

June 14, 2021

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 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

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 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program” published in the Federal Register as a proposed rule on May 10, 2021.

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 2022; a request for information on closing the health equity gap; a proposal to use 2019 MedPAR data and FY 2018 HCRIS file for analyzing MS-DRG changes and determining MS-DRG relative weights; repeal of private payer MS-DRG relative weight data to inform future Medicare rates; continuation of the Low Wage Index Value Hospital Policy; PPS-Exempt Cancer Hospital Quality Reporting Program, Medicare Promoting

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.*

Interoperability Program, and the Hospital Inpatient Quality Reporting Program. Below are ASTRO's comments on each of these issues:

Proposed New Technology Add-On Payments (NTAP) for New Services and Technologies for FY 2022

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. While there were no new NTAP applications related to the delivery of radiation therapy included in the 2022 IPPS proposed rule, we are supportive of CMS's proposal to extend the NTAP for AZEDRA® for one year.

Under the 2022 Proposed Rule, CMS is proposing to use FY 2019 MedPAR data instead of FY 2020 data for FY 2022 rate setting in situations where the FY 2020 data was significantly impacted by the COVID-19 public health emergency (PHE). The agency believes it would be appropriate to allow for a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022. Therefore, AZEDRA® would receive another one-year extension under this proposal. The agency seeks comments on its proposal to provide for a one-year extension of new technology add-on payments for FY 2022 for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022.

ASTRO applauds CMS' proposal to use FY 2019 MedPAR data instead of FY 2020 data for FY 2022 rate setting. We urge the Agency to consider similar approaches to other payment methodologies that rely on historical data. The COVID-19 public health emergency had a significant impact on the delivery of healthcare services across all specialties; therefore, 2020 data points should be considered an anomaly.

Additionally, ASTRO supports CMS's proposal to continue new technology add-on payments in 2022 for those technologies that would otherwise be discontinued, including AZEDRA®. Based on the decision to use FY 2019 MedPAR data to inform FY 2022 rates, we are also in support of the Agency's proposed maximum new technology add-on payment remaining at \$98,150 for cases involving AZEDRA.

Closing the Health Equity Gap in CMS Hospital Quality Programs—Request for Information

For purposes of the 2022 IPPS proposed rule, CMS is using the definition of equity established in Executive Order 13985, issued on January 25, 2021, "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+)

persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.”

The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas, which inform Agency policies and programs: 1) Increasing understanding and awareness of health disparities; 2) developing and disseminating solutions to achieve health equity; and 3) implementing sustainable actions to achieve health equity.

In the 2022 IPPS proposed rule, CMS is seeking comment on three potential future expansions of the CMS Disparity Methods, including 1) stratification of quality measures results by race and ethnicity, 2) improving demographic data collection, and 3) the creation of a Hospital Equity Score to synthesize results across multiple risk factors.

The Health Equity Score would be based off the Medicare Advantage Health Equity Summary Score, which uses two social risk factors: dual eligibility and race and ethnicity. The score would be adapted to the context of risk-adjusted hospital outcomes measures and potentially other hospital quality measures used in CMS programs, as well as multiple social risk factors.

Below are specific solicitations found in the 2022 IPPS proposed rule:

- Future stratification of data:
 - o Potential stratification of quality measure results by race and ethnicity, including the potential application of an algorithm to estimate race and ethnicity to permit stratification of measures for hospital level disparity reporting, until more accurate forms of self-identified demographic information becomes available.
 - o Appropriate privacy safeguards with respect to when and if properly identified data is shared with providers.
 - o Ways to address challenges of defining and collecting, accurate and standardized, self-identified demographic information. (race, ethnicity, disability, language preference)
 - o Recommendations for other types of data elements that measure disadvantages and discrimination.
 - o Recommendations for other types of quality measures or measurement domains
 - o Examples of approaches, methods, research, and/or considerations for use of data-driven technologies that do not exacerbate health inequities.
- Improving demographic data collection
 - o Experience of CEHRT users on the collection of data elements and how data is used to improve decision making and delivery of care
 - o Benefits and disadvantages of collecting and using more granular, structured demographic data, such as race and ethnicity

- The possible collection of a minimum set of demographic data elements (race, ethnicity, sex, sexual orientation, gender identity (SOGI), primary language, tribal membership, and disability status)
- Potential Creation of a Hospital Equity Score to Synthesize Results Across Multiple Risk Factors
 - Creation of confidential reporting of a Hospital Equity Score
 - Interventions to improve a low hospital equity score and how improved demographic data can assist with these efforts

ASTRO supports the stratification of quality measures results by race and ethnicity, but also encourages CMS to consider stratification by patient residency in rural versus urban locations. These indicators lend themselves to demonstrating whether a hospital or other healthcare settings may provide healthcare services to an underserved population that is at higher risk for experiencing healthcare disparities.

As for the collection of additional demographic data, the collection of a minimum set of demographic data elements such as race, ethnicity, sex, sexual orientation, gender identity, primary language, tribal membership, and disability status can be valuable to better understanding the patient population served. However, these indicators can be further enhanced through the collection of additional data points such as employment status, education level, insurance status, income level, and distance from provider, which may further inform whether a patient needs additional social and financial supports to ensure they are able to initiate and complete care.

The collection of demographic data and stratification of quality measures can be used to better understand quality measures performance across different patient populations. It will allow for more granular analysis to determine whether interventions that are in place to improve quality are successful for some populations but not for others. Thus, informing the need for modifications or changes to quality measures metrics that can be designed to truly drive quality improvement across all patient populations.

Additionally, this data could be used to establish a Hospital Equity Score, but why stop there? Hospital Equity Scores can synthesize reported metrics to better inform decision making for addressing healthcare disparities, but it could be taken one step further and applied to patients seeking care in these facilities by ensuring that they have access to social and financial supports necessary to access and complete medical treatment. **ASTRO supports the concept of developing beneficiary-specific equity scores that are established to identify those patient populations that require wrap around services, such as nutritional counseling, access to healthy food, transportation, housing, etc.** A health equity score can then be further used to tie community need to additional reimbursement that supports the delivery of specific services that are supportive of patients who experience health inequities.

While ASTRO is supportive of efforts to collect better data points for informing improved patient care and outcomes, we continue to urge the Agency to consider the burden—on practices and patients—associated with collecting this data. Not only are time and money needed to upgrade software and implement new programming, but also hospitals and other healthcare settings will require staff to collect data and manage the related programming. CMS cannot meaningfully address the healthcare equity gap without investing in the resources necessary to reach our nation’s most vulnerable populations.

Many physicians are frustrated with the existing Certified Electronic Health Records Technology (CEHRT) requirements associated with the Promoting Interoperability programs. Clinicians do not have any control over the electronic health records (EHR) products issued by vendors, yet they are penalized for not achieving CEHRT status. More data submission requirements require a stronger reporting framework, more commonly applied standards, and changes to workflow, for which there is currently no funding. Additionally, these changes cannot be made overnight, they take time to implement. For example, the Cures Update Edition is set for 2023, yet only Cerner has made adequate upgrades to meet these new requirements. CMS needs to provide adequate time for vendors to prepare and implement upgrade requirements.

Additionally, vendors must be held accountable for the upgrades required to CEHRT systems to ensure improved care coordination and patient access. Hospitals and physicians should not shoulder the burden of meeting these requirements nor should they bear the cost associated with system upgrades. As previously stated, CMS needs to invest in the technological and social resources necessary to improve patient care across all populations. As COVID-19 has demonstrated, a “one-size-fits-all” approach has left many Americans behind. Therefore, the way to achieve health equity will be to target high risk populations with the social support and resources necessary to ensure they are able to achieve better health outcomes.

Proposal to use 2019 MedPAR data and FY 2018 HCRIS file 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 would use 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, the data that CMS would analyze, in normal circumstances, would be from FY 2020. However, in light of the COVID-19 public health emergency, CMS is proposing to use FY 2019 MedPAR claims data rather than FY 2020 MedPAR data.

As previously mentioned, ASTRO supports CMS’s proposal to use FY 2019 MedPAR claims data rather than FY 2020 MedPAR data. Given the impact that the COVID-19 public health emergency has had on claims data, FY 2019 is likely the best data available for evaluating MS-DRG changes and setting MS-DRG relative weights.

Proposed Repeal of Market-Based Data Collection and Market-Based MS-DRG Relative Weight Methodology

CMS uses hospital charge master data to inform rates for both hospital inpatient and outpatient services. To reduce its reliance on hospital charge masters, last year the agency finalized a rule that would require hospitals to report market-based payment rate information in their Medicare cost report for periods ending on or after January 1, 2021. CMS proposed using this information to change the methodology for calculating the IPPS MS-DRG relative weights to reflect market-based pricing. The Agency specifically asked that hospitals report the median payer-specific negotiated charge that the hospital negotiated with Medicare Advantage organizations and third-party payers by Medicare Severity-Diagnosis Related Group (MS-DRG).

While there are problems with the fee-for-service (FFS) policy of developing rates based on charges and the cost to charge ratio, the premise of that 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. In the 2022 Proposed Rule, CMS is proposing to repeal this market-based policy and not move forward with the use of payer-specific negotiated charge data.

ASTRO applauds the Agency’s proposal to repeal the market-based data collection and market-based MS-DRG relative weight methodology. While we appreciated the concerns regarding existing FFS methodology, we did not think it was appropriate to apply a new methodology that had the potential to cause rate fluctuations based on market trends.

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 2022, the Agency proposes to continue the low wage index hospital policy and to continue to do so in a 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.

PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR), Medicare Promoting Interoperability Program, and the Hospital Inpatient Quality Reporting Program

CMS is proposing to remove the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology measure beginning with the FY 2024 program year. The Agency has concluded it is no longer feasible to implement the measure due to recent changes by the measure steward. The measure steward has decided to revert to a previous version of the measure that requires a plan of care to address any, rather than just moderate-severe, pain and will no longer maintain the specifications for this measure as it is currently used in the PCHQR Program.

ASTRO disagrees with the Agency’s proposal to remove the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #144) measure. Ensuring that physicians are creating a plan of care for any pain is necessary. Patients with cancer manage multiple painful side effects and measuring the pain level is key to managing a patient’s quality of life. ASTRO supports the measure steward’s reversal of the denominator statement to include all patients. This, and its paired measure, Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (NQF #143), have been utilized since the Physician Quality Reporting System (PQRS) was initiated and are reliable quality measures. Both measures are capturable by systems and are meaningful to the holistic care of patients. **We therefore recommend that CMS retain the Plan of Care for Pain measure in the PCHQR program, not only to maintain harmonization across quality reporting programs but also to maintain continuity between the paired measures.**

Additionally, the Oncology: Plan of Care for Pain quality measure is included in the Merit Based Incentive Payment System (MIPS), the Oncology Care Model, the proposed Oncology Care First Model and the Radiation Oncology Model. ASTRO finds it difficult to understand why it is no longer feasible to implement a measure that has been in use for more than a decade in multiple programs and clinical settings. Removing the Plan of Care for Pain measure from the PCHQR program means that it will not align with other reporting programs. Additionally, the National Quality Forum recently re-endorsed this measure, highlighting the importance of this measure from a pan-oncology panel and adding credence to the statements above.

The Agency is proposing to adopt the COVID-19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the FY 2023 program year and for subsequent years. CMS believes it is important to require that PPS-Exempt Cancer Hospitals (PCH) report their rates of vaccination in order to assess whether they are taking steps to limit the spread of COVID-19, and to help sustain the ability of U.S. hospitals to continue serving their communities throughout the COVID-19 PHE and beyond. PCHs would be required to report data on the measure for the fourth quarter of CY 2021 (that is, from October 2021 through December 2021). **ASTRO supports the adoption of the COVID-19 Vaccination Coverage Among Healthcare Personnel measure.** The entire radiation oncology treatment team, not just physicians, have

daily contact with patients over the course of treatment, which can last several weeks, and measuring vaccination status protects both patients and staff.

Value-Based Purchasing (VBP)

CMS is proposing to revise the scoring and payment methodology for the FY 2022 Performance Year (PY) such that hospitals will not be scored using quality measure data that are distorted by the effects of the PHE and will not receive total performance score (TPS) or adjustments to their payments as a result. **We seek clarification on how this accommodation will affect those physicians that utilized the VBP in other programs such as MIPS.**

Medicare Promoting Interoperability Program

CMS is proposing changes to the Medicare Promoting Interoperability Program, which are consistent with the policies finalized for MIPS-eligible clinicians in the CY 2021 Physician Fee Schedule Final Rule. **In general, ASTRO supports these changes as they will align with other quality reporting programs.** However, as we have stated in previous comment letters, we urge the Agency to tread carefully when requiring additional functionality of electronic health records systems without putting the onus of development and implementation on the vendor. **Clinicians should not be adversely penalized because a vendor has not developed or implemented CMS requirements.**

CMS proposes to maintain the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure as optional while increasing its available bonus from five points to 10 points for the Electronic Health Records (EHR) reporting period in CY 2022. As a result, the maximum total points available for the Electronic Prescribing Objective would increase to 20 points for CY 2022. **ASTRO supports the increase in bonus points to highlight the need of this technology and its use.**

The Agency is proposing to add a new Health Information Exchange (HIE) Bi-Directional Exchange measure, as a yes/no attestation, to the HIE objective as an optional alternative to the two existing measures beginning with the EHR reporting period in CY 2022. **ASTRO supports this proposal as it is integral for complete care coordination and believes it will promote adoption of standards and Office of the National Coordinator for Health Information Technology (ONC) requirements by vendors.**

CMS is proposing to modify the Provide Patient's Electronic Access to Their Health Information measure to establish a data availability requirement beginning with encounters with a date of service on or after January 1, 2016, beginning with the EHR reporting period in CY 2022. **ASTRO appreciates the clarification for indefinite data availability; however, we request further clarification for when an organization changes software platforms or other scenarios when data is not available.** This is especially important if not all data is transferrable.

The Agency is also recommending the continuation of the EHR reporting period of a minimum of any continuous 90-day period for new and returning eligible hospitals and critical access hospitals (CAHs) for CY 2023 and to increase the EHR reporting period to a minimum of any

continuous 180-day period for new and returning eligible hospitals and CAHs for CY 2024. The Agency believes that by increasing the EHR reporting period in CY 2024, eligible hospitals, CAHs, and vendors will have time to plan in advance, build upon, and utilize investments already made within their infrastructure. Additionally, the Agency believes that increasing the EHR reporting period in CY 2024 is important for the continued improvement of interoperability and health information exchange by producing more comprehensive and reliable data for patients and providers, which are key goals of the Medicare Promoting Interoperability Program.

The Agency has proposed the removal of attestation statements, 2) CEHRT implementation and 3) specific use, from the Promoting Interoperability Program's prevention of information blocking requirement. **ASTRO supports the removal of attestation statements 2 and 3 if the goal is to align with the ONC Information Blocking requirements.**

Finally, given the widespread success of participating hospitals, CMS is proposing to increase the minimum required score for the objectives and measures to be considered a meaningful EHR user from 50 to 60 points. **ASTRO supports highlighting the need for this category; however, as mentioned earlier in this comment letter and in previous comment letters, we remain concerned that the emphasis is on clinicians, when in fact, the vendors are responsible for the functionality.** Emphasis for implementation should fall solely on the vendors without penalizing clinicians.

Safety Assurance Factors for EHR Resilience (SAFER) Guides

The ONC developed the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) to support hospitals' ability to address EHR safety. Collectively, the guides help healthcare organizations conduct self-assessments to optimize the safety and use of EHRs, and were intended to be utilized by EHR users, developers, patient safety organizations, and those who are concerned with optimizing the safe use of Health IT. By completing a self-assessment using the SAFER Guides, providers can help to develop a culture of safety within their organizations and ensure they are responsible operators of technology tools, including certified health IT products, which they utilize in the delivery of care. CMS is proposing to add a new SAFER Guides measure to the Protect Patient Health Information objective beginning with the CY 2022 EHR reporting period. The Agency is proposing that an eligible hospital or CAH must attest to having conducted an annual self-assessment of all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs with one "yes/no" attestation statement accounting for a complete self-assessment using all nine guides. As proposed, this measure would be required, but not scored for CY 2022, and that reporting "yes" or "no" will not affect the total score of the Medicare Promoting Interoperability Program. **ASTRO supports the addition of this new measure and agrees with the Agency's proposal not to score this measure during implementation.**

Certified Electronic Health Records Technology (CEHRT)

CMS is proposing that, beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years, hospitals use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital Inpatient Quality Reporting (IQR) Program data. In May 2020, the Office of the National Coordinator for Health

Information Technology (ONC) finalized additional updates to the 2015 Edition in the 21st Century Cures Act Final Rule, including an e-prescribing standard required for alignment with other CMS programs.

The 21st Century Cures Act final rule finalized updates to a number of certification criteria, which are currently associated with objectives and measures under the Promoting Interoperability Program, as well as criteria that are included in the 2015 Edition Base EHR² definition. In general, ONC finalized that health IT developers have until May 2, 2022 to make technology certified to these updated criteria available to their customers. During this time, developers are expected to continue supporting technology certified to the prior version of certification criteria for use by their customers.

In general, health IT developers have up to 24 months from May 1, 2020 to make technology certified to the updated criteria available to their customers, plus the additional three-month period during which ONC will exercise enforcement discretion around compliance dates finalized in the 21st Century Cures Act final rule in response to the COVID-19 PHE. As a result, where the 21st Century Cures Act final rule requires health IT developers to make technology meeting new and updated certification criteria available by May 2, 2022, developers taking advantage of enforcement discretion would be permitted to delay making updated certified technology available until August 2, 2022. *After this date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.*

Health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to implementing updates, and healthcare providers participating in QPP may use such technology for the purposes of these programs while working with health IT developers to implement updates in a manner that best meets their needs. Several certification criteria were removed because they are already in widespread use, including medications, medication allergies and smoking status. A new criterion, “electronic health information export,” was established. This new criterion requires a certified health IT module to electronically export all electronic health information (EHI) that can be stored at the time of certification by the product of which the health IT module is a part. A health IT developer of a certified health IT products, which, at the time presented for certification, electronically stores EHI must certify such products to this new criterion and make these products available to their customers by May 2, 2022. However, the new EHI Export criterion is not included in the Base EHR definition, and it is not associated with any objectives or measures in the Promoting Interoperability Programs.

Additionally, the Agency is proposing to require all EHR technology to be certified to all available electronic Clinical Quality Measures (eCQMs), if the proposal to require hospitals to

² 2015 Edition Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists; (2) Has the capacity: (i) To provide clinical decision support; (ii) To support physician order entry; (iii) To capture and query information relevant to health care quality; (iv) To exchange electronic health information with, and integrate such information from other sources; and (3) Has been certified to the certification criteria adopted by the Secretary.

use the 2015 Edition Cures Update is finalized. **ASTRO is concerned with this recommendation because many EHR vendors no longer support collection of eCQMs and have outsourced this functionality. We request clarification on whether outsourcing this functionality is allowed under this proposal.**

As we have mentioned in this comment letter, and in previous comment letters, eligible clinicians do not have control over the EHR products issued by vendors, and penalizing providers for not achieving any level of CEHRT status must be avoided. **ASTRO believes that CMS and ONC must continue to issue clear direction to vendors so a complete and timely upgrade of EHR products are available by the 2022 deadline to increase care coordination and patient access. The onus on updating required software should rest solely on the vendor, not the clinician.** Additionally, when vendors are required to upgrade their products to maintain compliance with federal regulations, it requires significant investment in the products. However, these costs are often passed on directly to physicians. **As we have mentioned previously, we are concerned that vendors will use every new, regulatorily-required update or module as an opportunity to generate additional charges and fees for their products.** These excess charges are a financial burden for many practices, especially for small and rural practices, which often find these costs prohibitive. **Additionally, most of the systems used in radiation oncology do not yet have a Cures edition, and we are concerned that with the long lead time needed to upgrade, train staff, and change workflows, clinicians will be unduly punished, especially since this comes during the PHE.**

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs Request for Information (RFI):

The Agency included a request for information regarding the modernization of quality measurement to digital quality measurement. **ASTRO supports moving to digital quality measurement by 2025 and supports moving from the initial focus on electronic data capture to enhancing information exchange and expanding quality measurement. We also support alignment with the Cures Act and technology requirements for payers, healthcare providers, and health IT developers. Finally, we support alignment between VBP program measurement and ONC priorities and the use of Fast Healthcare Interoperability Resources (FHIR®) standard.**

Clarifying the definition of digital quality measures (dQMs)

CMS is proposing to clarify the definition of dQMs as a software that processes digital data to produce a measure score or measure scores. Data sources include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, patient portals or applications, health information exchanges or registries, and other sources. **ASTRO supports the proposed definition. We agree that the focus must be on multiple sources.** Currently, it is difficult to get the necessary radiation oncology data because of the lack of interface between the disparate systems.

Use of FHIR for Current eCQMs

CMS is continuing to promote the use of the FHIR® standard for eCQMs that are currently in the various quality programs. **ASTRO supports the use of FHIR and commends the Agency**

for promoting this standard. The availability and use of data standards is key to interoperability, data transparency, and liquidity. ASTRO is currently engaged in the Common Oncology Data Elements eXtension (CodeX) FHIR Accelerator and has recently completed work to standardize data elements necessary in the end of treatment summary, which promotes care coordination between the numerous clinicians required for holistic cancer treatment. Prior to this initiative, limited standards existed, outside of Digital Imaging and Communications in Medicine (DICOM), that could transfer data between non-radiation oncology systems. To date, the CodeX project has created four radiation therapy profiles, six extensions, and nine value sets, resulting in 322 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.

Leveraging and advancing standards for digital data and obtaining all EHR data required for quality measures via provider FHIR-based Application Programming Interfaces (APIs)

The Agency is seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. **ASTRO recommends that CMS provide funding for the transition to provider FHIR-based APIs.** The infrastructure needed for this transition does not exist and must be developed. Measure stewards must test any re-specification needed to support the transition, and new standards will need to be developed. Quality measure development and maintenance are costly and burdensome, and there is no reason to believe that dQMs will be cheaper to develop and test.

Redesigning quality measures to be self-contained tools

The Agency is seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. ASTRO requests clarification on the following:

- Is CMS going to develop these tools?
- What is the timeline?
- How will it be deployed?

This seems like a collection tool, but interoperability issues remain on the data entry side, not only on the collection side. **We recommend that the Agency look to other countries that collect similar data before embarking on this proposal.**

Building a pathway to data aggregation in support of quality measurement

CMS is considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Quality Registries that report quality measures for eligible clinicians in MIPS are potential examples. **ASTRO supports the establishment of policies and processes for data aggregation and measure calculation.** This will allow physicians to report data using multiple mechanisms. However, we urge CMS to establish standards to ensure that data collection is the same for every data collection mechanism.

Potential future alignment of measures across reporting programs, federal and state agencies, and the private sector

The Agency is considering the future potential development and multi-staged implementation of a common portfolio of dQMs across CMS-regulated programs, agencies, and private payers. This portfolio would require the alignment of: (1) measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate measure logic. **ASTRO supports alignment across federal, state, and payers and supports a cohesive dQM portfolio.** However, radiation oncology finds it difficult to participate in “general medicine” measurement, as it falls outside the scope of practice, and therefore, we urge the agency think more broadly when developing measures.

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