

June 24, 2019

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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma,

The American Society for Radiation Oncology (ASTRO) 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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals” published in the Federal Register as a proposed rule on May 3, 2019.

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.

The Inpatient Prospective Payment System (IPPS) proposed rule contains several issues of interest to the field of radiation oncology, including proposed New Technology Add-On Payments (NTAP) for three technologies involving radiation treatment delivery; proposed changes to the criterion and payment for evaluating NTAPs; proposed modifications to the

Medicare wage index; and modifications to several quality measures and interoperability requirements. Below are ASTRO's comments on each of these issues:

Proposed New Technology Add-On Payments (NTAP) for New Services and Technologies for FY2020

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 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:

AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution

Progenics Pharmaceuticals submitted an application for AZEDRA®, 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. These are rare tumors with an incidence of approximately 2 to 8 people per million per year.

CivaSheet®

CivaTech Oncology, Inc. submitted an application for CivaSheet®, which is intended for use as a brachytherapy for placement into a body cavity or tissue as a source for the delivery of radiation therapy. CivaSheet® may be used either for primary treatment or for the treatment of residual disease after excision of the primary tumor. It can also be used concurrently, or sequentially, with other treatment modalities such as external beam radiation therapy or chemotherapy.

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. 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.

ASTRO supports the NTAP applications for each of these technologies. These technologies represent new and expensive treatments for disease sites with a limited number of clinical treatment options. As evidenced in the papers submitted with each NTAP application, patients treated with these technologies experience improved clinical outcomes that are otherwise unattainable due to the uniqueness of their disease, thus meeting the “substantial clinical improvement criterion”.

Evaluation of Substantial Clinical Improvement Criterion for IPPS NTAP and OPSS Transition Pass-Through Payments for Devices

CMS is seeking comment on the “substantial clinical improvement” criterion for evaluating applications for both the IPPS NTAP and the Hospital Outpatient Prospective Payment System (OPSS) transitional pass-through payment for devices. Existing regulations provide that a new technology is an appropriate candidate for additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available.

ASTRO appreciates CMS’ interest in improving the “substantial clinical improvement” criterion for evaluating applications for both the NTAP and OPSS transitional pass-through payment for devices. In the 2019 OPSS proposed rule, ASTRO supported a transitional pass-through payment application submitted by Augmenix, Inc. for SpaceOAR®. We were disappointed that the Agency did not grant pass through payment, despite the fact that a randomized clinical trial confirmed that the biodegradable gel material reduces toxicity for patients treated with radiotherapy for prostate cancer¹. Furthermore, the benefits documented in the initial report were confirmed with a subsequent report of the same trial, with a median follow-up period of 3 years. At 3 years, more men in the control group than in the spacer group had experienced a decline in bowel quality of life (41 percent versus 14 percent). Additionally, the control group were more likely to experience large declines in bowel quality of life (21 percent versus 5 percent). Use of rectal spacer resulted in a sustained 75 percent reduction in any rectal toxicity persisting at 3 years, as well as significant reductions in urinary toxicity.² It is ASTRO’s opinion, that this evidence demonstrates that SpaceOAR reduces the number of hospitalizations or physician visits and reduces the recovery time associated with rectal toxicity compared to existing technologies, thus demonstrating “substantial clinical improvement”.

In the 2019 OPSS final rule, CMS did not grant pass through payment because it did not believe that SpaceOAR® met the “substantial clinical improvement” criterion. This was due to the Agency’s request for a “head-to-head” trial of SpaceOAR® versus a comparator. The comparator was a rectal balloon, which is a significantly different device and not an appropriate comparator. A rectal balloon is useful for prostate immobilization, but it does little to protect the rectum from any toxicity associated with the radiation dose. When the rectal balloon is placed in the rectum it displaces the anterior rectal wall pushing it toward the radiation dose, whereas SpaceOAR® does the opposite by protecting the rectum from the radiation dose. It is not possible to do a randomized comparison of two products that are intended for different purposes.

¹ Mariados N, Sylvester J, Shah D, et al: Hydrogel spacer prospective multicenter randomized controlled pivotal trial: dosimetric and clinical effects of perirectal spacer application in men undergoing prostate image guided intensity modulated radiation therapy. *Int J Radiat Oncol Biol Phys* 92:971-977, 2015.

² Hamstra, D.A. et al: Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. *Int J Radiation Oncol Biol Phys*, 97:5:976-985, 2017.

ASTRO urges CMS to reconsider how it determines whether a new technology meets the “substantial clinical improvement criterion”. The criterion should recognize that there are new technologies that are not designed to replace existing technologies but rather improve care in creative ways that have previously not been possible. As CMS proposes in the 2020 IPPS, “improvement” might be demonstrated “by reference and comparison to diagnosis or treatment achieved by existing technology” thus recognizing these types of innovations and how they improve patient outcomes over time. Otherwise, the Agency runs the risk of hampering innovation and the proliferation of services that benefit patients, not to mention potential cost savings generated over time due to reduced symptoms management and care needs in the long run.

New NTAP Pathway for Transformative New Devices

CMS is also proposing a new NTAP pathway for transformative new devices. This new approach would recognize devices that are part of the Federal Drug Administration’s (FDA) Breakthrough Devices Program and receive FDA marketing authorization. These devices would be considered new and would not be required to meet the requirement that it substantially improves, relative to the existing technologies, the diagnosis or treatment of Medicare beneficiaries. This new approach would apply to applications for FY 2021.

Additionally, the Agency is proposing to modify the NTAP payment methodology. Currently, if the costs of care exceed the Diagnosis Related Group (DRG) payment, then Medicare will make an add-on payment equal to the lesser of: 1) 50 percent of the costs of the new medical service or technology; or 2) 50 percent of the amount by which the cost of the case exceeded the DRG payment. CMS has received concerns that the existing 50 percent cap does not provide sufficient incentive for the use of new technology and is proposing to increase the cap to 65 percent beginning October 1, 2019.

ASTRO supports CMS efforts to recognize devices that are part of the FDA Breakthrough Devices Program. The program is intended to provide patients with more timely access to these devices, which provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating disease or conditions, by expediting development, assessment and review. In recent years, the field of radiation oncology has seen significant growth in technologies that allow for more targeted cancer treatments. Additionally, radiation therapy techniques are being used in novel ways to treat other types of disease, such as ventricular tachycardia and Parkinson’s disease. The NTAP pathway for transformative new devices will enable patients to benefit from advances in the application of a variety of radiation therapies, including radiopharmaceuticals, brachytherapy and external beam therapy.

Additionally, ASTRO supports the proposed modification of the NTAP payment methodology, which would increase the add-on payment cap from 50 percent to 65 percent of the lesser of the cost of the new technology or the amount in excess of the DRG payment. This more appropriately recognizes the significant cost associated with many new devices that are coming to market.

Medicare Wage Index Disparities

In the 2020 IPPS proposed rule, CMS recognizes concerns regarding disparities between high and low wage index hospitals as a result of the application of the current Medicare Wage Index system. To address these concerns, the Agency is proposing to increase the wage index values for hospitals with a wage index below the 25th percentile and decrease the wage index values for hospitals with index values above the 75th percentile.

CMS is proposing to increase 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 would be used to reduce the wage index value for hospitals above the 75th percentile wage index value, thus keeping the proposal budget neutral.

CMS is also proposing to modify 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 is proposing to remove the wage data of urban hospitals that have reclassified as rural from the rural floor methodology. CMS believes that the inclusion of these hospitals in the past has exasperated Medicare wage index disparities between low and high wage hospitals.

This policy would be effective for at least four years, beginning in FY2020, and includes a transition period for those hospitals that experience a significant decrease in their wage index values due to this proposed change. The Agency is proposing a 5 percent cap on any decrease in a hospital's wage index for FY2020 in comparison to the hospital's final wage index in FY2019. This policy will be in effect for two years.

While ASTRO appreciates that CMS recognizes the disparities between high wage and low wage index hospitals, we are concerned that the proposed methodology for addressing the issue does not really fix the problem but rather shifts funds from one group to another with little consideration for the potential impact. ASTRO 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. The CMS proposal to remove the wage data of urban hospitals that have reclassified as rural from the rural floor methodology is a step in the right direction.

IPPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

ASTRO is pleased that CMS is proposing to remove the External Beam Radiotherapy for Bone Metastases measure (NQF #1822) beginning in FY2022. According to the Agency, the costs associated with the measure outweigh the benefit of its continued use in the program. CMS recognizes ASTRO's concerns that the radiation treatment delivery CPT codes used for the measure, which were part of a re-specification after the measure was finalized, have required additional exclusions proving burdensome on PPS-exempt Cancer Hospitals (PCHs). Additionally, NQF endorsement was removed in 2018 and is no longer being maintained by the measure steward.

In light of the opioid epidemic, CMS proposes removing the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) pain management questions out of an abundance of caution. ASTRO opposes this proposal since cancer is excluded from pain and opioid measures in all other cases.

Hospital Inpatient Quality Reporting (IQR) Program

CMS is proposing to institute two new opioid-related electronic clinical quality measures (eQMs) in the IQR program beginning with the 2021 reporting period. The Agency believes these measures would address the Meaningful Measures priorities regarding prevention and treatment of chronic disease and reduce harm caused in the delivery of care. The measures include: 1) Safe Use of Opioids – Concurrent Prescribing eQCM (NQF #3316e) and 2) Hospital Harm – Opioid Related Adverse Events eQCM. The first measure calculates the portion of patients 18 and older who are prescribed two or more opioids at discharge, with the goal of identifying and monitoring patients at risk. The second measure assesses the proportion of an acute care hospital's patients with an opioid-related adverse event during an admission as indicated by the administration of naloxone. ASTRO is pleased that CMS recognized that patients diagnosed with cancer can benefit from treatment with opioids, and that both measures exclude patients with an active cancer diagnosis.

Promoting Interoperability Program

ASTRO appreciates the Agency's proposal to retain the minimum 90-day Electronic Health Records (EHR) reporting period for the Promoting Interoperability Program (PI). This aligns with other quality programs using PI and it recognizes that many healthcare providers are continuing to move towards 2015 Certified Electronic Health Records Technology (CEHRT). We agree with the stipulation that all reported PI actions need to occur in the reporting period, with the exception of the security risk assessment.

As we have mentioned in previous comment letters, we urge CMS to include using an EHR to participate in a qualified clinical data registry (QCDR) as an interoperability activity. Allowing providers to receive credit under Promoting Interoperability for interoperability activities would reduce health care provider burden while giving providers the flexibility to pursue innovative applications of health IT. The inclusion of electronic reporting through a QCDR as an interoperability activity is consistent with Congress's mandate under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) that the Secretary of the Department of Health and Human Services (HHS) encourage the use of QCDRs and certified EHR technology for reporting measures under the Quality performance category of the Merit-based Incentive Payment System (MIPS).

ASTRO encourages CMS to look at interoperability not only from the perspective of different EHRs and electronic clinical documentation portals, but also from the same EHRs and electronic clinical documentation portals. ASTRO members report that often their EHR or electronic clinical documentation portals cannot communicate with the same EHR or electronic clinical

documentation portals in a different office, causing a disruption in care coordination between two providers. This lack of data exchange can also lead to delayed treatment and/or potential patient safety scenarios. Giving practices flexibility to customize their systems in terms of implementation results in variation of use and makes data transfers difficult.

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs

CMS requests comments on the potential for a metric to assess provider efficiency using EHRs. The Agency expresses concern regarding slow adoption of EHRs and requests comments regarding how the implementation of efficient workflows and technologies can be effectively measured to improve efficiency as it relates to the meaningful use of CEHRT and the furthering of interoperability.

ASTRO appreciates the identification of best practices and opportunities to improve efficiency as reported in the ONC report “Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs”, and the subsequent work required by the 21st Century Cures Act. Radiation oncologists use both enterprise and specialty specific EHR technologies but have the added responsibility of the connection to a large array of treatment planning systems and treatment delivery machines. These additional layers of technology add to the complexity of normal health information transfer as hardware and software solutions within a radiation oncology practice can represent a myriad of technology vendors.

Quality measure availability is a useful way to measure the efficiency of health care processes related to the use of health IT (HIT). They can encourage physician use of functionality built into information systems; however, interoperability, data transfer functionality and the adoption of data standards is ultimately dependent on the hardware and software vendors. If the functionality is relevant and available to a provider, but not utilized, then the provider can be held accountable. Vendors should be included in regular measurement along with the physicians using the tools. The sort of measures necessary in the current HIT atmosphere should not be focused solely on whether a physician did an action. CMS can utilize the PI program to assess the availability of functionality, the scenarios of use and the success of connectivity to other software and hardware options. This level of measurement would allow CMS to have a more holistic view of HIT use and the related issues.

CMS seeks comments on key administrative processes that could benefit from more efficient electronic workflows, for instance, conducting prior authorization requests. ASTRO believes that providing electronic platforms where medical records, and other interactions, are shared between benefits management companies and physicians, would alleviate the burden of administrative processes related to prior authorization requests. But more must be done to reform prior authorization than simply standardizing electronic exchange of information. Radiation oncologists report that prior authorization, including onerous requirements from Medicare

Advantage Organizations, is the biggest challenge facing their practices, regardless of whether they are in private practice or academic practices. Results from a recent ASTRO survey show:

- 63% of respondents have hired staff to handle prior authorization requests.
- 93% of respondents said their patients experienced delays in care as a result of prior authorization.
- 70% of respondents said patients express concern to their radiation oncologists over prior authorization delays.
- 44% of respondents stated that peer-to-peer reviews typically are not performed by a radiation oncologist
- 85% of radiation oncologists report having to generate multiple treatment plans.
- Almost 20% of radiation oncologists report spending more than 10% of their time on prior authorization.

ASTRO members have relayed the following stories to illustrate their frustrations with prior authorization requirements:

- “I am routinely told: Approval requests can be obtained "on line". When I do this, there are questions that do not apply to my cases, and I have to call anyway. Pre-auth paperwork is requested to be sent to a Fax # (often out of date), or even slower: by mail (with a 60-day waiting period for a decision).”
- “This morning I sat on the phone 40 minutes and was dropped once during that wait and had to punch through all the data again. Then when I do get someone on the phone, they ask for all the data again. Then I'm set up for peer to peer review. And they have not yet called when they were supposed to 3 hours ago.”
- “PET scan delayed 10 days while our staff had to complete several pages of details on the make, model, settings, protocols of our PET scanner.”

Cancer patients have been particularly hard hit by this unnecessary burden and interference in care decisions. Radiation Oncology Benefit Managers (ROBMs) require a significant amount of information related to patient care. Frequently, practices submit this data only to learn that the ROBM didn't receive it or that the information was submitted after an arbitrarily defined deadline. Standardized electronic submission processes will ease the uncertainty, lessen the time spent by providers submitting for prior authorization, and patients can receive the treatment they need, but should only be considered a first step in reforming this burdensome process.

ASTRO is also concerned that the data needed for prior authorization for radiation oncology may not be found in the proposed data sets, and we urge CMS to include data from other electronic clinical documentation portals (such as treatment planning systems for radiation oncology).

Request for Information (RFI) on the Provider to Patient Exchange Objective

In the 2019 IPPS proposed rule, CMS discusses its focus on improving electronic patient access to their health information. Specifically, the role of Application Programming Interfaces (API) in

allowing patients to use an application of their choice for this purpose. ASTRO supports patients having transparent, easy access to their health information, and proposals to ease burden on providers. However, while APIs can help, the true issue is the lack of uniformity in data entry and standards. Currently, most cancer care data exists in a foundational level of interoperability, where even data exchanged between cancer specialists working with the same vendor product does not occur. Bi-directional data exchange is necessary for multi-disciplinary treatment and cancer research, but the lack of codified language and standards makes this impossible. Once collected, the data, whether in a registry or other system, can be meaningless without hours of human-curation and aggregation. Many organizations, such as universities and specialty societies, are currently working on data standards through Fast Healthcare Interoperability Resources (FHIR) standards and other HL7 profiles, but there remains a lack of standardization on simple data elements as demonstrated in the Duke Clinical Research Institute and the Pew Charitable Trusts [Registry Data Standards project](#). This work showed that simple, demographic data elements like patient sex are not uniform. ASTRO feels that data standardization is the crux of interoperability, and in that vein, is developing a list of required data elements in radiation oncology for use in EHRs, registries, or clinical trials. The public comment period for this list has closed, and we expect it to be finalized by the end of the year. Again, API technology will help, but we encourage CMS, together with the Office of the National Coordinator, to provide resources for organizations seeking to undertake the costly and complicated task of developing common standards where none exist and encouraging use where they do.

Current barriers to patient data access include the lack of existing standards, and specific to those patients receiving radiation therapy, the lack of interoperability between treatment planning systems, oncology information systems, and electronic health records. The lack of interoperability and standards results in a fragmented view of treatment. The lack of consistency results in massive variability, even with standards and APIs.

ASTRO cautions CMS, as it moves to implement this type of data exchange outside of the inpatient setting and into episode-based care, that without specific standards regarding when data must be available to patients – after treatment is completed or after each visit – there will be variability, which will cause confusion, especially among patients. We urge the Agency to develop specific, detailed standards that incorporate the complexities of medical specialties, like radiation oncology, to avoid patient confusion and make the transfer of information seamless.

CMS asks whether the “Provide Patients Electronic Access to Their Health Information” measure should be more specific with respect to the experience patients should have regarding their access. The Agency also seeks comment on whether stakeholders would support a possible bonus under the Promoting Interoperability Programs for early adoption of a certified FHIR-based API in the interim before ONC’s proposal for a certification standard is finalized. ASTRO believes that to encourage interoperability and consistency in health information technology (HIT), more regulations should be promulgated. How and when information is made available to a patient should be standardized across all practice settings, specialties, and technology. However, as we have stated in past comment letters, we caution CMS that there is no “one size fits all” answer to these questions.

Finally, we believe that providers should receive a bonus for using the API, if the API is available. However, the performance and functionality of a technology, including an API, should be placed on the vendor alone. Providers should not be punished if an API does not function properly.

Provider to Patient Exchange – Electronic Health Information (EHI) Criteria

CMS seeks comment on an alternative measure under the Provider to Patient Exchange objective that would require health care providers to use technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR. ASTRO believes that this should be a phased-in bonus measure allowing the vendor community to catch up, and the physician community to financially plan for what will inevitably be a costly upgrade. To increase system interoperability, ASTRO believes that the measure should not rely on attestation. The uptake of technology is based on regular use, not in the one-time use, or availability of technology.

The bidirectional exchange of data is imperative for interoperability and a holistic view of patient care. For this type of exchange to occur, all systems must have the same understanding of a concept or data element, the same definition, and code it the same way. Currently, the systems used within radiation oncology cannot accomplish this with one another, or with a broader EHR. The data must be entered and found in the same place in a medical record across all practices (not in clinical notes) and platforms and must be understood by the receiving technology.

Request for Information (RFI) on Integration of Patient-Generated Health Data into EHRs using CHERT

CMS believes that patients should be able to import their health data into their medical record and have it available to health care providers. The Agency seeks comments on ways that the PI program can adopt new elements related to patient-generated health data (PGHD). ASTRO suggests that information from a pedometer be shared in EHR settings. Many papers³⁴ have been published linking regular activity (including walking) with lowered side effects and better outcome for cancer patients.

³ Anders Hansen, Karen Sjøgaard & Lisbeth Rosenbek Minet (2019) Development of an exercise intervention as part of rehabilitation in a glioblastoma multiforme survivor during irradiation treatment: a case report, *Disability and Rehabilitation*, 41:13, 1608-1614, DOI: [10.1080/09638288.2018.1432707](https://doi.org/10.1080/09638288.2018.1432707)

⁴ Samuel, S.R., Maiya, A.G., Fernandes, D.J. et al. *Support Care Cancer* (2019).
<https://doi.org/10.1007/s00520-019-04750-z>

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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 Anne Hubbard, Director of Health Policy, at 703-839-7394 or anne.hubbard@astro.org.

Respectfully,

A handwritten signature in cursive script that reads "Laura Thevenot".

Laura I. Thevenot
Chief Executive Officer