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August 29, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

RE: CMS-4203-NC—Request for Information on Medicare

Dear Administrator Brooks-LaSure,

The American Society for Radiation Oncology¹ (ASTRO) appreciates the opportunity to provide written comments on the “Medicare Program; Request for Information on Medicare,” as published in the Federal Register on August 1, 2022. According to the RFI, Medicare’s vision is to “put the person at the center of care and drive towards a future where people with Medicare receive more equitable, high quality, and whole-person care that is affordable and sustainable.” Unfortunately, this goal is rarely achieved because many Medicare Advantage plans and their affiliate benefits management teams have inserted themselves into the center of care, disregarding physician-patient decision making, delaying care through onerous prior authorization requirements, and at times, outright denying services that would allow Medicare beneficiaries to experience equitable, high quality and whole person care.

We appreciate CMS’ interest in focusing on the advancement of health equity, expansion of coverage and care access, as well as stakeholder engagement as part of the broader Medicare Advantage program. Below are responses to the questions posed to the provider community in response to the Request of Information:

Advance Health Equity

Decades of research has demonstrated that minority and rural populations frequently present with advanced stage disease due to limited access to preventative services. African Americans (12.3%) and Hispanics (10.5%) present with clinically advanced-stage prostate cancer

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 people living with cancer 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.

more frequently than whites (6.3%)². Additionally, African American women are more likely than white women to receive a breast cancer diagnosis at an advanced stage of disease³. Frequently, patients with advanced stage disease receive palliative radiation therapy, which reduces pain and improves quality of life for patients with metastatic cancer. Despite this benefit, African American patients with prostate cancer are 20% less likely to receive palliative radiation therapy and, for colorectal cancer, 28% less likely to receive palliative radiation therapy when compared to white patients.⁴

In addition to limited access to preventative care resulting in advanced stage disease, minority and rural populations also struggle with access to care once diagnosed. Radiation oncology care frequently involves daily treatment regimens that take place over a period of several weeks. This presents a challenge for minority and rural patients who are frequently labeled “non-compliant” and effectively blamed for their inability to initiate or continue treatment⁵. Delays or interruptions in radiation treatment can negatively impact a patient’s ability to control disease progression.

While it is unclear what prevents some minority patients from beginning and completing radiation treatments, evidence points to lack of transportation, lower socioeconomic status, lack of childcare, inability to take the necessary time off work, underinsured/uninsured, and limited social supports (housing, access to fresh food, etc.) as key barriers. Resource investment and interventions are necessary to address the barriers facing these populations to ensure that they have adequate access to treatment, otherwise disparities in care will persist.

Current payment structures under the Medicare Advantage program inhibit efforts to improve access to high quality care and potentially exacerbate health disparities as many of the wrap around services that so many patients with cancer rely on are not covered or reimbursed. Additionally, practices are not provided with the tools to proactively identify at-risk patient populations and intervene with the provision of wraparound services designed to help patients successfully access and complete radiation treatments.

ASTRO recommends the issuance of an additional payment based on social determinant of health (SDOH) data scoring that would establish wraparound services to address healthcare disparities. A similar concept was recommended to CMS as part of the RO Model: the Health Equity Achievement in Radiation Therapy (HEART) payment, which was based on SDOH data points. Payments associated with a SDOH scoring mechanism could support services, not currently billable, such as:

- Triage patient needs 24/7;

² Richard M. Hoffman, Frank D. Gilliland, J. William Eley, Linda C. Harlan, Robert A. Stephenson, Janet L. Stanford, Peter C. Albertson, Ann S. Hamilton, W. Curtis Hunt, Arnold L. Potosky, Racial and Ethnic Differences in Advanced-Stage Prostate Cancer: the Prostate Cancer Outcomes Study, *JNCI: Journal of the National Cancer Institute*, Volume 93, Issue 5, 7 March 2001, Pages 388–395, <https://doi.org/10.1093/jnci/93.5.388>

³ Baquet, Claudia R et al. “Breast cancer epidemiology in blacks and whites: disparities in incidence, mortality, survival rates and histology.” *Journal of the National Medical Association* vol. 100,5 (2008): 480-8. doi:10.1016/s0027-9684(15)31294-3

⁴ Murphy JD, Nelson LM, Chang DT, Mell LK, Le QT. Patterns of care in palliative radiotherapy: a population-based study. *J Oncol Pract*. 2013 Sep;9(5):e220-7. doi: 10.1200/JOP.2012.000835. Epub 2013 Apr 16. PMID: 23943892.

⁵ Marquez, BS, MPH, Rachel. “Implementing a Transportation Hub: A Holistic Approach to a Systemic Problem.” [AJCC-Cancer.Org](https://www.ajcc-cancer.org/). Vol. 36, No. 3, 2021

- Provide patient care navigation, including patient education and symptom management, as well as financial support;
- Assess and address patient's nutrition, transportation and lodging needs, personal support system and identify resources to address barriers to accessing treatment and compliance with treatment care plan;
- Coordination of care and communication of information following evaluation and treatment with other care providers engaged in the patient's treatment;
- Documented survivorship plan that is developed in coordination with the patient, as well as other care providers and issued upon completion of treatment.

Symptom management clinics or triage units established in oncology settings have proven to be successful at reducing costs and ensuring patients have access to resources that improve their quality of life during their treatment. A 2017 UNC Chapel Hill study demonstrated significant savings associated with the implementation of a symptom management program leading to reduced unnecessary emergency department visits and inpatient admissions⁶. Programs such as this are currently not reimbursable -- and therefore difficult for smaller practices to establish -- yet have a significant impact on the patient's quality of life and the cost of care.

A similar initiative pursued by Cone Health, a regional multi-hospital health system in Greensboro, NC, created a transportation hub to remove barriers to treatment by identifying patients at risk for not pursuing or completing treatment through the establishment of a real-time registry managed by care navigators.⁷ Treatment completion historically showed statistically significant Black-White differences (Blacks 79.8% vs. Whites 87.3%). The disparity lessened within the intervention period to 88.4% for Blacks and 89.5% for Whites. The program also was found to improve survival over time for black and white patients and reduce the racial gap in survival among lung and breast cancer patients. A SDOH payment could support initiatives such as these to ensure that underserved populations achieve improved health outcomes.

Data associated with those episodes with a SDOH payment could be collected and used to determine the effectiveness of SDOH interventions. By learning more about what causes disparities and understanding what interventions are most effective and are closing gaps, it could test measures to ensure participants are accountable for reducing disparities. As an example, research has shown significant disparities for Black patients who are less likely to receive curative therapy for early-stage lung cancer. A recent study involving the use of stereotactic body radiation therapy for lung cancer patients demonstrated an increase in the proportion of Black patients receiving definitive treatment, reducing disparities between White and Black patients.⁸

⁶ Chera, Bhisamjit S., Reducing Emergency Room Visits and Unplanned Admissions in Patients with Head and Neck Cancer, University of North Carolina Cancer Hospital Lineberger Comprehensive Cancer Center, Clinical Journal of Oncology Nursing – June 2017.

⁷ Stern, Joseph. Tackling racial disparities in cancer care by creating new ways for institutions to operate.” Washington Post, 25 October, 2021

⁸ Henderson, B.Sc., Emily. “Increased use of stereotactic body radiation therapy for NSCLC patients can reduce treatment disparities.” News Medical Life Sciences. August 8, 2022.

Expand Access: Coverage and Care

The egregious use of prior authorization is one of the most significant factors impacting coverage and care within the Medicare Advantage program. The Office of the Inspector General (OIG) report issued in April 2022 highlighted a long-held concern within the medical community that MA plans have been using prior authorization as a blunt tool for reducing costs that also limits access to medically necessary care. As enrollment in MA plans continues to grow, CMS needs to ensure that beneficiaries have adequate access to care that is appropriately reimbursed.

ASTRO endorses professionally developed and vetted clinical practice guidelines, appropriateness of care criteria, and consensus-based model policies developed in a transparent manner with peer review and input as a foundation for clinical decision making. We are opposed to restrictive prior authorization practices that oversimplify the process of individual patient management and subvert the physician-patient decision making process. A recent ASTRO survey demonstrated that for almost 70% of respondents, the burden of prior authorization has increased since the onset of the COVID-19 pandemic. Action must be taken to curb the abusive practice that prior authorization has become, while still ensuring appropriate access to high quality patient care.

Many delays in care for cancer patients are due to onerous prior authorization reviews. In ASTRO's 2019 prior authorization survey, 93 percent of radiation oncologists noted their patients experience delays in treatment, with 31 percent reporting average delays of more than five days. This is cause for great concern, when research demonstrates a 1.2 to 3.2 percent increased risk of death with each week of delay in starting cancer treatment.⁹ This is especially concerning given that about 75% of appealed denials are successful in overturning the denial, as referenced in the [2018 OIG report on Medicare Advantage appeal outcomes and audit findings](#). However, only 1% of denials were appealed by physicians and patients, with many citing the complicated and burdensome appeals process. Such a high successful appeal rate represents the unnecessary delay in treatment patients experience when most treatments are ultimately approved anyways. Expediting the time frame for decisions to 48 hours would ensure that patients are able to begin treatment as quickly as possible.

Gold-carding programs also could help alleviate prior authorization burden. ASTRO recommends that CMS consider requiring Medicare Advantage plans to allow providers with high rates of approvals over a specific time to be exempt from prior authorization requirements when performing treatments considered standard of care. Payers and vendors should be required to consult scientifically accepted guidelines to determine standard of care, rather than the current practice which involves selectively citing sources and guidelines as part of the denial process. Creating a gold-card program and standardizing denial rationale will reduce the time that providers and patients spend waiting on prior authorization decisions.

Drive Innovation to Promote Person Centered Care

Person centered care begins with shared decision making between the patient and their physician. Too often, Medicare Advantage plan beneficiaries have their care interrupted, delayed and even denied due to prior authorization policies that disregard the patient-physician relationship. The prior authorization process

⁹ Khorana AA, Tullio K, Elson P, Pennell NA, Grobmyer SR, et al. (2019) Correction: Time to initial cancer treatment in the United States and association with survival over time: An observational study. PLOS ONE 14(4): e0215108. <https://doi.org/10.1371/journal.pone.0215108>.

needs to be streamlined and standardized, as well as transitioned to an electronic platform that reduces burden and improves care.

ASTRO has long supported the Improving Seniors Timely Access to Care Act, which seeks to address the inappropriate and excessive denials for services that are frequently covered by traditional Medicare. The Act establishes requirements for prior authorization, including an electronic prior authorization process to streamline approvals, reducing the amount of time a health plan is allowed to consider a prior authorization request, creates a process for “real-time” decisions for services that are routinely approved, requires MA plans to report their use of prior authorization and the rate of approvals and denials, and encourage MA plans to adopt policies that adhere to evidence based guidelines.

In addition to supporting legislative initiatives that tackle prior authorization, ASTRO is currently engaged in the Common Oncology Data Elements eXtension (CodeX) Fast Healthcare Interoperability Resources (FHIR) Accelerator. The CodeX project has created four radiation therapy profiles, six extensions, and nine value sets, resulting in new radiation oncology-specific data elements. These concepts have not only been added into the Minimal Coding Oncology Data Elements (mCODE) standard, but also have been approved for new Systemized Nomenclature of Medicine-Clinical Terms (SNOMED CT) codes.

Standardization of Patient Access Application Programming Interface (API) Implementation Guides (IGs) that are utilized by payers, are necessary to facilitate data exchange. The current Electronic Health Record (EHR) landscape illustrates that interoperability is indeed interpreted differently by payers and third-party vendors, exacerbating many of the challenges associated with transitioning to an electronic prior authorization process.

In previous RFIs, CMS has proposed that prior authorization decision making criteria be made available to patients through the Patient Access API, allowing them a better understanding of the prior authorization process and how it directly impacts their care. ASTRO remains supportive of this proposal and notes that providers are often left to explain a prior authorization denial to a patient, and deal with the corresponding fallout of a decision they did not make. In a 2019 survey¹⁰, 70 percent of ASTRO members stated their patients regularly express concerns to them about delays caused by prior authorization.

Including the date of prior authorization approval, the date the authorization ends, and the units and services approved in the Patient Access API will help alleviate some patient concerns and empower them to participate as an active agent in their care delivery and coverage determination process. Sharing this same information via the Provider Access API, upon the provider’s request, facilitates more open discussions about the prior authorization process between patients and providers.

Additionally, the adoption of Provider Access APIs and FHIR standards can address the significant burden associated with data reporting that frequently takes significant time away from treating patients by requiring uniformity of data standards. At this time, the majority of cancer care data lacks a standardized language, so at times even data exchanges between cancer specialists working with the same third-party vendor product does not occur. Data standardization is the crux of interoperability.

¹⁰<https://www.astro.org/ASTRO/media/ASTRO/News%20and%20Publications/PDFs/ASTROPriorAuthorizationPhysician-SurveyBrief.pdf>

Support Affordability and Sustainability

Medicare Advantage Plans, as do other private payer plans, base payment on existing Medicare payment systems, such as the Medicare Physician Fee Schedule (MPFS). Over the past decade payments for radiation oncology services in the MPFS have declined over 20%.

A recent study underscores ASTRO's long held concern that Medicare reimbursement has been inadequate and runs the risk of limiting access to radiation therapy, a standard of care that time and again has demonstrated its effectiveness in curing cancer. According to the study, the total inflation adjusted radiation oncology Medicare reimbursement was \$1,848M in 2019, a 19% decline from \$2,281M. When adjusted to account for 2019 utilization, which includes higher adoption rates of hypofractionation (a shorter course of treatment) total reimbursement was \$2,534M in 2010 compared to \$1,848M in 2019, this represents a 27% reduction¹¹. Effectively, in today's Medicare Physician Fee Schedule environment, physicians are getting paid significantly less.

The reductions associated with the MPFS have likely translated to lower reimbursement rates set by Medicare Advantage plans and other private payers. There is a critical need for rate stability to ensure Medicare beneficiaries have adequate access to radiation therapy treatments. The current payment system runs the risk of not only creating access to care issues, but also setting back the numerous advances that have been made in the last 50 years related to the effective, guidelines-based approach to the use of radiation therapy services for the treatment of cancer.

ASTRO has long advocated for an alternative payment model for radiation oncology that shifts payment from fee-for-service to value-based payment. While CMS was not willing to pursue the RO Model with the necessary adjustments to make it viable, perhaps Medicare Advantage plans may be interested in exploring a concept specifically applied to the MA beneficiary population.

An ideal payment model should recognize the important role associated with investments in the cancer treatment infrastructure to ensure that all patients have access to high quality care using advanced technology, as well as reduce unnecessary and burdensome reporting requirements that do not contribute to improved patient outcomes.

Additionally, mechanisms should be established in a payment model to identify and support patient populations with limited access to radiation therapy, to ensure initiation and completion of treatment. A commitment to evidence-based approaches to care and investment in wraparound services, including patient navigation and transportation, will improve care for people from historically marginalized populations.

Engage Partners

While we appreciate the CMS' request for input regarding how to best engage partners, we are concerned by the short comment period associated with this RFI. Additionally, we note very similar requests for

¹¹ Jacob Hogan, Amit Roy, Patricia Karraker, Jordan R. Pollock, Zachary Griffin, Neha Vapiwala, Jeffrey D. Bradley, Carlos A. Perez, Benjamin W. Fischer-Valuck, John C. Baumann, Brian C. Baumann, "Decreases in Radiation Oncology Medicare Reimbursement Over Time: Analysis by Billing Code," *International Journal of Radiation Oncology*Biography*Physics*, Volume 114, Issue 1, 2022, Pages 47-56, ISSN 0360-3016, <https://doi.org/10.1016/j.ijrobp.2022.05.018>.

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information over the past several years that have not led to the reforms supported by wide swaths of the health care community. The time for RFIs is over; instead, it's time for CMS to take action and make consensus-backed changes that protect Medicare Advantage beneficiaries.

Again, we appreciate the Agency reviewing our comments and look forward to actionable next steps. If you have any questions or would like more information about radiation oncology coverage issues related to Medicare Advantage plans, please contact Emilio Beatley, Health Policy Analyst, at 703-839-7360 or Emilio.Beatley@astro.org.

Sincerely,



Laura I. Thevenot
Chief Executive Officer



Laura Dawson, MD
President