475,000. We believe that the trimming policy used to address outliers is having an outsized impact on the CAR-T MS-DRG 018.

Treatment for adults with advanced lymphomas is reported to have a list price of $373,000 and $475,000 for pediatric indication. These list prices do not include the hospitalization costs for patients, or the care involved in managing the often-life-threatening side effects and adverse events. Hospitals and other clinical settings also incur additional costs not captured during the rate setting process, including the costs associated with required certification from the manufacturer and the costs associated with training, staff, and coordination required to successfully administer CAR-T. The Medicare payment system does not adequately reimburse for variable patient care costs or the cost of the product itself.

Patients who undergo CAR-T therapy may have severe, often life-threatening reactions and side effects that require extensive care; some may have less severe reactions. Because there is great variability in how patients respond to CAR-T therapies, hospital resources needed to care for these patients are also widely varied. The trimming policy used to address outliers does not properly consider this variability, leading to artificially low reimbursement rates.

To set rates, CMS uses cost data from prior years, with outliers removed and trimmed from the data so as not to skew the results. However, because of the relatively few cases included in MS-DRG 018, removal of these outlier cases drastically affects the outcome. In a review of all DRGs, we found that MS-DRG 018 has the highest percent of cases removed (1.3%), yet this represents only five total cases. To put this into perspective, when combining all other MS-DRGs, only 0.03% of cases are removed. The removal of a large proportion of cases when the total number of cases is relatively small—and when patients require highly variable intensity of care and resources—can have a powerful impact on the resulting rate, as shown below in Table 1a.

Table 1a. Cost per Inpatient Stay

<table>
<thead>
<tr>
<th>Proposed Rule</th>
<th>Standardized Cost Per Inpatient Stay for MS-DRG 018</th>
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<tbody>
<tr>
<td></td>
<td>Before Outliers Removed</td>
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<tr>
<td>2023 Proposed Rule (2021 Data)</td>
<td>$320,056</td>
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ASCO recommends that Medicare cover the full cost of CAR-T therapy, with the exception of any applicable patient or provider cost-sharing that would apply to any other covered drug or therapy under the Medicare program.

ASCO also recommends that the agency closely monitor and consider the impact statistical methodologies such as “trimming outliers” will have on MS-DRG 018 and other low volume services.

Targeted treatments such as CAR-T therapies have enormous potential to cure previously untreatable cancers, offering some patients with cancer hope for the first time. However, the financial loss associated with Medicare’s under-reimbursement for CAR-T is not sustainable and threatens patient access to life-saving therapies.

Providers do not set list prices for drugs or treatments and should not be penalized for providing this evidence-based, innovative cancer care therapy. For additional information, please see ASCO’s CAR-T Therapy Policy Brief, developed by our affiliate organization, the American Society of Clinical Oncology (the Society).

Social Determinants of Health Diagnosis Codes – Request for Information

CMS is soliciting information on how the reporting of diagnosis codes in categories Z55-Z65 may improve the agency’s ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS-DRGs. CMS is also interested in receiving feedback on how the agency can foster the documentation and reporting of diagnosis codes describing social and economic circumstances to reflect each health care encounter and improve the reliability and validity of the coded data in support of efforts to advance health equity.

In its 2020 statement, Cancer Disparities and Health Equity: A Policy Statement from the American Society of Clinical Oncology, the Society identified four strategic goals and underlying recommendations, including addressing structural barriers through the optimal use of SDOH in cancer care, education, practice, and policy development.

Achieving cancer health equity requires broad approaches that address the social, economic, and environmental factors that influence health. The social determinants of health [conditions in which people are born, grow, live, work, and age along with factors such as socioeconomic status, education, neighborhood, employment, and social support] should be addressed in addition to health care access. Addressing the social determinants of health is critical to achieving health equity, and community

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engaged strategies are an essential way to do so.\textsuperscript{3,4} Vital to achieving cancer health equity is engagement by professional organizations with community stakeholders to support health promotion activities over the lifespan. Community efforts may address multiple conditions that are important drivers of health and wellness, including safe, physical environments and neighborhoods that promote health; access to early, high-quality education; affordable housing; structurally safe sidewalks; open spaces, such as parks; access to recreation centers; and clean drinking water, food, and transportation.

Multisector collaborations can assist in identifying strategies to address social determinants of health and can promote and sustain the infrastructure, policies, and implementation activities that are crucial to reducing disparities.\textsuperscript{5,6} This includes partnering with local health professionals, health care teams, and community leaders.

**ASCO strongly supports policies and practices that address the SDOH of patients with cancer to improve health equity.** As CMS develops future policy and issues guidance, the Agency should consider physician and other provider capacity to collect SDOH information and whether Z codes are the most appropriate way to identify and record social risk.

Physicians in under resourced practices and/or communities have expressed hesitation to ask questions about SDOH when the physician or practice does not have specific resources to address identified needs, or if a community resource is unavailable to assist the patient. Patients may find this type of questioning intrusive, or they may question the provider’s intent and be reluctant to share information, especially if the issue goes unaddressed or unresolved.

We strongly support understanding and addressing the SDOH of patients with cancer. However, CMS should understand the potential administrative burdens that may accompany more robust SDOH data collection. Physicians or other staff collecting the SDOH information may need training on how to best collect SDOH information, why it is important to do so, and appropriate strategies for initiating such conversations with their patients. Gathering SDOH information may require significant additional time to capture and then code into the patient’s EHR, which will require additional staff time and resources. Because patient’s social needs and SDOH are always changing, SDOH screening should happen more than once, which also demands additional time, staff, and resources to stay current.

\textsuperscript{4} Cummins S, Flint E, Matthews SA: New neighborhood grocery store increased awareness of food access but did not alter dietary habits or obesity. Health Aff (Millwood) 33:283-291, 2014
We question whether Z codes are the most effective method to recognize severity of illness, complexity of illness, and/or utilization of resources. According to a Medicare study\(^7\), most beneficiaries with Z codes reported were white (approximately 75%), and only 1.4% of claims included coding. Codes should also be evaluated for duplicity and ambiguity. Multiple codes describe insufficient housing situations (homelessness, instability, etc.). One code describing “insufficient social insurance and welfare support” is generally reported for patients without medical/health insurance. However, it may be difficult to determine whether this code could be reported for situations where patients have insufficient insurance coverage or need additional services but cannot access them either due to eligibility or resource limits.

In summary, ASCO supports the understanding and addressing of SDOH of patients with cancer, and we recommend the following measures related to the collection of such data:

- **ASCO recommends that CMS define the scope of information collection burden on physicians and other providers that will be required to report SDOH data.**
- **ASCO recommends that CMS work with the provider community on the technical issues of streamlining data collection efforts.**
- **ASCO recommends CMS work with the provider community to develop guidance on SDOH data collection as well as strategies to address SDOH issues when appropriate resources are not available in their community.**

**Assessment of the Impact of Climate Change and Health Equity – Request for Information**

Literature has established a clear relationship between climate change and cancer.\(^8,9\) Fossil fuel-related and/or wildfire-induced air pollution, specifically very fine particulate matter (PM2.5), has a demonstrable effect on cancer incidence and survival, and has been classified as a carcinogen by the International Agency for Research on Cancer. The impacts of PM2.5 are felt across all stages of the cancer care continuum, contributing to increased lung cancer incidence and mortality, as well as increased mortality in pediatric tumors.\(^10,11,12\) There exist well-developed bodies of literature examining the impact of climate change on cancer via increased exposure to ultraviolet radiation, declining nutrition, environmental contamination, and infectious vectors.\(^13\)

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\(^8\) Hiatt RA, Beyeler N: Cancer and climate change. Lancet Oncol 21:e519-e527, 2020

\(^9\) Nogueira LM, Yabroff KR, Bernstein A: Climate change and cancer. CA Cancer J Clin 70:239-244, 2020


\(^12\) Ou JY, Hanson HA, Ramsay JM, et al: Fine Particulate Matter Air Pollution and Mortality among Pediatric, Adolescent, and Young Adult Cancer Patients. Cancer Epidemiol Biomarkers Prev, 2020

\(^13\) Hiatt RA, Beyeler N: Cancer and climate change. Lancet Oncol 21:e519-e527, 2020
Beyond increasing risk of cancer via carcinogen exposures (e.g. during hurricanes or wildfires), climate change has potential to affect oncologists’ ability to care for patients with cancer. Extreme weather events such as wildfires, floods, and hurricanes can prevent access to cancer treatment facilities, resulting in the disruption of cancer prevention, detection, and management.\textsuperscript{14} Retrospective reviews indicate that among patients undergoing definitive radiotherapy for non-small cell lung cancer, those who were additionally exposed to a natural disaster had longer durations of radiotherapy and worse overall survival, both of which were proportional to the duration of the disaster.\textsuperscript{15} Experts have further pointed out that climate-induced disruptions to screening access, similar to what has already occurred due to COVID-19, should be expected to have similarly large effects on downstream stage at diagnosis and related excess mortality.\textsuperscript{16}

Cancer patients are a vulnerable population who require consistent care and follow-up, medical supplies, and support. Recognizing the disruption emergencies force on cancer patients, ASCO has developed resources to guide cancer patients as they cope with emergencies, natural disasters, or situations when they must suddenly leave their home.\textsuperscript{17}

The negative impacts of policy action (or inaction) are disproportionately experienced by the most vulnerable members of a society. The relatively sparse literature on SDOH and cancer has focused on survival and mortality, though emerging research is beginning to explore linkages between SDOH and carcinogenesis.\textsuperscript{18} In the context of climate change, structural inequities increase the vulnerability of marginalized communities across three primary domains; increased likelihood of exposure, increased sensitivity to the health hazards of climate change, and decreased adaptive capacity.\textsuperscript{19}

ASCO joined the Medical Society Consortium on Climate and Health, an organization that convened associations representing over 600,000 medical providers to amplify the message about the devastating impact climate change is having on the health of Americans, and to pursue policies that achieve equitable solutions to promote and protect health. ASCO is an organizational signatory of the Consortium’s consensus statement recognizing the need to reduce the use of fossil fuels to limit global climate change.

\textsuperscript{17} https://www.cancer.net/navigating-cancer-care/managing-your-care/managing-your-cancer-care-during-emergency
\textsuperscript{19} https://ascodaily.libsyn.com/climate-change-and-cancer
Because physicians are directly involved in patient care and witness current practices that could potentially be improved, they are a great resource and collaborator in developing solutions to mitigating the impact of medical waste and other ways that healthcare itself contributes to climate change. ASCO looks forward to ongoing collaboration with the Administration and CMS as we explore the policy levers ASCO might be best positioned to employ for both short- and long-term benefit.

**Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs – Request for Information**

CMS solicits information from stakeholders for considerations in developing future policies around the use of measure stratification as one quality measurement tool to address healthcare disparities and advance health equity across all quality programs.

The Society’s *Cancer Disparities and Health Equity Policy Statement*\(^{20}\) summarizes past efforts and offers numerous recommendations to the broader cancer care community to address health equity. 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.

ASCO is pleased that CMS has placed an emphasis on addressing health equity across all quality programs in its continued efforts to move toward a value-based model of care delivery. **ASCO urges CMS to establish consistent measures across its various programs to reduce reporting burden and to enhance robustness of the data collected.**

**Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs**

We appreciate CMS recognizing that stratified measures are vulnerable to measurement and algorithmic bias, and that efforts are needed to ensure disparity reporting avoids these biases. We agree with CMS that it should carefully examine stratified results and methods to mitigate the potential for drawing incorrect conclusions from results.

**Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs**

We agree with CMS that decisions about how to identify and prioritize measures for possible

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stratification should be made at the program level. We agree with CMS that they should prioritize existing clinical quality measures as they have already been vetted and will reduce provider burden. We agree that measures for stratification should be supported by evidence of underlying healthcare disparities in the procedure, condition, or outcome being measured. Measures for stratification should have sufficient cohort sample sizes to ensure that reported results of the disparity calculation are reliable and representative of the healthcare provider’s patient population. Finally, we agree with CMS that to complement stratification of measures focused on clinical outcomes, quality programs could consider prioritizing measures with a focus on access to and the appropriateness of care.

Principles for Social Risk Factor and Demographic Data Selection and Use

ASCO supports the collection of demographic elements and use of relevant data for quality improvement. Standard data elements for race, ethnicity, sexual orientation, and gender identity should be self-reported and collected in all clinical settings. 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.

ASCO recognizes that patient data are often incomplete, inaccurate, or overly simplified and usually do not consider many social and community factors. 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 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. 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 addresses should be collected and geocoded, to assess neighborhood and structural effects on health, and so that physical and other contextual effects can be considered.

23 Ibid.
24 Ibid.
Many tools to capture patient demographic and social risk factors are validated and widely used, such as the NCCN Distress thermometer.\textsuperscript{25} When capturing certain social risk factor information from patients, providers should have a choice in which tool to use based on the patient population.

Identification of Meaningful Performance Differences

We agree with CMS that it should consider multiple approaches to identifying meaningful differences in performance, including statistical differences, rank ordering and percentiles, the threshold approach, and benchmarking. While ASCO appreciates CMS’ desire to implement standardized approaches across programs, we suspect appropriate assessment of differences in performance may need to be tailored to each individual quality program.

Guiding Principles for Reporting Disparity Results

ASCO is in the process of developing a health equity score card for oncology practices and is considering adapting existing frameworks and measures occurring in the cancer care delivery system, developing new measures, and the possibility of alignment with future equity-related data collection/measures. Our goal is to develop a sound and reliable scoring system that can assess equity wherever cancer care is delivered and thereby inform needed quality improvement initiatives. We look forward to sharing the results of these efforts with the Agency upon completion.

As we develop the equity scorecard, one concern has been the potential for early and unfair penalties stemming from unmet scorecard benchmarks, scores, or standards. We ask the agency to consider approaching equity scorecards and indices as an opportunity to provide sites with a baseline score highlighting current performance with a clear path to improvement. We are developing an equity scorecard as we stress the need to begin assessing sites for health equity performance. However, we understand that it will take time and resources for sites to adequately prepare to address and meet all performance standards. We urge CMS to balance the requirement of these measures at a pace that allows sites to prepare for successful implementation; the primary goal should be to improve health equity, not to penalize for failure to meet unattainable benchmarks.

Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs – Request for Information

Refined potential future definition of (Digital Quality Measures) dQMs

CMS requests input on a refined potential future definition of dQMs. ASCO agrees that a multitude of data sources, as outlined in the proposed rule [e.g. administrative systems, electronically submitted clinical assessment data, case management systems, electronic health records (EHRs), laboratory

\textsuperscript{25} https://www.nccn.org/docs/default-source/patient-resources/nccn_distress_thermometer.pdf?sfvrsn=ef1df1a2_4and
systems, prescription drug monitoring programs (PDMPs), instruments, patient portals or applications, health information exchanges (HIEs) or registries, and other sources], is appropriate and will allow for more granular quality measures. However, as ASCO has previously noted, the list of data sources may be too broad to be realistic, and FHIR is not yet mature enough to integrate all these data sources within one measure. ASCO also supports the concept of leveraging interoperability standards to decrease mapping burden and align standards for quality measurement with interoperability standards used in other healthcare exchange methods. ASCO maintains its broad, overarching concern about the potential for dQMs to significantly increase 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.

**Potential considerations or challenges related to non-EHR data sources**

CMS also requests feedback on potential considerations or challenges related to non-EHR data sources. Although the list of data sources named in the dQM definition may be too broad to be realistic, ASCO agrees the list of data sources 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 feasible, but ASCO reiterates the need for specialty-specific implementation guides (IGs). We ask CMS to consider what the requirements will be for the third-party intermediaries for the ability to aggregate multiple data sources, and or whether CMS would instead perform the data aggregation and calculate measure scores from these data sources.

A dQM paradigm also significantly increases the burden of testing for measure developers. It is already a challenge to test electronic clinical quality measures (eCQMs) from one data source (EHRs), and testing measures that have data from multiple data sources may be impossible and could be too expensive for measure developers 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.

Additionally, 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.

While ASCO fully agrees that standardization across data elements and data models is critical in support of multiple use cases, without efforts to improve electronic data capture and availability of nuanced
oncology clinical data, standardization is not ipso facto sufficient to enable the learning health system CMS envisions. 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.

Data standardization Activities to Leverage and Advance Standards for Digital Data

ASCO agrees with the importance of standardized value sets and implementation guides to advance data standardization. Notably, it is important to follow FHIR standards, ONC USCDI standards, and HL7 standards. Through the development of eCQMs, ASCO emphasizes the need to address gaps in data standardization and capture of pathology and genomic data, which is critical to oncology measure reporting, and encourages CMS to work with the appropriate stakeholders to standardize and improve data for electronic capture.

Approaches to Achieve FHIR eCQM Reporting

ASCO is concerned by the lack of explicit requirements for health service providers and health data companies to comply with FHIR standards. Additionally, financial incentives to implement FHIR standards are nonexistent, so the cost of the implementation is entirely absorbed by an organization that wants to implement a measure. ASCO encourages the availability of free education sessions on FHIR-based digital quality measure development, and the provision of user-friendly measure authoring and testing tools.

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We appreciate the opportunity to comment on the FY 2023 Hospital Inpatient Prospective Payment System proposed rule. Please contact Gina Hoxie (gina.baxter@asco.org) with any questions or for further information.

Sincerely,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology