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June 13, 2022

Ms. 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: <http://www.regulations.gov>

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

Dear Administrator Brooks-LaSure:

The American Society for Radiation Oncology (ASTRO)¹ appreciates the opportunity to provide written comments on the “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” published in the Federal Register as a proposed rule on May 10, 2022.

The Inpatient Prospective Payment System (IPPS) proposed rule contains several issues of interest to the field of radiation oncology, including New Technology Add-On Payments (NTAP) for new services and technologies for FY 2023 and modifications to existing NTAP designations; a proposal to revert to historical two-year data periods for determining MS-DRG relative weights; a proposal to reclassify laser interstitial therapy’s MS-DRG; establishment of a permanent cap on wage index decreases and continuation of the Low Wage Index Value Hospital Policy; Medicare Promoting Interoperability Program; and

¹ ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

overarching principles for measuring health care quality disparities and collection of data associated with social determinants of health that can be used to improve health equity. Below are ASTRO's comments on each of these issues.

Proposed New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2023 and Modifications to Existing NTAP Designations

A new medical service or technology may be considered for NTAP if the DRG prospective payment rate is inadequate based on the estimated costs incurred with respect to services delivered involving a new medical service or technology. To secure a new technology add-on payment, the new medical service or technology must demonstrate that it is 1) new; 2) costly such that the applicable DRG rate is inadequate; and 3) represents a substantial clinical improvement over existing services or technologies.

In FY 2020, Progenics Pharmaceuticals, Inc. submitted an NTAP application for AZEDRA® (iobenguane Iodine-131), which is a drug solution formulated for intravenous use in the treatment of patients with iobenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma. For FY 2023, AZEDRA® will no longer be considered new as its three-year anniversary date (May 21, 2022) will occur prior to April 1, 2023.

ASTRO agrees that it is appropriate to sunset AZEDRA®'s NTAP designation as its three-year anniversary date will occur prior to April 1, 2023.

Proposed Reclassification of Laser Interstitial Thermal Therapy (LITT) MS-DRG

In the 2022 IPPS Final Rule, CMS finalized the reassignment of 31 ICD-10-PCS procedure codes describing Laser Interstitial Thermal Therapy (LITT) of various body parts to more clinically appropriate MS-DRGs. For FY 2023, CMS received requests from LITT technology manufacturers (Medtronic and Monteris® Medical) to reverse the MS-DRG reassignment for the ICD-10 procedure codes that identify LITT of the brain and brain stem (codes D0Y0KZZ and D0Y1KZZ) from the MS-DRGs for peripheral, cranial nerve and other nervous system procedures (MS-DRGs 040, 041, and 042) back to the MS-DRGs for craniotomy and endovascular procedures (MS-DRGs 023, 024, 025, 026, and 027).

The requestors both noted the distinct clinical differences between the invasiveness of LITT, which involves instrumentation being placed deeply within the brain tissue, and the non-invasiveness of stereotactic radiosurgery (SRS) that does not involve entering the brain with instrumentation. The requestor also indicated LITT utilizes a different modality via direct thermal ablation compared to SRS, which utilizes externally generated ionizing radiation.

ASTRO recommends that the MS-DRGs for LITT of the brain and brain stem (ICD-10 codes D0Y0KZZ and D0Y1KZZ) revert back to the MS-DRGs for craniotomy and endovascular procedures (MS-DRGs 023, 024, 025, 026, and 027) rather than peripheral, cranial nerve and other nervous system procedures (MS-DRGs 040, 041, and 042). LITT is intrinsically different from the other cranial nerve and other nervous system procedures included in MS-DRGs 040, 041, and 042 and is much more akin to the invasive procedures of MS-DRGs 023, 024, 025, 026, and 027.

2021 MedPAR data and FY 2020 HCRIS for analyzing MS-DRG changes and determining MS-DRG relative weights

In evaluating MS-DRG changes and setting MS-DRG relative weights, CMS has relied on claims data captured in the Medicare Provider Analysis and Review (MedPAR) file and cost report data captured in the Hospital Cost Reporting Information System (HCRIS) file. In a traditional year, for rate setting purposes, CMS uses data that captures claims from discharges that occurred for the fiscal year that is two years prior to the fiscal year addressed in the rulemaking. For FY 2022, in light of the COVID-19 public health emergency, CMS used FY 2019 MedPAR claims data rather than FY 2020 MedPAR data.

For FY 2023, however, the Agency is proposing to return to its historical practice of using the most recent data available, including FY 2021 MedPAR claims and FY 2020 cost report data, with certain proposed modifications to its usual rate-setting methodologies to account for the anticipated decline in COVID-19 hospitalizations of Medicare beneficiaries at IPPS hospitals as compared to 2021. It is also considering, as an alternative, to use FY 2021 data for purposes of FY 2023 rate-setting without the proposed modifications to their usual methodologies.

ASTRO agrees that it is appropriate for the Agency to return to its historical practice of using the most recent data available. However, we believe that 2021 should be considered a transitional year from a data perspective because many hospitals were in the process of reopening their doors and resuming regular services when a new wave of COVID-19 began appearing around the country. This uptick caused many facilities to cancel elective surgeries and other, similar services.

Proposed Permanent Cap on Wage Index Decreases

CMS adjusts the IPPS standardized amounts for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level and updates the wage index annually based on a survey of wages and wage-related costs of short-term, acute care hospitals. In last year's comments for the FY 2022 IPPS Proposed Rule, a 5% cap policy to prevent large year-to-year variations in wage index values was recommended. As such, for FY 2023 and subsequent years, CMS is proposing to apply a 5% cap on any decrease to a hospital's wage index from its wage index in the prior fiscal year, regardless of the circumstances causing the decline. Additionally, this proposal would be applied in a budget-neutral manner through a national adjustment to the standardized amount.

ASTRO encourages the Agency to adopt the application of a 5% cap on any decrease to a hospital's wage index from its wage index in the prior fiscal year, as many hospitals are still recovering financially from the COVID-19 public health emergency. A permanent cap on any decrease from year to year will provide a better sense of financial stability for many health care facilities around the country.

Proposed Continuation of the Low Wage Index Hospital Policy

In the 2020 IPPS Final Rule, CMS adopted a policy to increase the wage index values for certain hospitals with low wage index values (below the 25th percentile) and decrease the wage index values for hospitals above the 75th percentile in order to maintain budget neutrality. Low wage index value hospitals received an increase of half of the difference between each individual hospital's wage index value and the 25th percentile wage index value. A similar methodology was used to reduce the wage index value for hospitals above the 75th percentile wage index value, thus keeping the policy budget neutral.

At the time, CMS indicated the policy would be effective for at least four years, beginning in FY 2020, so that employee compensation increases implemented by these hospitals would have time to be reflected in the wage index calculation. For FY 2023, the Agency proposes to continue the low wage index hospital policy and will continue to do so in the budget neutral method by applying an adjustment to the standardized amounts.

ASTRO continues to appreciate CMS's recognition of the disparities between high wage and low wage index hospitals, but we remain concerned that the proposed methodology for addressing the issue merely shifts funds from one group to another with little consideration for the potential impact. ASTRO again urges CMS to consider alternative methods that involve the collection of more accurate wage data, such as tasking Medicare Administrative Contractors with conducting wage data audits to verify local labor prices. Additionally, until alternative methods are implemented, we again encourage CMS to adopt the permanent 5% cap on wage index decreases, as discussed above.

Medicare Promoting Interoperability Program

CMS is proposing to make the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure mandatory, expand the measure to include Schedule II, III, and IV drugs and maintain the 10-point maximum. **ASTRO supports the proposed changes, provided that current exclusions for providers that do not prescribe drugs are maintained.**

The Agency also is proposing to add a new Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) measure under the Health Information Exchange (HIE) Objective as a yes/no attestation measure as an optional alternative to the three existing measures under the HIE Objective. **ASTRO appreciates that this measure is optional because we believe this proposal will disproportionately apply to providers and not vendors.** CMS is adding more and more technical requirements without confirming that the functionality of vendor systems is actually useful. For decades, Meaningful Use certification criteria has confirmed only that certain technology exists, but has not measured the system integration, user interface, or workflow of the technology. For example, APIs have existed in most vendor systems since the 2015 Edition Cures Update; however, this technology is still not utilized by most clinicians because the APIs were developed and implemented to check a box for ONC. Only now that the 21st Century Cures Act deadline is approaching are the vendors implementing robust APIs that can actually transmit the appropriate amount of data to be useful. The Agency, along with ONC, has an opportunity to reassess measurement of compliance for vendor systems instead of continuing to place the burden on the backs of clinicians.

Finally, CMS is proposing to modify the eCQM reporting and submission requirements to increase eCQM reporting from four eCQMs (one mandatory and three self-selected) to six eCQMs (three mandatory and three self-selected). **ASTRO has significant concerns with the constant change in measure specification. It is both time consuming and expensive to constantly change measure specifications to comply with the ever-changing rules. CMS should offer financial incentives to offset the costs of these constant changes.**

Hospital Inpatient Quality Reporting (IQR) Program

Electronic Clinical Quality Measure (eCQM) and Hybrid Measures

CMS is proposing to modify the eCQM validation policy to increase the submission requirement from 75% to 100% of the requested medical records to successfully complete eCQM validation beginning with the FY2025 payment determination period. **ASTRO has serious concerns with this proposal. Vendor systems must be thoroughly vetted before these changes are implemented so that providers are not punished for things that are out of their control. As we have mentioned in previous comment letters, we believe that the onus of these requirements should be placed on the vendors, not the providers.**

The Agency is also proposing to modify the eCQM reporting and submission requirements to increase eCQM reporting from four (one mandatory and three self-selected) to six (three mandatory and three self-selected) beginning with the CY2024 reporting period. As mentioned earlier, ASTRO has significant concerns with the constant change in measure specification. It is both time consuming and expensive to constantly change measure specification to comply with the ever-changing rules. CMS should offer financial incentives to offset the costs of these constant changes.

Health Equity

Social Determinants of Health (SDOH) Diagnosis Codes – Request for Information

CMS is seeking comments on how it can foster the documentation and reporting of the diagnosis codes describing social and economic circumstances (social determinants of health) to reflect each health care encounter and improve the reliability and validity of the coded data, including efforts to advance health equity more accurately.

The US Core Data for Interoperability (USCDI) is a standardized set of health data classes and data elements for nationwide, interoperable health information exchange. Currently, health IT vendors are required to incorporate USCDI in health IT systems; however, SDOH data elements are currently not a specific requirement. While the collection of SDOH diagnosis codes is important to address healthcare inequities, any reporting requirement that involves manual collection and reporting of data can be a significant burden for physician practices. **ASTRO supports the collection of SDOH data codes but urges CMS to consider reporting on a voluntary basis until the codes are incorporated into USCDI as a requirement.**

Current Assessment of Climate Change Impacts on Outcomes, Care, and Health Equity – Request for Information

CMS notes there is evidence that climate change disproportionately harms underserved populations (for example, racial and ethnic minority groups, indigenous people, members of religious minorities, people with disabilities, sexual and gender minorities, individuals with limited English proficiency, older adults, and rural populations). Long-term discrimination and disparities based on social determinants of health mean that these groups are often less equipped to withstand climate threats and are more susceptible to associated harm. Out of concern for the health of individuals, and to maintain uninterrupted operations in service of patients, the Agency believes the healthcare sector should more fully explore how to effectively prepare for climate threats. Because healthcare facilities also emit greenhouse gases (GHGs)

that contribute to climate change and its impacts, CMS believes that they should study how best to reduce those emissions, as well.

In this request for information, CMS is seeking comment on how hospitals, nursing homes, hospices, home health agencies, and other providers can better prepare for the harmful impacts of climate change on their patients, and how they can support them in doing so.

ASTRO appreciates CMS' interest in addressing the impact of climate change on outcomes, care and health equity. In recent years, ASTRO members have reported on the challenges associated with delivering care after devastating hurricanes, forest fires and other natural disasters. These events destroy the fabric of their communities and prevent many from resuming normal operations within a reasonable amount of time. For cancer patients, time is of the essence. Every day that a radiation oncology clinic is offline, due to a power failure or worse, is a day without treatment which causes anxiety already amplified by the natural disaster.

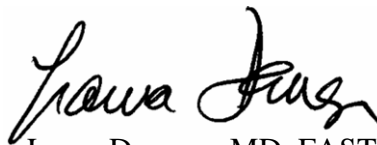
CMS needs to invest resources into ensuring that cancer treatment does not stop as a result of a natural disaster. This means supporting the infrastructure necessary, including generator systems and other emergency deployment systems, to ensure continuity of care. Too often these types of disasters happen in communities that already serve disadvantaged communities. These are the same communities that struggle to recover from natural disasters and are in the greatest need of structural investments that can help them resume services quickly and efficiently.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Adam Greathouse, Senior Manager, Health Policy, at 703-839-7376 or adam.greathouse@astro.org.

Sincerely,



Laura I. Thevenot
Chief Executive Officer



Laura Dawson, MD, FASTRO
Chair, ASTRO Board of Directors