September 17, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1753-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (CMS-1753-P)

Submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure:

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the recent proposed rule for the Hospital Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2022 published in the Federal Register on August 4, 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 including Medicare beneficiaries.

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ASCO supports some updates CMS has proposed; however, we have significant concerns that several of the policies proposed by CMS for 2022 have the potential to undermine patient access to cancer care for Medicare beneficiaries. We submit the following comments for your consideration.

• ASCO continues to object to CMS’s policy that sets a differential Medicare payment rate for separately covered outpatient drugs purchased under the 340B program. ASCO urges CMS to instead implement reforms to the 340B Drug Pricing Program which are needed to ensure the program meets its

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original intent to support high-quality care for the uninsured, underinsured, and low-income patients.

- ASCO strongly urges CMS to collaborate closely with ASTRO on implementation of the Radiation Oncology Model and to implement the recommendations they have outlined, including establishing rate stability through the application of a discount factor set at 3% or less.

- ASCO supports the agency’s decision to halt the elimination of the Inpatient Only (IPO) List. Prior to implementing any changes or modifications to the IPO List, ASCO urges the agency to fully evaluate the impact of any further proposed changes.

- ASCO thanks CMS for not expanding the hospital outpatient prior authorization (PA) process in this rulemaking cycle. We urge the agency to review the current program to assess its impact on utilization, patient access to care and the administrative burden it generates. ASCO did not support the CMS policy in 2020 to establish the program or its expansion in 2021.

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

We offer our full perspective and comments on provisions in the CY 2022 Hospital Outpatient Prospective Payment System proposed rule in greater detail in the balance of this letter.

**Outpatient Prospective Payment System**

**340B Purchased Drugs**

ASCO continues to object to CMS’s policy that sets a differential Medicare payment rate for separately covered outpatients drugs purchased under the 340B program. ASCO urges CMS to instead implement reforms to the 340B Drug Pricing Program which are needed to ensure the program meets its original intent to support high-quality care for the uninsured, underinsured, and low-income patients.

For CY 2022, CMS proposes to maintain payment for 340B drugs furnished to hospital outpatient departments at Average Sales Price (ASP) minus 22.5 percent. Prior to 2018, Medicare reimbursed 340B drugs through the Part B benefit at ASP plus 6 percent. The discounted purchase price combined with the higher reimbursement rate allowed hospitals to realize significant savings on high-cost drugs, which in turn would be used to support uncompensated care costs and other safety net programs. Beginning in 2018, the agency changed its policy to dramatically reduce the reimbursement rate of separately payable drugs to ASP minus 22.5 percent. ASCO strongly opposed this reduction in the 2018-2021 proposed rules, and we are deeply disappointed that CMS continues to implement this flawed and potentially harmful policy.

ASCO urges CMS to consider recommendations outlined in the ASCO 340B drug pricing reform statement1 in its approach to reforming the 340B Program. When proposing further policy changes and updates, we urge CMS to analyze the impact of these policies including whether the proposals satisfy

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the original intent of the legislation, the presence or absence of appropriate safeguards for compliance and oversight, and the unique considerations related to cancer patients and other vulnerable patients.

The impacts of the 340B Drug Pricing Program are especially significant in oncology given the integral role that drug therapies play in the treatment of individuals with cancer. We remain concerned that continued reimbursement reductions for 340B drugs fail to take these recommendations into account.

**Radiation Oncology (RO) Model**

In September 2020, CMS finalized the Radiation Oncology (RO) Model, a Centers for Medicare and Medicaid Innovation Center (CMMI) demonstration model. The RO Model is a mandatory nationwide demonstration model encompassing approximately 30 percent of eligible radiation oncology episodes. The model pays a prospective payment on a site neutral basis, and the rate does not vary based on the modality of treatment. CMS had intended to implement the RO Model effective January 1, 2021, but the model was delayed due to the COVID-19 pandemic and legislation designed to respond to the pandemic. CMS proposes to proceed with implementation on January 1, 2022, but with several proposed changes.

**ASCO strongly urges CMS to collaborate closely with the American Society of Radiation Oncology (ASTRO) on execution of the Radiation Oncology Model and to implement the recommendations ASTRO has outlined, including establishing rate stability through the application of a discount factor set at 3% or less.**

ASTRO members are medical professionals who make up the radiation treatment teams that are critical in the fight against cancer, treating more than one million cancer patients each year. ASTRO initiated conversations with CMMI to develop an alternative payment model (APM) allowing clinicians to fully participate in the Quality Payment Program, and to ensure fair and predictable payment for the radiation oncologist while protecting cancer patients’ access to care across all settings. ASTRO is expertly positioned to provide input on the inherently complex issues related to Medicare payment policy and APM development for radiation oncology services. We urge CMS to work with ASTRO to finalize an APM which incentivizes cancer treatments that result in the highest quality of care and best patient outcomes.

In the 2022 OPPS proposed rule, CMS proposes a .25 percentage point reduction in the discount factor on both the professional component (PC) and technical component (TC). This reduces the RO Model discount from 3.75% on the PC and 4.75% on the TC to 3.50% and 4.50% respectively. While we appreciate the slight decrease in discount factor, we remain concerned about the impact of this significant reduction. We urge the agency to set the discount factor at 3% or less. Reducing these cuts to 3% would still generate significant savings for Medicare and better align the RO Model’s discount factors with those of other APMs. Additionally, CMS must act to address the continued declines in the Medicare physician fee schedule (MPFS) payment rates. Continued MPFS rate declines will exacerbate rate instability issues, putting practices that are compelled to participate in the RO Model in double jeopardy, as they will be subjected not only to steep discount factors, but also the declines in MPFS rates, preventing them from successful participation.

**Inpatient Only Services List**
ASCO supports the agency’s decision to halt the elimination of the Inpatient Only (IPO) List. Prior to implementing any changes or modifications to the IPO List, ASCO urges the agency to fully evaluate and disclose the impact of any further proposed changes.

Historically, CMS has identified services that are safely provided only in an inpatient setting and thus would not be paid by Medicare under the OPPS. Services identified as such were designated on the inpatient only (IPO) list. In the CY 2021 OPPS Final Rule, CMS announced that it would eliminate the IPO List over the course of three years. In CY 2021, the first year of the transition, CMS removed 298 codes from the list. CMS is now proposing to stop the phased-in elimination of the IPO List and to restore all 298 codes to the list beginning in CY 2022; however, CMS is not abandoning the idea of eliminating or modifying the IPO List and is seeking feedback on alternatives.

ASCO thanks CMS for pulling back the proposal to eliminate the IPO list. As we discussed in our comments to CMS on the 2021 PFS rulemaking cycle, ASCO has concerns that this proposal could have an unintended negative impact on access to care, patient safety, and additional administrative burden. As CMS begins to consider alternative to eliminating the IPO list, we ask that it be clear in future guidance and rules about the intent and implementation of this proposal, especially during the COVID-19 pandemic. CMS should critically evaluate how each policy affects patient access to care, patient safety, and potential additional administrative burdens to the providers who care for the most vulnerable and severely ill patients with cancer.

As CMS continues to analyze future policy proposals, we encourage the agency to address and consider how payment rates for these newly reimbursed outpatient services will be set and whether these changes may affect access to care. We urge CMS to collaborate with stakeholders to fully evaluate how quickly facilities can absorb these changes in payment rates, and whether there is a potential for payment rate changes to affect patient access to care.

Site of care continues to be a policy area in which CMS is investing substantial resources. This comes at a time when technology and other advances support and accelerate the shift of services from the inpatient to the outpatient setting. We urge the agency to work collaboratively with clinicians, hospitals, health systems, and other stakeholders as it considers updates to the IPO List policy.

Currently, when a stakeholder believes it is appropriate to remove a code from the IPO List, there is a process in place to submit a request to CMS and present evidence as to why the code should be removed from the List. We believe that this process has worked well for the agency, hospitals and physicians, and patients, and we urge CMS to continue the current process while investigating other options, including the retention of the current policy and IPO List.

Prior Authorization

ASCO commends CMS for not expanding the hospital outpatient prior authorization process in this rulemaking cycle. We urge the agency to review the current program to assess its impact on utilization, patient access to care, and the administrative burden it generates. ASCO did not support the CMS policy in 2020 to establish the program or its expansion in 2021.

For CY 2020, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization (PA) request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. CMS originally applied
this process to five categories of services beginning on July 1, 2020. As part of the CY 2021 rulemaking cycle, CMS expanded the list of services subject to the prior authorization process to include cervical fusion with disc removal and implanted spinal neurostimulators, effective July 1, 2021. CMS is not proposing to supplement or otherwise change the list of services subject to prior authorization in this rulemaking.

ASCO is committed to supporting policies that reduce cost while preserving or increasing quality of cancer care, but we believe that utilization management tools such as PA should be implemented in a transparent and evidence-based manner and in a way that does not undermine patient access to medically necessary care. ASCO is concerned with the use and application of prior authorization requirements and the negative impacts that PA can have on patient access to care and an increasing administrative burden for providers without any evidence of clear benefit.

ASCO refers CMS to its 2017 policy statement on utilization management in which we recommend an appropriate framework for the design of utilization management programs. We remain committed to the principles and recommendations conveyed in this document, and to working with stakeholder groups to develop and implement policies that benefit patients with cancer while reducing unnecessary or wasteful costs. We urge CMS to incorporate the principles of ASCO’s statement as it works to develop streamlined, transparent, and evidence-based policies that support appropriate utilization of healthcare services. We set forth six critical principles that any utilization management policy must meet to ensure medically necessary care for patients with cancer is not jeopardized or unreasonably delayed:

- Individuals with cancer should have full access to the anti-cancer therapy most appropriate for their disease when used in accordance with current clinical and scientific evidence.
- Cost should not be the primary driver of utilization management policies.
- Utilization management policies should be evidence-based and reflect the most current science and understanding of cancer treatment.
- Utilization management processes should result in timely and clear determinations that are consistent with the health insurer’s coverage and other policies.
- Payer cost containment strategies and decision-making processes should be transparent and without conflicts of interest.
- Payers should implement utilization management policies in a way that minimizes administrative burdens—specifically time and effort—on both providers and patients.

We believe that the PA process established by CMS fails to meet these principles. It lacks transparency, CMS has failed to provide information on how its policies are evidence-based, and significant concerns remain related to the administrative burden of the process and its impact on patient access to care. This is especially challenging as clinicians and their patients continue to weather the impact of an ongoing pandemic and related public health emergency.

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. We offer our perspective below.

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. This is especially concerning in light of the Agency’s assertion that specialty society measures, once submitted, are “owned” by CMS and may be altered without input or permission by the originating society. This reality, together with increasing administrative burden associated with enhanced testing requirements and the significant financial burden, may lead professional organizations to discontinue their investment in measure development for federal reporting programs.

- 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 is not enough to say “use FHIR.” CMS should consider its requirements for third-party intermediaries and their ability to aggregate multiple data sources. Will CMS be the data aggregator and calculate the measure score from the range of data sources, or will this function fall to third-party intermediaries?
  - This approach also increases the testing burden for measure developers. It is already a challenge to test eCQMs from one data source (EHRs). Testing measures with data from multiple sources may not be feasible. Regardless, the expense would be prohibitive.
  - ASCO is concerned that the requirement for all measures to be digital could limit the types of measures developed, potentially straying from clinical quality of measures and more towards data capture and availability.
  - ASCO is concerned that wholesale shift to an ecosystem with multiple data sources may be premature, as use of 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, however the Agency should recognize its use in quality measurement programs remains 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 currently 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 has an important 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 would be possible, even by 2025, without a broad requirement for 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™.

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Thank you for the opportunity to provide comment on the CY2022 Hospital Outpatient Prospective Payment System Proposed Rule. Please contact Gina Baxter at gina.baxter@asco.org or Karen Hagerty at karen.hagerty@asco.org with any questions.

Sincerely,

[Signature]

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