June 24, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, DC 20201

Re: CMS-1716-P: 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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule

Dear Administrator Verma:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (“ASCO”) in response to the recent fiscal year 2020 Hospital Inpatient Prospective Payment System proposed rule published in the Federal Register on May 3, 2019 (84 Fed. Reg. 19158).

ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.

I. Increasing the New Technology Add-on Payment and Reimbursement for Chimeric Antigen Receptor T-Cell Therapy.

ASCO supports and is committed to promoting policy solutions that ensure access to innovative therapies for cancer patients. Chimeric Antigen Receptor T-Cell Therapy (CAR-T) and similar technologies provide exciting opportunities to improve outcomes and hope for cures for certain cancer patients. We applaud the Agency for recognizing the need to increase the New Technology Add-on Payment to facilitate access to emerging technologies.
However, the proposed N-TAP increase from 50% to 65% is still insufficient to cover the cost of CAR-T therapy and additional related services resulting in an unsustainable situation for providers furnishing this therapy to their patients. Patients and physicians should not be burdened with the large gap in payment, which could hinder access.

Cancer care made a significant step forward with the FDA’s approval of two CAR-T therapies in 2017. Their approval is a meaningful breakthrough and achievement based on years of cancer research into immunotherapy. Targeted treatments, including CAR-T therapies, have vast potential to cure previously untreated cancers and, for the first time, some cancer patients have hope for a cure. The following principles outline ASCO’s support for coverage of CAR-T therapies and the need for appropriate reimbursement.

- ASCO supports coverage for all FDA-approved indications of CAR-T therapy.
- 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 any and all care required for adverse events and follow-up.
- ASCO supports CMS in their proposed National Coverage Determination (NCD) approach of Coverage with Evidence Development, conditional on a minimization of unnecessary, duplicative or additional administrative requirements.
- ASCO believes that Medicare should 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 believes that all patients should be supported by the right therapy at the right time. Providers do not set list prices for drugs or treatments and should not bear the financial burden of any unpaid portion of an innovative cancer care therapy simply because a manufacturer has set a high launch price.

In response to the 2019 proposed rule, ASCO urged the Agency to create policy that is consistent with the needs of Medicare beneficiaries with cancer. Such policy should promote and secure access to evidence-based and medically appropriate treatment that is supported by fair and adequate reimbursement. We therefore acknowledge and appreciate the Agency’s efforts to address reimbursement of emerging therapies broadly; and specifically increasing the N-TAP for CAT-T therapy.

The increase in the N-TAP payment acknowledges that providers may be providing CAR-T at a financial loss, a scenario which is unsustainable. The estimated cost per treatment of CAR-T is $373,000, and CMS currently reimburses a maximum of $186,000. By increasing the NTAP from 50% to 65% of the estimated cost, CMS estimates the reimbursement for CAR-T would increase to $242,450, which is still well below the actual cost for treatment and the accompanying services. However, we also note that the temporary nature of the NTAP payments do not provide certainty to cancer care experts who are undertaking great effort and expense in order to deliver this life saving treatment.

While ASCO believes providers should never have to bear the financial burden when payors do not reimburse for the full cost of a therapy, this is especially egregious and unsustainable for high cost
therapies. There is a significant and meaningful difference in a loss of 35% for a therapy that costs almost $400,000 versus a therapy that costs $400. As additional CAR-T therapies are introduced to the market, it is important that the Agency continues to work towards the development of sustainable, long-term payment solutions to ensure that cancer patients have access these treatments. It is not appropriate, nor is it realistic, to merely set reimbursement below cost and expect to incentivize value-based care and lower drug prices.

ASCO is sensitive to the financial considerations that face our health care system and has continued to promote value-based cancer care. ASCO has developed and is implementing several initiatives to promote high-quality, high-value cancer care for Medicare beneficiaries. These efforts include the creation of standards for identifying high-quality clinical pathways, the use of “big data” approaches to unlock new treatments, and the creation of a value framework to help patients and their oncologists evaluate and select the most appropriate treatments for their individual prognosis. Additionally, ASCO is working to refine its physician-focused payment model, which enables physicians to more appropriately meet the needs of oncology patients. ASCO stands ready to assist CMS and collaborate on short- and long-term solutions to improve the value of cancer care provided to Medicare beneficiaries. We believe that the best way to secure access to therapies like CAR-T is through cancer-focused value-based approaches. ASCO welcomes the opportunity to assist the Agency in developing these strategies.

ASCO also notes that increasing the payment for CAR-T therapies from 50 percent to a minimum of 80 percent, and ideally provide reimbursement for the provider's cost is fully consistent with CMS's authority for new technologies and services under the N-TAP program.1

II. Addressing Rural Disparities

ASCO is committed to ensuring all patients have access to high-quality cancer care, regardless of where they live. In April, we announced a new task force aimed at reducing disparities and improving outcomes for patients and survivors of cancer who live in rural communities. Our efforts are focused on addressing provider education and training, workforce, and other systemic barriers that hinder cancer care access for rural populations.

ASCO applauds the agency’s acknowledgement of disparities in rural healthcare. Moreover, we support CMS’s efforts to refine the calculation of the wage index to help address them. The gap in payments between rural and urban hospitals is great and contributes to disparities in care. We do, however, urge CMS to make these changes without budget neutrality offsets. Many rural hospitals are particularly vulnerable and in urgent need of support, and the wage index is one way to quickly channel that support, but CMS should not do so at the expense of urban hospitals, which also are chronically underpaid by Medicare relative to many other payers. The proposed changes to the

1 Under the statutory authority under which the N-TAP program has been established, Congress specified that the additional payment be sufficient to cover the average cost of the new technology item or service: “... provide for additional payment to be made under this subsection with respect to discharges involving a new medical service or technology described [above] that occur during the period described [above] in an amount that adequately reflects the estimated average cost of such service or technology; ...” Soc. Sec. Act 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III))
wage index boost payments to rural hospitals by decreasing Medicare payments to other, mainly urban hospitals. As such, ASCO is concerned about the impact that these changes may have on access to cancer care provided by other hospitals, especially those that are negatively impacted by the proposed changes. While we support steps towards improving rural cancer care, such steps should not put at risk the cancer care provided by other hospitals.

We likewise urge CMS to explore and pursue other ways to buttress healthcare in rural areas.

III. Implementing Meaningful Measures to Reduce Administrative Burden and Improve Patient Care

ASCO supports the Agency’s continued efforts to implement Meaningful Measures across all programs to reduce unnecessary burden and increase efficiencies, so that providers can spend more time with patients. CMS should work to create measures that are meaningful and reflective of modern oncology practice, including the measures related to quality reporting in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

ASCO shares the Agency’s goal of putting patients first and focusing measures on what is important in delivering high quality cancer care. While in recent years there has been some improvement in measures used in quality programs, quality measures and payment programs still emphasize documenting irrelevant tasks, which increases administrative burden on physicians and reduces the time physicians spend with their patients. Measures must support the goal of improving patient outcomes. Therefore, it is important for CMS to facilitate the use of measures that are crosscutting, and that evaluate valuable cancer care objectives.

CMS is proposing the removal of three pain management measures in order to enhance alignment across programs and out of concern that these measures may encourage inappropriate opioid prescribing. ASCO supports efforts to combat the opioid epidemic but cautions that undertreatment of pain is still a real concern; CMS should work with stakeholders in the development of measures that appropriately capture pain management without the adverse effect of inadvertently encourage over-prescribing of opioids.

ASCO supports the Agency’s efforts to reduce the number of admissions and emergency department visits for patients receiving outpatient chemotherapy in the PPS-exempt cancer hospitals. Reducing unplanned readmissions related to cancer care is crucial to building a higher-value cancer care system and transparency is important in achieving this goal. ASCO urges the Agency to ensure the integrity of reported data and the analysis of that data prior to posting on hospital compare.

We agree that measuring inpatient admissions and emergency department visits for cancer patients receiving chemotherapy provides a critical indicator of the quality and value of cancer care provided. However, a major concern for physicians is integrity of the data regarding ED visits and admissions and the attribution of often unrelated diagnosis to the oncologists, who see them more frequently than other specialists—including their primary care physicians. We encourage the Agency to use performance data from related measures to further examine how providers can improve performance and implement policies that would reduce the overall number of admissions and emergency department visits for cancer patients.
ASCO has championed many efforts in Medicare Part B, including ASCO’s Patient Centered Oncology Payment Model, that are designed to reduce unplanned readmissions and emergency department visits. Regardless of the site of service, the value of care improves when the necessary resources exist to appropriately coordinate and manage care to avoid both outcomes. To date, the Oncology Payment Model has been the sole Medicare Part B program that supports oncology practices by providing resources to support the infrastructure needed to manage care to achieve meaningful reductions in unplanned readmissions and emergency department visits. ASCO is available to assist the Agency in developing additional strategies, including our proposals for alternative payment models that support improvements in these outcomes.

**ASCO supports the removal of the “Verify Opioid Treatment Agreement measure” in CY 2020.**

CMS should continue to work to develop more meaningful measures to address the opioid epidemic.

ASCO supports the overall efforts of the Administration to address the ongoing opioid epidemic. However, implementing a measure requiring facilities to verify the existence of opioid treatment agreements is not a meaningful way to achieve this goal. As CMS notes in the proposed rule, there are several fundamental barriers to the implementation and adoption of this measure as a part of performance measurement. These include disagreement among the medical community regarding the use and effectiveness of Opioid Treatment Agreements, lack of a standardized definition for an Opioid Treatment Agreement, and complexities resulting from differences in state laws. The Agency also notes that practitioners may have significant difficulties locating the appropriate sources to query to identify the existence of a treatment agreement. These issues are likely to create additional burdens for providers and will not facilitate the Agency’s end-goal of promoting interoperability rather than securing additional documentation.

**We encourage the Agency to finalize the minimum 90-day reporting period in CY 2021.** This allows for the collection of adequate data to assess an institution’s use of EHR technology without imposing an onerous year-long burden. CMS should continue to work towards the development of policies which will provide flexibility for institutions without overemphasizing achievement of performance goals in individual measures.

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Thank you for the opportunity to provide comment on the Fiscal Year 2020 Hospital Inpatient Prospective Payment System proposed rule. Please contact Sybil Green at Sybil.Green@asco.org if you have any questions.

Sincerely,

Howard A. Burris III, MD, FACP, FASCO
President, American Society of Clinical Oncology