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Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
P.O. Box 8013
7500 Security Boulevard
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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma,

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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals" published in the Federal Register as a proposed rule on May 29, 2020.

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 technologies involving radiation treatment delivery; technical clarification of the alternative pathway for the FDA's Breakthrough Devices Program; continuation of the Low Wage Index Hospital Policy; a proposed policy involving the collection of private payer MS-DRG relative weights to inform payment methodology changes; and a proposed policy change related to Medical Residents affected by Residency Program or Teaching Hospital closure. Below are ASTRO's comments on each of these issues:

[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.*

Proposed New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2021

A new medical service or technology may be considered for NTAP if the Diagnosis-Related Group (DRG) prospective payment rate is inadequate based on the estimated costs incurred with respect to discharges involving a new medical service or technology. In order 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) a substantial clinical improvement over existing services or technologies. The following applications were received for services related to the delivery of radiation therapy in the inpatient setting:

GammaTile™

GT Medical Technologies, Inc. submitted an application for GammaTile™, which is a brachytherapy technology for use in the treatment of patients who have been diagnosed with brain tumors. GT Medical Technologies, Inc. submitted a previous application for the same technology for consideration during the FY 2020 IPPS rulemaking period. The technology uses cesium-131 radioactive sources embedded in a collagen matrix that are designed to provide adjuvant radiation therapy to eliminate remaining tumor cells in patients who required surgical resection of brain tumors. The GammaTile™ is biocompatible and is left in the body permanently without need for future surgical removal.

In the 2020 IPPS final rule, CMS finalized that GammaTile™ did not meet the criteria for new technology add-on payments. CMS was unable to make a determination that GammaTile™ technology represented a substantial clinical improvement over existing therapies because there was no statistically significant data that supported the GammaTile™ NTAP application.

In the FY 2021 IPPS proposed rule, GT Medical Technologies, Inc again submitted an application for new technology payments, and the agency is seeking comment on whether the GammaTile™ meets the NTAP criterion.

ASTRO supports the NTAP application for GammaTile™ as it represents new and costly treatments for disease sites with a limited number of clinical treatment options. As evidenced in the papers submitted by GT Medical Technologies, Inc, patients treated with the technology experience improved clinical outcomes that are otherwise unattainable due to the uniqueness of their disease thus meeting the "substantial clinical improvement criterion".

AZEDRA NTAP Status Proposed to be Extended through 2021

Every year, CMS reviews the status of technologies approved for NTAP and determines whether or not to continue NTAP status. In FY 2020, Progenics Pharmaceuticals, Inc. submitted an application for new technology add-on payments for AZEDRA® (iobenguane Iodine-131). AZEDRA® 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. These are rare tumors with an incidence of approximately 2 to 8 people per million per year.

CMS considers the beginning of the newness period to commence when AZEDRA® was approved by the FDA, which was on July 30, 2018. CMS extends new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Since the 3-year anniversary date of the entry of AZEDRA® into the U.S. market (July 30, 2021) will occur in the second half of 2021, CMS is proposing to continue new technology add-on payments for 2021. CMS is also proposing that the maximum new technology add-on payment for cases involving AZEDRA remain at $98,150. CMS is inviting public comments whether to continue new technology add-on payments for AZEDRA® for 2021.

ASTRO supports CMS' proposal to continue new technology add-on payments for AZEDRA® in 2021. ASTRO also supports the Agency's proposed maximum new technology add-on payment for cases involving AZEDRA remain at $98,150.

Technical Clarification to the Alternative Pathway for the FDA Breakthrough Devices Program

In the 2020 IPPS final rule, CMS finalized a new NTAP pathway for transformative new devices. This new approach recognized devices that are part of the Federal Drug Administration's (FDA) Breakthrough Devices Program and receive FDA marketing authorization. These devices are considered new and are not required to meet the requirement that it substantially improves, relative to the existing technologies, the diagnosis or treatment of Medicare beneficiaries. This new approach applies to applications beginning October 1, 2020. Additionally, the Agency finalized modifications to the NTAP payment methodology. If the cost of care exceed the Diagnosis Related Group (DRG) payment, then Medicare will make an add-on payment equal to the lessor of: 1) 65 percent of the cost of the new medical service or technology; or 2) 65 percent of the amount by which the cost of the case exceeded the DRG payment. This represents an increase from the existing add on amount of 50 percent, which many commenters felt did not adequately reflect the cost of many expensive therapies.

In the 2021 IPPS, CMS addresses public concern with respect to the "marketing authorization" required for purposes of approval under the alternative pathway for transformative new devices. Specifically, CMS is addressing concern that technology would meet the marketing authorization requirement so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program. To address this potential confusion, CMS clarifies existing policy that a new medical device under the alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program. Specifically, with regard to the eligibility criteria, CMS is proposing to amend the regulations to state that "A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation."

ASTRO continues to support the Agency's efforts to recognize devices that are part of the FDA Breakthrough Devices Program. ASTRO applauds CMS for providing amendments to these regulations to provide clarification to the "market authorization" component of these regulations.

Private Payer MS-DRG Relative Weight Data to Inform Future Medicare Rates
CMS currently uses hospital charge master data to inform rates for both hospital inpatient and outpatient services. To reduce its reliance on hospital charge masters, the Agency is proposing to require hospitals to report market-based payment rate information in their Medicare cost report for periods ending on or after January 1, 2021. CMS proposes to use this information to change the methodology for calculating the IPPS MS-DRG relative weights to reflect market-based pricing.

In the FY2021 IPPS proposed rule, the Agency is specifically asking that hospitals report the median payer-specific negotiated charge that the hospital has negotiated with Medicare Advantage organizations and third-party payers by Medicare Severity-Diagnosis Related Group (MS-DRG). CMS is considering adopting this policy in the 2021 IPPS Final Rule and seeks comments on the potential methodology change.

In the proposed rule, the Agency cites the 2019 Executive Order (EO): "Protecting and Improving Medicare for Our Nation's Seniors" as the basis for this proposal. The EO described the market benefits of the Medicare Advantage program as offering an "efficient and value-based care through choice and private competition and has improved aspects of the Medicare program that previously failed seniors". However, the use of market-based data points in the determination of FFS pricing will not result in alignment with existing market rates because CMS will still be required to apply the budget neutrality factor to the market-based MS-DRG relative weights. The proposal merely results in a shift in payment for services across different service lines and does not represent true reform of the existing FFS payment methodology.

While there are problems with the existing policy of developing rates based on charges and the cost to charge ratio, the premise of the existing policy is the estimation of the relative resources used to provide care, which recognizes change in the clinical staff requirements, equipment, supplies, technology, etc. required to deliver care over a period of time. Reliance on market based pricing decouples the existing rate methodology from a resource based approach that accounts for each of these components and shifts it to an approach that is reliant on market trends, which may not accurately value the cost of the resources used to deliver the service.

ASTRO urges the Agency to consider alternatives to the market-based approach. While we appreciate concerns regarding the existing FFS methodology, we do not believe it appropriate to apply a new methodology that has the potential to cause rate fluctuations based on market trends.

Continuation of the Low Wage Index Hospital Policy
In the 2020 IPPS final rule, CMS finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor.

CMS addressed concerns regarding disparities between high and low wage index hospitals as a result of the application of the current Medicare Wage Index system and finalized an increase in the wage index values for hospitals with a wage index below the 25th percentile and a decrease in the wage index values for hospitals with index values above the 75th percentile. CMS also finalized an increase in the wage index value for hospitals below the 25th percentile by half of the difference between each individual hospital's wage index value and the 25th percentile wage index value. A similar methodology is used to reduce the wage index value for hospitals above the 75th percentile wage index value, thus keeping the proposal budget neutral.

In addition, CMS modified the "rural floor" policy which dictated that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that same state. The Agency finalized the decision to remove the wage data of urban hospitals that have been reclassified as rural from the rural floor methodology.

CMS stated that this policy is effective for at least four years, beginning in 2020, and includes a transition period, which caps the decrease at 5 percent, for hospitals that experience a significant decrease in the hospital wage index for the first two years. Therefore, CMS will continue this policy in 2021. Based on the data for this proposed rule, the 25th percentile wage index value across all hospitals would be 0.8420. To offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, CMS is proposing to apply the budget neutrality adjustment in the same manner as applied in FY 2020, as a uniform budget neutrality factor applied to the standardized amount.

ASTRO appreciates that CMS recognizes the disparities between high wage and low wage index hospitals. However, 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.

Proposed Policy Change Related to Medical Residents Affected by Residency Program or Teaching Hospital Closure

CMS is proposing policy changes related to closed teaching hospitals and residency programs to address the needs of residents attempting to find alternative hospitals in which to complete their training and to foster seamless Medicare indirect medical education and direct graduate medical education funding. Currently, displaced residents include those who are physically training in the hospital or program on the day of or day prior to closure and those who would be at the closing hospital or program but for the fact that they were on approved leave. The proposed policy change would expand the existing definition of "displaced" resident to include those who leave a program after closure is publicly announced; those residents assigned to and training at planned rotations at other hospitals; and medical students or would-be fellows who matched into GME programs at the closing hospital or program but have not yet started training. These proposed

policies would provide greater flexibility for the residents to transfer while the hospital operations or residency programs were winding down and would allow funding to be transferred for certain residents who are not physically at the closing hospital/closing program.

ASTRO supports CMS' proposed changes and applauds the Agency for addressing concerns about whether Medicare IME and direct GME funding could be seamlessly maintained for the medical residents that would have to find alternate training hospitals to complete their training

Promoting Interoperability (PI)
The Agency is proposing to maintain current PI measures for the 2021 performance year. ASTRO appreciates the continued consistency in PI measures from year to year, and between Medicare programs.

ASTRO appreciates the incremental approach to expanding PI reporting from 1 quarter to 4 over a three-year period. However, given the COVID-19 Public Health Emergency-related delays afforded by the Office of the National Coordinator for Health Information Technology (ONC) for the implementation of *Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule*, we are concerned that hospitals will have difficulties in complying with this requirement. We therefore recommend the Agency delay the implementation of this expansion by one year.

Finally, ASTRO appreciates the focus and promotion of Fast Healthcare Interoperability Resources (FHIR) as a healthcare standard across all Medicare programs. We agree that the Agency's focus on promoting interoperability, alignment, and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery. ASTRO believes that data standardization is the crux of interoperability, and in that vein, developed a list of required data elements in radiation oncology for use in EHRs, registries, or clinical trials. We are developing, testing and deploying data standards that enable interoperable, multi-purpose exchange of radiation treatment summary data for care coordination and data reuse through a CodeX use case.

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 Bryan Hull, Assistant Director of Health Policy, at 703-839-7376 or bryan.hull@astro.org.

Respectfully,

Laura Thevenot

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