



September 17, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Submitted electronically via www.regulations.gov

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]

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Breast Surgeons (ASBrS), we would like to thank you for the opportunity to comment on the calendar year (CY) 2022 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Payment System (ASC) proposed rule. ASBrS, the primary leadership organization for surgeons who treat patients with breast cancer and benign breast diseases, is committed to continually improving the practice of breast surgery by serving as an advocate for those who seek excellence in the care of breast patients. Founded in 1995, the Society now has more than 3,000 members throughout the United States and in 35 countries around the world.

Packaged Items and Services: Non-Opioid Pain Management Treatments

As part of CMS' ongoing reviewing of packaging policies and access to non-opioid pain management treatments, CMS proposes to continue its policy to pay separately (ASP +6%) for non-opioid pain management drugs that functions as surgical supplies in the ASC setting. However, CMS maintains that it will continue packaging for these non-opioid pain management in the OPPS setting. **ASBrS supports**

CMS' efforts to ensure that packaging policies do not inhibit patient access to medically necessary non-opioid pain management treatments and, therefore, supports CMS' proposal.

As part of CMS' original review of other packaging policies it should consider however, the Agency states that it did not believe that there are changes needed to its packaging policies under the OPPS for nerve blocks, surgical injections, and neuromodulation products at the time. CMS states that it continues to hold this belief. ***ASBrS recommends that CMS revisit its packaging policy for nerve blocks as we believe that they are a key non-opioid alternative in surgical cases.*** We remain concerned that CMS bundling approach to nerve blocks in cases performed in hospital outpatient departments and ASCs are inhibiting access to these effective treatments and should receive special consideration as CMS seeks to avoid overuse of opioid products.

CMMI Radiation Oncology (RO) Model

In the CY 2022, CMS revisited the Radiation Oncology (RO) Model originally proposed in 2019 and delayed by Congress in the *Consolidated Appropriations Act, 2021* until January 1, 2022. As you are aware, in the past we have asked that you reconsider capturing intraoperative radiation therapy (IORT) as one of the included modalities as originally proposed under the model.

For background, the RO Model was first announced in the *Specialty Care Models To Improve Quality of Care and Reduce Expenditures* proposed rule published in the *Federal Register* on July 18, 2019. As part of this original proposal, CMMI and the Centers for Medicare and Medicaid Services (CMS) stated,

We propose to include the following RT modalities in the Model: Various types of external beam RT, including 3- dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy (PBT); intraoperative radiotherapy (IORT); image-guided radiation therapy (IGRT); and brachytherapy. We are proposing to include all of these modalities because they are the most commonly used to treat the 17 included cancer types and including these modalities would allow us to determine whether the RO Model is able to impact RT holistically rather than testing a limited subset of services.¹

However, in issuing the final rule in September of last year and addressing changes to the model, CMMI and CMS changed course on IORT and stated,

. . . A commenter recommended excluding IORT since it is used so rarely. A commenter was concerned that the proposed payment structure will promote the use of short course, less costly forms of treatment such as IORT in cases where traditional external beam radiation would have been preferred.

Response: We thank these commenters for these suggestions. We agree with the commenter that it would be appropriate to exclude IORT from the RO Model because it is not a standard

¹ 84 *Fed. Reg.* 34,502 (July 18, 2019).

approach to treatment, and we believe that including IORT may incentivize misuse of this treatment . . .²

In the CY 2022 OPPI/ASC proposed rule, CMS acknowledged our and other stakeholder requests to re-introduce IORT as an included modality. However, the Agency replied,

At this time, episode payment rates are modality-agnostic. They include all Medicare FFS claims paid during the baseline period as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period so long as the RT service furnished is not of a modality excluded from the RO Model. We do not have separate national base rates per included cancer type based on a specific modality. Given that the evidence base for IORT is limited to certain cancer types, it does not meet the qualifications for inclusion in this Model. As we have reconsidered IORT's inclusion, we also note that it is a modality that is not site neutral, meaning that the TC of IORT is primarily delivered in HOPDs (during surgery) instead of freestanding radiation therapy centers. One of the primary goals of the RO Model is to test site neutral payments, where care delivered in HOPDs or freestanding radiation therapy centers are paid the same bundled payment. Given that this modality is only provided in one of those locations, it is not site neutral, and therefore does not meet the goals of the RO Model. Modalities that are not included in the RO Model, including IORT, would continue to be paid under Medicare FFS.

We are soliciting comments on whether and how we might include IORT in our pricing methodology in future years of the RO Model, for example whether CMS should include cancer-specific modalities in the RO Model.

ASBrS respectfully requests that you reconsider the CMMI decision to exclude IORT and place IORT on the list of included modalities of the RO Model as originally proposed in order to ensure that the model achieves its initially stated goal of avoiding evaluation of a limited subset of services and rather assesses the radiation therapy course of treatment that best fits the needs of breast cancer patients, affecting outcomes that are of the most importance to patients, including sparing of skin and other non-cancerous tissue, potential for avoidance of post-operative radiation therapy (and the time and activity savings that accrues from that), and reduced financial liabilities.

As we previously mentioned, we are concerned that by excluding IORT from the RO Model, the agency could be inadvertently marginalizing a therapy that has been proven to be cost-effective and a patient-driven choice in treatment for patients living with breast cancer. We do not wish to suggest that IORT does not provide value and benefit in cancer types outside of breast cancer, but breast cancer is the only cancer service line where the IORT is delivered in an outpatient setting and thus affected by exclusion of the therapy under the model. Inpatient claims are already excluded from RO model episode construction and attribution, thus for most cancer types IORT would already be outside of the model parameters. However, this is not the case in breast surgery where IORT is delivered in the outpatient

² 85 Fed. Reg. 61,174 (September 29, 2020).

setting. We focused on this as our area of expertise and the need that our members see in ensuring that Federal policies support rather than marginalize this valuable therapy.

CMS specifically requests input on whether it should include cancer-specific modalities. To the extent that a modality is not applicable across all included cancer types, **ASBrS firmly believes that the Agency should and can create parameters to a bundle that differ by cancer type.** Already, the RO Model sets the episode payments precisely by cancer-type. We see no reason that the inclusion of a modality for only some cancer-types could not be accommodated, and would then be reflected in the episode payment calculation for the type of cancer for which the modality was included. **For IORT, ASBrS believes it is imperative that the model support the full continuum of care for patients receiving a breast cancer diagnosis and if accommodating that by allowing included modalities to vary by cancer type.**

ASBrS believes that for appropriate cases, IORT in the treatment of breast cancer is the standard of care. We believe it is crucially important that no matter CMS' decision that the Agency remove any question about whether this is the case as it did by suggesting that it was excluded because it is not the standard of care. We again direct the Agency to the *ASBrS Consensus Guideline on Accelerated Partial Breast Irradiation*^{3,4} for your review and to illustrate the industry consensus around the utilization of IORT. This is supported in the randomized TARGIT-A (targeted intraoperative radiotherapy-alone) trial, "a single dose of TARGIT-IORT given at the time of surgery could eliminate the need for whole-breast EBRT in over 80% of suitable patients."⁵ And as such, a study from 2018 found that from 2009 and 2014 there was an 20-fold increase in the use of IORT as a percentage of accelerated partial breast irradiation (APBI) treatments.⁶

Just as important, we believe that the inclusion of IORT as a modality will offer patients a better array of options and provide the opportunity for model participant success under the model. As you well know, key to any alternative payment model (APM) are the quality measures to ensure that the payment mechanisms do not result in the stinting of care and focus on quality outcomes in addition to cost of care. As such, the RO model has planned for the incorporation of patient experience measures based on the *CAHPS® Cancer Care Survey*. While the date of incorporation into the program is yet to be finalized by the Agency given the delays in commencement of the model, we believe its use is critical to evaluating the model and ensuring that the model is patient-focused and not a "cost only" program. However, to evaluate patient experience with the *CAHPS® Cancer Care Survey* for breast cancer patients in the model while excluding consideration of IORT would fundamentally undermine the survey, the

³ <https://www.breastsurgeons.org/docs/statements/Consensus-Statement-for-Accelerated-Partial-Breast-Irradiation.pdf>

⁴ See also, Correa, C., et al, *Accelerated Partial Breast Irradiation: Executive summary for the update of an ASTRO Evidence-Based Consensus Statement*, *Practical Radiation Oncology* (2017) 7, 73-79.

⁵ Alvarado MD, Mohan AJ, Esserman LJ, *Cost-Effectiveness Analysis of Intraoperative Radiation Therapy for Early-Stage Breast Cancer*. *Ann Surg Onc*. 2013; 20(9):2873-80. DOI 10.1007/s10549-013-2782-9.

⁶ Morrison C, Gonzalez VJ, Hsu CC, *Intraoperative Radiation Therapy (IORT) As Sole Adjuvant RT Modality for Breast Cancer: Patterns of Care in the United States and Utilization after Publication of Guidelines and Randomized Trials*. *Int J Rad Onc Biol Phys*, 2018; 102(3); Supp E603.

model evaluation, and the needs and choices of patients. It is precisely CMS/CMMI's original comment in the proposed rule that the full list of modalities was needed for inclusion in order to holistically evaluate radiation therapy, and we believe it is of the utmost importance that CMS finalize updated regulations that implement its original proposal.

Finally, we agree with the Agency statement in the proposed rule that inclusion of IORT will allow for a holistic evaluation of approaches to radiation therapy. We are extremely concerned that excluding only this modality will serve as an unintended barrier to accessing IORT, relegating it to form of radiation therapy that is treated separately from the full RT continuum of services. We are concerned that patient access to care will be undermined, thus decreasing patient quality of life, outcomes, and potentially increasing their financial liabilities. We are likewise concerned that its exclusion will undermine the goals and integrity of the model which will provide questionable results upon evaluation of the model.

ASBrS appreciates the opportunity to provide input on the provisions contained in the proposed rule. We look forward to working with you to ensure that Medicare policies support patient-centered care and continue to provide the appropriate incentives to drive quality improvement. If you have any questions, please contact Sharon Grutman, Manager, Advocacy, Communications, & Quality Initiatives at sgrutman@breastsurgeons.org.

Sincerely,

A handwritten signature in cursive script that reads "Julie Margenthaler".

Julie Margenthaler, MD
President