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September 17, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals

Dear Administrator Brooks-LaSure:

The American College of Radiology (ACR), representing nearly 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Hospital Outpatient Prospective Payment (HOPPS) and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.

The ACR provides comment on the following important issues:

- Proposed APC Placement of Low-Dose Lung Cancer Screening Code
- Proposed APC Placement of Medical Physics Dose Code
- Proposed APC Placement of Cardiac CT Codes
- Proposed Low Volume APC Policy
- Updates to the Hospital OQR Program
- Radiation Oncology Model Proposed Changes

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Proposed APC Placement of New and Revised CY 2022 Category I and III CPT Codes

CMS included proposed APC placement of new and revised CY 2022 Category I and III CPT Codes in Addendum B with a "NI" modifier indicator meaning CMS will accept comments in the proposed rule on the interim APC assignment for the new code.

Proposed APC Placement of Low-Dose Lung Cancer Screening Code

Proposal
CMS proposes placing 71271 (Low Dose CT for Lung Cancer Screening) in the lowest Imaging without Contrast APC (5521), with payment rate of $83.01.

ACR Perspective and Comments
The ACR has raised concerns about the inadequate payments for CT lung screening based on flawed hospital data in past comment letters to CMS. ***The ACR believes placing 71271 APC 5523 (Level 3 Imaging without Contrast) would be more appropriate based on clinical similarity and resource use.***

Based on clinical similarity and resource use, CPT code 71271 should be placed a higher APC than CPT code 71250 (Ct thorax dx c-0), the more appropriate predecessor code for 71271. In the CY 2022 HOPPS proposed rule, CPT code 71250 has a geometric mean of $91.37. The CPT code 71271 should be placed in a higher APC than 71250 due to the increased reporting and staff requirements for conducting LDCT screening. Included in LDCT screening there are registry reporting requirements, necessary nurse navigators, and additional certifications required for the service that add costs to providing the service. ***The ACR believes placing 71271 APC 5523 (Level 3 Imaging without Contrast) would be more appropriate based on clinical similarity and resource use. Appropriate APC placement of 71271 will ensure that patients have access to this life-saving screening service***.

Proposed APC Placement of Medical Physics Dose Code

Proposal
CMS proposes to place CPT code 76145 (Med physic dos eval rad exps) in APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) with a proposed payment rate of $130.19.

ACR Perspective and Comments
APC 5611 currently has nine, clinically similar, radiation oncology therapeutic radiation treatment codes. Newly created CPT Code 76145 is not a radiation oncology code, rather a service that will be performed in interventional radiology or interventional cardiology. ACR requests that CPT Code 76145 be placed in APC 5724 Level 4 Diagnostic Tests and Related Services. APC 5724 currently has 17 services, with a range of clinical variability (urology, neurology, internal medicine, radiology, dermatology, allergy, etc). The resource consumption in APC 5724 more closely aligns with the resources used to perform CPT code 76145. ***The ACR believes the most appropriate placement of 76145 would be in APC 5724 (Level 4 Diagnostic Tests and Related Services) with a payment rate of $943.95.***

Proposed APC Placement of Cardiac CT CPT Codes

Proposal
CMS proposes to place CPT codes cardiac CT codes 75572, 75573, and 75574 into APC 5571 (Level 1 Imaging with Contrast) with a payment rate of $181.41.

ACR Perspective and Comments
The ACR does not agree with CMS's placement of cardiac CT codes 75572, 75573, and 75574 into APC 5571. ***Cardiac CT should be reassigned to APC 5572 or 5573, to bring into better alignment with clinical homogeneity and cost/resource utilization***. The three cardiac CT codes (75572, 75573, 75574) should never have been placed in APC 5571, as cardiac CT exams require substantially more time and resources than any of the tests assigned to APC 5571. Cardiac CT uses a CT scanner and is far more similar to services in APCs 5573 than to services in APC 5571.

Cardiac CT exams require more time, require highly trained technologists who reformat non-orthogonal projections, involve higher risk patients, require administration of vasoactive medications, and require close monitoring of patients during and after the procedure. The need for all these resources is vastly different from other contrast-enhanced imaging studies in 5571 which are simpler and may only take a fraction of the time. Moreover, this test has been shown to be highly cost-effective in evaluating acute chest pain in the emergency setting by reducing hospital admissions and precluding the need for costlier interventional procedures. APC misallocation will only serve to stunt further adoption. Additionally, CPT codes 75573 and 75574 will fall under the DRA cap for CY 2022 if these proposals are finalized. The inappropriate placement of CPT code 75572, 75573, and 75574 in the HOPPS will negatively impact reimbursement under the physician fee schedule. The APC placement of these codes will continue to erode access to these services. ***The ACR asks that CMS uses its authority to move 75572 & 75573 contrast-enhanced cardiac CT codes to APC 5572 and move 75574 to APC 5573***.

Proposed APC Placement of Quantitative Multiparametric MR

Proposal
CMS proposes to place Category III CPT code 0648T (Quan mr tis wo mri 1orgn) in APC 5523 Level 3 Imaging without Contrast. CMS proposes to not provide separate payment for Category III CPT code 0649T (Quan mr tiss w/mri 1orgn).

ACR Perspective and Comments
CMS's proposal to assign 0648T to APC 5523 and package 0649T does not adequately distinguish quantitative multiparametric MR from other HCPCS procedures under the same APC. Secondly, it significantly under-reimburses code 0648T by neither covering the costs of delivery nor covering the cost of furnishing the service. ***The ACR asks that CMS place CPT code 0648T into APC 1515 - Level 15 ($1,301 - $1,400) to reflect both the uniqueness of the service and to ensure sufficient reimbursement for delivery and furnishing costs.***

The ACR requests that CMS place CPT code 0649T into APC 1513 - Level 13 ($1,101 - $1,200) to more appropriately reflect the costs of the procedure. CPT code 0649T should not be bundled with anatomical MRI, as quantitative multiparametric MR is a separate and distinct service from the primary procedure.

Other HOPPS Policy Proposals

Low Volume APC Policy

Proposal
CMS proposes to establish a Low Volume APC policy for New Technology APCs, clinical APCs, and brachytherapy APCs. For these APCs with fewer than 100 single claims that can be used for ratesetting purposes in the existing claims year, CMS proposes to use up to four years of claims data to establish a payment rate for each item or service as CMS currently does for low volume services assigned to New Technology APCs. Additionally, CMS proposes to calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost. CMS proposes to designate 5 brachytherapy APCs as Low Volume APCs for CY 2022.

ACR Perspective and Comments
The ACR agrees with CMS that low utilization of services can lead to wide variation in payment rates from year to year. Under the proposed Low Volume APC policy, the payment rates for these APCs would be set at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data. ***The ACR supports the proposed Low Volume APC policy effective January 1, 2022.***

Hospital OQR Program

New Measures for the Hospital OQR Program Measure Set

Proposal
CMS proposes to adopt the Breast Screening Recall Rates measure beginning with the calendar year (CY) 2023 payment determination period. The data reviewed will have been collected between July 1, 2020, to June 30, 2021. Future data collection periods will occur between July 1 and June 30 of the following year, starting three years before the applicable payment calendar year for subsequent years. As proposed, Breast Screening Recall Rates measure calculates the percentage of Medicare fee-for-service (FFS) beneficiaries (from claims at the facility level) for whom a traditional mammography or digital breast tomography (DBT) screening study was performed. These studies must have been followed by a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging (MRI) of the breast in an outpatient or office setting on the same day or within 45 days of the index image.

This measure would fill the gap in women's health and oncology care in the Hospital OQR Program following the removal of the Mammography Follow-Up Rates measure (OP-9). CMS intends for facilities to move toward the five to 12 percent range of recall rates. Facilities that are above or below the range should consider the implementation of quality improvement procedures to ensure they are not missing cases or recalling individuals unnecessarily.

ACR Perspective and Comments
The ACR considers Breast Screening Recall Rates a reasonable replacement for the previous Mammography Follow-Up Rates measure (OP-9). The inclusion of mammography, DBT, MRI, and US are the appropriate studies for diagnosis for most facilities, as this would exclude patients who have an additional evaluation with less common modalities. The ACR supports the numerator timeframe of the same day or within 45 days of the index image. The ACR BI-RADS Manual 2013[1] recommends a target recall rate range of five to12 percent and supports the measure's recommended recall rate. This measure addresses the issue of inappropriate recall rates; whereby, high recall rates can lead to radiation-induced cancers, while low recall rates can lead to delayed diagnoses or undetected cases of breast cancer.

To provide more clarity for the measure's intent, ***the ACR strongly recommends changing the measure title from Breast Screening Recall Rates to Breast Cancer Screening Recall Rates***.

According to the proposed implementation timeframe, hospital performance will be measured using data from services provided before CMS' notification of such measurement and potential public reporting of that performance. While it is notable that continual evaluation of quality should be and is likely an activity that breast cancer screening facilities regularly conduct, this rule does not provide advance notice of CMS' intention to publicly report a facility's performance. ***The ACR strongly encourages CMS to postpone posting data on Hospital Compare until the CY 2025 payment determination to provide facilities proper notification before implementing this measure.*** The ACR appreciates CMS' intention to create a suite of education and outreach material to aid stakeholders in understanding the measure structure and meaningfulness of performant ranges. We encourage CMS to include stakeholders, like the ACR, when creating these materials.

Hospital OQR Program Measures and Topics for Future Considerations

Introduction and Expansion of the CMS Disparity Methods to Hospital OQR Program

Proposal
CMS states the following in the proposed rule: "Significant and persistent inequities in health care outcomes exist in the United States." And that "belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area or being near or below the poverty level" is associated with worse health outcomes. Unfortunately, the COVID-19 pandemic highlights many of these longstanding health inequities with higher infection rates, hospitalization, and mortality among Black, Latino, and Indigenous and Native American individuals relative to their white counterparts. Although different factors result in disparate health outcomes, CMS cites that limited access to high-quality care significantly contributes. Therefore, CMS proposes improving data collection of the elements influencing inequities within their quality programs. CMS perceives that this would present opportunities for providers to receive the resources necessary to improve their care quality.

[1] D'Orsi, C. J., Sickles, E. A., Mendelson, E. B., Morris EA, et al. (2013). ACR BI-RADS® atlas, breast imaging reporting and data system. Reston, VA: American College of Radiology.

CMS mentions multiple ongoing efforts to close the health equity gap among its programs, including: transparency of health disparities, supporting providers and others with evidence-informed solutions to address social determinants of health for achieving health equity, and reporting to providers on gaps in the quality of the program in which they participate. CMS is considering incorporating the CMS Disparity Methods into the Hospital Outpatient Quality Reporting (Hospital OQR) program. These methods comprise two types of analyses, the Within-Hospital disparity method, and the Across-Hospital method. Both stratify quality measure data by dual eligibility status (a demonstrated predictor of poor health outcomes) and illustrate variations in outcome rates among patient groups within a provider's patient population. Each method's analysis renders different results informing how providers may improve their disparity gaps.

The Across-Hospital disparity method allows hospitals to make disparity size comparisons against other hospitals. In contrast, the Within-Hospital Method provides information on a hospital's performance when treating patients with certain social risk factors. Until CMS identifies specific factors for delivering the most valuable information to stakeholders, dual eligibility status is the proxy for social risk.

As part of their goal to achieve health equity across programs, CMS proposes bolstering the CMS Disparity Methods to consist of the following six Hospital OQR program quality measures.

- MRI Lumbar Spine for Low Back Pain (OP-8)
- Abdomen CT – Use of Contrast Material (OP-10)
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery (OP-13)
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
- (OP-32)
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35)
- Hospital Visits after Hospital Outpatient Surgery (OP-36).

CMS also proposes expanding the CMS Disparity Methods to include two social risk factors (dual eligibility and race/ethnicity). CMS perceives that broadening the comprehensiveness of health equity information provided to facilities would improve the care delivered by providers. CMS notes that barriers to immediately collecting Medicare beneficiaries' demographic information in a low burden and standardized way, CMS proposes that indirect estimation serves as the temporary method for identifying race and ethnicity populations.

ACR Perspectives and Comments

The COVID-19 pandemic highlighted many long-standing health inequities like higher infection rates, hospitalization, and mortality among Black, Latino, and Indigenous and Native American individuals relative to their white counterparts. The ACR applauds CMS' efforts across its quality payment reporting programs to ensure the equitable delivery of high-quality care. However, we are unsure of the degree to which hospitals/facilities participating in the Hospital OQR program institute health equity and antiracism strategies and policies and collect standardized social risk information. ACR is concerned that the imputation of race and ethnicity data collected for the proposed measures could exacerbate or mask existing disparities because the proposed approaches use the "statistical norm." Suppose current race

reporting is unrepresentative of the population (e.g., whites are the most likely to report their race). In that case, the estimates will perpetuate the biases in the data and could provide incorrect information about disparities/quality and lead to inappropriate action.

The ACR urges CMS to consider a three-pronged approach that supports the Hospital OQR program's assessment of hospitals'/facilities' health equity strategies and processes affecting health outcomes through:

1. Structural measurement.
2. Participation in quality improvement activities focused on health equity and anti-racism strategies and processes by outpatient hospital and facility leaders.
3. Careful standardization of demographic data collection across quality programs and measures while retaining key current elements that serve as proxy demographic data until a fuller set of demographic data is standardized for capture in measure data sources.

This approach would bolster the implementation of the hospital's/facilities' health equity and anti-racism strategies and associated processes and their capability to be included in health equity performance comparisons across and within hospitals/facilities, as proposed.

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

Proposal
CMS includes a formal Request for Information (RFI) on the transition of digital quality measurement (dQM) across Medicare quality performance programs by 2025. To maintain the alignment and harmonization outlined in the 2020 Department of Health and Human Services (HHS) Health Quality Roadmap, CMS is approaching HHS' priorities with other federal entities, like the Office of the National Coordinator on Health Information Technology (i.e., 21st Century Cures Act), to promote data interoperability and access.

ACR Perspectives and Comments
The ACR supports the concept behind CMS' adoption of FHIR to promote interoperability of measure data. ***However, we request a delay to the aggressive 2025 transition deadline***. We encourage the use of the data collection structure and single terminology to obtain electronic clinical quality measure (eCQM) data. We urge CMS to propose guidance for measure developers, vendors, and other stakeholders to inform the necessary details to transition to FHIR-based eCQMs at the hospital/facility level. For instance, which version of FHIR would vendors implement, what degree of complexity is expected of the FHIR queries, and what type of subject matter expertise is needed to engage in the transformation successfully (i.e., ensuring technical specifications capture the required data elements to assess performance).

ACR anticipates translating radiology eCQMs to dQMs will be complex. While most data elements may be extracted from electronic health record systems, much of it lives in non-structured data fields that lack the necessary standardized terminology for translation required of FHIR resources. It is possible to do the translation but prioritization of resources to do such will likely be at issue. We are encouraged by the intention for dQM to contain language that would process digital data for determining measure scores,

thereby promoting quality feedback reports more rapidly. The ACR is interested in learning more about CMS' plan for prioritizing components that would support the dQM portfolio, like measurement topics, measure development/digitization requirements, and data standards. Given the complexities of transitioning to dQM, ***The ACR recommends that CMS delay the timeline for complete dQM transition at least until two years after the end of the PHE and to allow for greater availability of information and guidance for stakeholders.***

Radiation Oncology (RO) Model

Proposals

Performance Period
CMS proposes to modify the RO Model performance period to January 1, 2022 through December 31, 2026. CMS is also proposing that each performance period will be a 12-month period, unless the initial model performance period starts mid-year, in which case performance year (PY) 1 will begin on that date and end on December 31 of that year.

Participant Exclusions
CMS proposes to exclude from the RO Model only the HOPDs that are participating in the Pennsylvania Rural Health Model (PARHM), rather than excluding both HOPDs in the PARHM and those that are eligible to participate in the PARHM. CMS is also proposing that the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model is excluded from the RO Model.

CMS proposes that an entity would not be eligible for low volume opt-out if its legacy Taxpayer Identification Number (TIN) or legacy CMS Certification Number (CCN) was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the two years prior to the applicable PY across all CBSAs selected for participation.

Changes to RO Model Episodes
CMS proposes to remove liver cancer from the list of cancer types included. The Agency also proposes to remove brachytherapy as an included modality in the RO Model.

Pricing Methodology
CMS proposes to lower the discount factor for PC from 3.75% to 3.5%, and for TC from 4.75% to 4.5%. CMS believes that their proposals to remove brachytherapy and liver cancer from the model will allow the Agency to lower these discounts. CMS proposes that RO participants submit quality measure data starting in PY1, and that starting in PY1, the 2% quality withhold for the PC will be applied.

Advanced APM/MIPS APM
CMS proposes that the CEHRT requirement begin in PY1 of the proposed model performance period and that RO Model participants must certify their use of CEHRT at the start of PY1. CMS proposes to define "Track One" of the RO Model to mean an Advanced APM or MIPS APM track for Dual participants and Professional participants that use CEHRT. CMS proposes to define "Track Two" of the RO Model to mean

an APM for Dual participants and Professional participants who do not meet the RO Model requirements to participate as an advanced APM or MIPS APM; and Technical participants.

Waiver of 5% bonus on Technical Services
In the 2020 RO Model final rule, CMMI approved a waiver that would prevent freestanding practices from recognizing the 5% Advanced APM bonus for technical payments, as prescribed by the Medicare Access and CHIP Reauthorization Act (MACRA).

Extreme and Uncontrollable Circumstances
CMS proposes to adopt an extreme and uncontrollable circumstances (EUC) policy for the RO Model which would allow CMS to revise the model performance period; grant certain exceptions for RO Model requirements to ensure the delivery of safe and efficient care; and revise the RO Model's payment methodology. In instances where an EUC is nation-wide, CMS proposes that CMS may delay the start date of the model performance period by up to one CY. RO Model participants would be notified no later than 30 days before the model start date. If an EUC impacts RO Model participants' ability to comply with the quality measure or CDE requirements, CMS proposes that CMS may delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, and/or extend the time for RO participants to report data to CMS. If CMS removes quality and CDE requirements for affected participants due to EUC, CMS proposes that the Agency could choose to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation for those affected (which would potentially increase episode payments). CMS proposes that the Agency may modify the trend factor calculation for the PC and/or TC of an included cancer type when RO participants experience EUC.

Monitoring Requirements
CMS states in the 2022 HOPPS proposed rule that "any failure, however minor, to comply with the RO Model Requirements set forth at sec. 512.220(a)(2) will have an impact on whether a RO Model participant is in Track One versus Track Two." Section 512.220(a)(2) contains the following monitoring requirements:

1) discuss goals of care with each Medicare beneficiary before initiating treatment and communicate to the beneficiary whether the treatment intent is curative or palliative;
2) adhere to nationally recognized, evidence-based treatment guidelines when appropriate in treating Medicare beneficiaries or document in the medical record the rationale for the departure from these guidelines;
3) assess the Medicare beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnosis;
4) assess the Medicare beneficiaries' performance status as a quantitative measure determined by the physician;
5) send a treatment summary to each Medicare beneficiary's referring physician within three months of the end of treatment to coordinate care;
6) discuss with each Medicare beneficiary prior to treatment delivery his or her inclusion in and cost-sharing responsibilities; and

7) perform and document Peer Review for 50 percent of new patients in performance year 1, 55 percent of new patients in performance year 2, 60 percent of new patients in performance year 3, 65 percent of patients in performance year 4, and 70 percent of patients in performance year 5, preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within two weeks of starting treatment.

According to the proposed rule, CMS is seeking input on whether some of the requirements associated with section 512.220(a)(2) should be modified and whether the RO Model can meaningfully improve the quality of care if any of the requirements are modified.

Participation Preparation
In the 2022 HOPPS proposed rule, CMS states that it plans to launch the RO Model on January 1, 2022. This is less than six months away from the time that the proposed rule was issued and will be a mere two months after publication of the final rule. In the proposed rule, CMS states that it will not be able to provide Case Mix or Historical Experience Adjustment data inputs to participating practices until after the final rule is issued.

ACR Perspective and Comments

Discount Factors
Due to the significant financial impacts of COVID-19, including declines in volume and revenue for radiation oncology practices, the ACR has recommended that CMS permanently reduce the discount factors in the model. Although CMS proposed to reduce the discount factors for PC and TC by 0.25%, these cuts remain extremely steep and inappropriate for practices still combatting and trying to recover from the financial impacts of the pandemic. **As the ACR urged CMS in a letter to the Agency in October 2020, the ACR recommends that CMS reduce the discount factors to no more than 3%.** Reducing the discount factors further will help this model be more consistent with MACRA's intent.

Participant preparation
ACR affirms CMS must supply Case Mix and Historical Experience adjustment data inputs to participating RO model participants immediately via the RO Model Administrative Portal (ROAP). The data used to inform these inputs is 2017-2019. This is the same data included in the data file published with the proposed rule. CMS must supply these data inputs immediately. This information is critical and can help RO Model participants better understand the financial implications of participating in the program. Additionally, CMS has issued its payment methodology tool for practices to use, but without these data inputs, that tool is ineffective. The RO model community requests the CMMI team educate providers on how to retrieve their unique calculated adjustment data and share with their respective teams. Interactive reports should be readily available based on the proposals outlined.

Small and Rural Practices, CEHRT
The ACR is very concerned about the effects this model will have with the inclusion of small and rural practices entering risk-based arrangements without sufficient resources. **The ACR is alarmed that such a significant number of small and rural practices are included in the model, while many large**

metropolitan areas have been spared, and are expected to use their limited resources to adopt and implement certified EHR technology (CEHRT), among all of the other reporting requirements for participation. Small and rural practices that have been exempted from requirements under MIPS, such as Meaningful Use, Advancing Care Information, and Promoting Interoperability, are now required to adopt and implement CEHRT. This is a significant undertaking, especially during a PHE, and a hardship that CMS seemingly understood under MIPS. CMS's opt-out option for low-volume entities does not fully recognize small and rural practices. For example, in small and rural counties, older adults (65+) are a larger share of the population, and young adults are a smaller share of the population, compared to urban and suburban areas.[2] This results in a large Medicare population to serve, thus making the 20-episode threshold impractical.

Advanced APM/MIPS APM
The ACR urges CMS not to finalize the "Track One" and "Track Two" approach for RO Model participants, as it further prevents practices from accessing upside of the model. ***Furthermore, the ACR objects to model participants being required to submit data for both MIPS and the RO Model, as it is contrary to MACRA.***

Additionally, excluding those HOPDs participating in the Community Track of the CHART model will have minimal impact. Participation in the CHART Model requires an extensive application process and the deadline was recent, in May 2021. Only 15 sites will be selected, and as a result it is highly unlikely that an RO practice would be part of this program. Out of about 950 practices that will be affected by the RO Model, the magnitude of this exemption will be minimal.

Waiver of 5% bonus on Technical Services
ACR continues to believe that this waiver is arbitrary and a clear violation of the spirit of MACRA. This waiver further limits community-based clinics, particularly those who provide services to underserved populations, from investing in the technology necessary to provide high quality care. The 5% Advanced APM bonus is not only an incentive to participate in the model, but is also designed to support practice transformation essential for meaningful APM participation. The RO Model participation requirements establish new, unreimbursed practice expenses that would normally be paid from technical fee revenue. **Unless the 5% bonus is applied to both the professional and technical charges for freestanding participants, those practices will be at a distinct disadvantage and unable to achieve true practice transformation.**

Monitoring Requirements
ACR is disappointed in CMS's decision to not reward RO model participants for additional work associated with fulfilling the RO model monitoring requirements as proposed.

As mentioned in previous comment letters, the monitoring requirements are not the issue, they are process of care activities that are meaningful and indicate a certain level of high-quality treatment. However, the ACR is concerned that EHR vendors need time to develop discrete fields for the requested monitoring data elements, as they may be typically captured in clinical notes or external systems, but not in EHRs. While

[2] Pew Research Center, May 2018, "What Unites and Divides Urban, Suburban and Rural Communities"

vendors can build something to be compliant, a new build can take between 12 and 18 months. Once the build is complete, practices must then implement and incorporate into workflows, taking even more time. Additionally, there is no reimbursement associated with the monitoring requirements—only the excessive payment cuts. ACR remains concerned regarding the related financial costs that participants will incur due to mandatory participation in the RO Model.

Given that the CMS has yet to provide additional clarifying guidance regarding how the Agency expects practices to collect and report on this data, the ACR recommends that compliance be voluntary until specific guidance is issued; EHR vendors have had the opportunity to develop the necessary software for the collection of the data; and RO Model participating practices have been able to upgrade their existing systems. Practices should not be penalized due to CMS' lack of guidance related to the monitoring requirements.

EUC Policy
The ACR appreciates CMS proposing an EUC policy. However, the ACR urges the Agency to clarify how it will determine "geographic region or geographic area" and whether it would consider expansion of the COVID-19 PHE as meeting the criteria for delay of implementation of the RO Model.

Submission of Encounter-Like (No Pay) Claims
The CMMI team has mentioned on educational webinars, in addition to the start-of-episode and end-of-episode claims, all RO participants must submit RO Model encounter data on no-pay claims for all included RT services identified on the RO Model Packaged/Bundled HCPCS Codes list within a given 90-day episode. The encounter data will be used for annual reconciliation of incomplete episodes and duplicate RT services, the RO Model evaluation and monitoring (such as understanding how the utilization of RT services changes over time), and other CMS research. These no pay claims can be submitted by RO participants once a start-of-episode claim has been adjudicated, using their typical coding and billing schedules and processes for Medicare services. However, ***ACR disagrees with this approach to monitor and evaluate RT services over time*. This proposal increases the administrative burden for radiation oncologists and their billing staff to comply with this mandate without any incentive. The encounter data requested will affect all RT services furnished in an RO episode this is a substantial amount of data. Additional encounter data requirements above what is reasonable and necessary will likely have an adverse effect on RO model participants.**

RO Model Billing Requirements and Potential OPPS Rate Setting Impact
CMS is asking hospital RO model participants to bill charges for the technical component twice (once to receive payment, and once with the no-pay claim). As a result, hospitals could report the charges twice on their cost report, while only reporting the costs once. This could distort the Medicare cost-to-charge ratio (CCRs) for radiation oncology services at RO model participating hospitals if the agency doesn't clarify how these charges are to be billed and reported. If charges submitted on claims for payment and no-pay claims are not appropriately accounted for by participating hospitals and the agency during the billing, cost reporting, and APC weight setting processes. This will result in under-reimbursing radiation oncology services in future years, but also increasing Medicare payments for all other services paid using the APC schedule given the weighting system's inherent budget neutrality. **Therefore, the ACR asks that CMS**

clarify its billing and cost reporting instructions and take appropriate steps to ensure that a distortion of APC weights does not occur as a result of the RO model.

COVID-19 Adjustment
Radiation oncology revenues declined by 8% in 2020 due to COVID-19. Patients that missed cancer screenings due to COVID-19 require more complex, expensive treatments due to more advanced disease. The National Cancer Institute expects increasing mortality rates related to advance stage cancers in coming years. **The ACR is disappointed that none of the additional modifications the College recommended in light of the COVID-19 PHE were taken into consideration.** These included: allowing for alignment with existing reporting requirements, modification of the 2023 trend factor methodology to exclude 2020 data, establishing a COVID-19 case mix adjustment, and allowing simplified monitoring requirements like accreditation that provides stability for participants and ensures quality of care.[3,4]

The ACR urges CMS to implement a Health Equity Achievement in Radiation Therapy (HEART) payment for wraparound services to address healthcare disparities, as outlined by the American Society for Radiation Oncology in previous letters to the Agency. Practices treating underserved populations will be hit hardest, preventing them from providing critical wraparound services, such as care navigation and transportation. Instead of cuts, CMS should be investing in special support services to improve access to radiation therapy for underserved populations.

Conclusion

The ACR appreciates the opportunity to comment on the HOPPS proposed rule. We hope you find these comments provide valuable input for your consideration. If you have any questions, please do not hesitate to contact Christina Berry at cberry@acr.org**.** If you have any questions on the ACR's comments on the RO Model, please do not hesitate to contact Alicia Blakey at ablakey@acr.org.

Respectfully Submitted,

William T. Thorwarth, Jr., MD, FACR
Chief Executive Officer

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