September 17, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
Submitted electronically to: http://www.regulations.gov

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospital (CMS–1753–P)

Dear Administrator Brooks-LaSure:

On behalf of the Premier healthcare alliance serving approximately 4,400 hospitals and health systems, hundreds of thousands of clinicians and 225,000 other provider organizations, we appreciate the opportunity to submit comments on the CY 2022 Outpatient Prospective Payment System (OPPS) proposed rule. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Additionally, Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our member hospitals and health systems which, as service providers, have a vested interest in the effective operation of the OPPS. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by CMS.

UPDATES TO HOSPITAL PRICE TRANSPARENCY REQUIREMENTS

Increasing Civil Monetary Penalties

Under current regulation CMS takes the following actions when hospitals are non-compliant with the price transparency requirements: (1) provides a written warning notice to the hospital of the specific violation(s), (2) requests a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements, (3) imposes a civil monetary penalty (CMP) not to exceed $300 per day on the hospital if the hospital fails to provide or comply with its corrective action plan; and (4) publicizes on the CMS website that the hospital has been assessed a CMP for failing to comply with the price transparency requirements.

In this rule, CMS is proposing to increase CMPs for noncompliance with price transparency requirements. The new CMP would be based on the hospital's number of beds: $300 for a hospital with 30 or fewer beds; the product of the number of beds and $10 for a hospital with 31 or more beds and less than 550 beds; and $5,500 for a hospital with 550 or more beds. CMS believes these penalties are commensurate with the severity level of the potential violation, taking into consideration that nondisclosure of standard

13034 Ballantyne Corporate Place
Charlotte, NC 28277
T 704.357.0022
F 704.357.6611

444 North Capitol Street, N.W.
Suite 625, Washington, DC 20001
T 202.393.0860
F 202.393.6499

PREMIERINC.COM

charges does not rise to the level of harm to the public as other violations (such as safety and quality issues).

Premier opposes increasing the civil monetary penalties for noncompliant hospitals. While we support price transparency and believe CMS should work to help consumers understand price information, several aspects of this regulation do not meet this intent. Providing negotiated rates via the internet will not address CMS' concerns with price transparency and will not provide meaningful information to consumers. Standard charges and negotiated rates are also not useful to patients in that they do not consider contractual allowances, plan coinsurance structures, charity care policies, and mission driven expenses, such as teaching programs. Most consumers also only bear a fraction of the cost of their care because of cost-sharing. As a result, posting standard charges or negotiated rates will do little to help consumers make more informed decisions about their healthcare. Additionally, it is difficult to identify the actual costs associated with care because the components, such as staffing, overhead, and materials costs, are accounted for inconsistently across the healthcare systems. Consumers ultimately need information on their financial responsibility for co-payments or coinsurance, as well as progress toward meeting relevant deductible and/or out-of-pocket maximums.

Moreover, meeting the requirement to post standard charges for all items and services has faced numerous operational challenges. On a CMS webinar on August 11, CMS highlighted examples of noncompliance that are subject to interpretation. For example, CMS suggested that if a hospital does not have a standard charge that is common for other hospitals, the hospital should still list the item or service in the machine-readable file and either include a footnote or indicate that the item or service is not applicable. The presenter noted that this would signal to reviewers that the information is not missing but rather not relevant to the hospital. In order to operationalize this guidance, hospitals would need to know all items or services furnished by other hospitals. This places an unnecessary burden on hospitals to understand the full pricing information for all other hospitals. With the lack of specificity in regulation or CMS guidance, we are concerned that oversight will be highly variable across CMS reviewers resulting in inconsistent penalties across hospitals. Within this rule, CMS seeks comment on standardizing this standard charge information. As we discuss below, **CMS must engage in an iterative process with ongoing feedback from stakeholders to update the requirements for posting standard charges; we believe it is unfair to increase penalties for hospitals until this has been done.**

Finally, DOL, HHS and Treasury have delayed enforcement on key parts of the Transparency in Coverage rule, which requires health plans to meet price transparency requirements, until July 1, 2022 in order to give plans more time to comply. We believe CMS should similarly recognize that hospitals need more time to comply with the price transparency requirements. Hospitals are still actively responding to the coronavirus pandemic, adapting to surges in the delta variant and implementing public health campaigns to encourage vaccination of their communities. It is disingenuous to recognize the need for additional time for health plans but not recognize the needs of our frontline providers during a public health emergency.

During the August 11 webinar, CMS noted that their initial warnings to hospitals have largely been regarding the machine-readable file of all standard charges. In our experience hospitals have readily been able to produce a consumer-friendly tool, with many having already made these tools available long before the price transparency requirements went into effect. **If CMS' intent is to ensure consumers have price information, CMS should base penalties on the availability of a consumer-friendly tool. With the machine-readable file, CMS should assess compliance based on whether a hospital is making a good faith effort to meet the requirement.**

Prohibiting Barriers to Accessing Machine-Readable Files

CMS has found that hospitals have taken a number of actions that create barriers to accessing price transparency information. Among them, CMS notes that requiring the user to agree to all terms and conditions in a legal disclaimer prior to permitting the machine-readable file and its contents to be downloaded is an unnecessary barrier. **We disagree with CMS' assertion; disclaimers are the only protection hospitals have to avoid negative consequences of misinterpreting information.**

We strongly urge CMS to not finalize its proposal to codify in regulatory text that hospitals must make standard charge information easily accessible without barriers. CMS should work with stakeholders to identify ways to improve accessibility of data and to address any perceived barriers through provider education and subregulatory guidance.

Price Estimator Tool

In the 2020 hospital price transparency final rule, CMS adopted a policy allowing a hospital to meet the shoppable services requirement by offering an internet-based price estimator tool. Among other requirements, the price estimator tool must allow healthcare consumers to obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service at the time of using the tool. CMS' review of hospital compliance has identified that some hospital price estimator tools do not tailor a single estimated amount based on the individual's circumstances. Others do not combine hospital standard charges with the individual's benefit information directly from the insurer to create the estimate but use information from prior reimbursements or require the user to input benefit information. Still others indicate that the price is not what the hospital anticipates that the individual would be obligated to pay, even in the absence of unusual or unforeseeable circumstances.

CMS seeks comment on best practices, common data elements to be included in price estimator tools, and technical barriers. **We ask CMS to maintain flexibility in its review of price estimator tools**. Several barriers exist to the ideal implementation CMS describes:

- Providing accurate price estimates to consumers requires information sharing between hospitals and insurers. In instances when payers are not providing full and accurate information it may be because the hospital does not have information from the beneficiary to know out-of-pocket costs. For example, in the 271 (health eligibility/benefit response transactions) responses not all payers return benefits that are specific enough to provide information tailored to the beneficiary. While CMS indicates that historical information cannot be used, in the absence of detailed information in the 271 responses, averages and historical information provide patients with a ballpark estimate. **We recommend that CMS support hospitals by requiring payers to provide consistent and accurate information**.
- Depending on the procedure, additional information may be needed from the patient to ensure the tool returns the most accurate price. Health systems use the most common concurring procedures; for example, if a base procedure is commonly done with three other procedures the price estimator tool will only show the estimate for the base procedure unless the patients are required to enter more information. Similarly, certain other aspects of a procedure may cause the price estimate to vary considerably. If three types of implants are commonly used in a procedure, none of them meet a threshold of being used for 50 percent of procedures or more and thus included in the price estimate. Without requiring the patient to add additional information on the type of implant the hospital cannot provide an accurate price estimate.

- It is difficult to produce cost estimates for patients who reside outside of the hospital's region. Hospitals have built cost estimator tools by incorporating information from the insurers and plans that are most commonly used in the region. Requiring hospitals to produce estimates for patients residing outside of the area, and thus covered by insurers or plans not typically used in the area, will place an undue burden on hospitals.

Plain Language

In reviews of hospital compliance with the price transparency requirements, CMS has found that not all hospitals appear to be using what could reasonably be considered "plain language" to describe shoppable services. While CMS recommends using federal plain language guidelines, it does not require it. CMS seeks public comment on whether to require specific plain language standards. We believe this is an opportunity to better support hospitals with meeting the requirements. Plain language versions of all common services do not exist. **CMS should provide a consumer-friendly translation for the most common shoppable services**. CMS could look to states that have already done so as an initial start.

Highlighting Exemplar Hospitals

Due to the challenges of operationalizing these requirements, we believe it is inappropriate to highlight exemplar hospitals at this time. Rather, CMS should provide additional guidance and example best practices.

Improving Standardization of Machine-Readable Files

As we note above, the machine-readable files are not intended for consumer consumption. CMS has cited its belief that the price transparency policy will promote competition in the healthcare marketplace and lead to lower healthcare costs for consumers. While these are goals that Premier supports, we believe that the policy will not achieve either of them. Rather, the policy instead interferes with ongoing efforts in the private sector to leverage the benefits of private sector competition to advance both quality of care and value of healthcare services. However, **if CMS would like to improve this policy, it should seek input from hospitals, insurers and other stakeholders who would use the publicly available information.** Additionally, we believe that implementation of the payer transparency rule will lead to additional confusion. It will be unclear how to resolve instances where the hospitals and insurers are providing different information. **CMS should employ multistakeholder working group to consider the best approaches for implementing both price transparency regulations.**

Finally, the hospital price transparency requirements fail to accurately account for non-fee-for-service contractual arrangements. Value-based contracts such as capitated arrangements, shared savings arrangements and bundled payments rely on agreed-upon budgets based on patient risk profiles and healthcare spending trends. While providing patient cost estimates is not impacted by value-based arrangements. These arrangements do not individually price items and services in a way that easily allow hospitals to calculate standard charges for all items and services. Additionally, requiring hospitals to parse out prices for individual items and services from value-based arrangements will result in inaccurate price estimates, as these arrangements typically include significant discounts on payment, with the opportunity to earn retrospective payment adjustments based on cost and quality performance.

CMS' approach to hospital price transparency does not recognize the nature of value-based arrangements and ultimately discourages the movement to value. Rather than retrofitting value-based contracts to fee-for-service, CMS should take every step possible to recognize that these

arrangements are in the best interest of patients and reflect collaboration between payers and providers. **We recommend that CMS establish a different framework for reporting value-based arrangements as part of the requirement to make available standard charges for all items and services.**

CHANGES TO THE MEDICARE INPATIENT ONLY (IPO) LIST AND ASC COVERED PROCEDURES LIST (ASC-CPL)

The Medicare inpatient-only (IPO) list includes procedures that are only paid for under the IPPS, and thus are not paid by Medicare in other settings. Each year, CMS reviews the list against established criteria to determine whether any procedures should be removed. Additionally, CMS maintains a list of procedures that CMS has deemed as appropriate for coverage and payment in the Ambulatory Surgical Center (ASC) setting. As part of last year's rulemaking, CMS finalized a policy to eliminate the IPO List in its entirety over three years, starting with removal of nearly 300 musculoskeletal procedures in CY 2021. Additionally, CMS finalized removal of certain criteria for evaluating additions to the ASC CPL, which resulted in CMS adding more than 270 new procedures in 2021.

Stakeholders, including Premier, raised a number of concerns with these policies last year, including the pace at which CMS looked to eliminate the IPO List and the lack of transparency around determining which procedures were removed from the IPO List or added to the ASC CPL. As a result, CMS has reconsidered these policies and proposes to halt elimination of the IPO List in CY 2022. CMS also has reevaluated the 298 procedures removed last year and has determined that none of procedures met the criteria for removal. CMS proposes to add the procedures back to the IPO list in 2022. CMS seeks comment on whether it should maintain a longer-term objective of eliminating the IPO List.

Additionally, CMS is proposing to readopt the criteria it removed for assessing additions to the ASC CPL. As a result, it proposes to remove 258 of the 267 procedures that were added to the list in 2021. CMS is also proposing to adopt a nomination process, whereby external stakeholders could nominate additions to the ASC CPL which would be considered through annual rulemaking.

Premier applauds CMS for reinstating a transparent process for modifying both the IPO List and ASC CPL. We continue to urge caution as CMS evaluates procedures for removal from the IPO List or for addition to the ASC CPL. For many procedures, we do not have enough information to understand whether these procedures would be clinically appropriate to be performed in an outpatient or ASC setting. Some private payers already allow for these procedures within the commercial population; however, the Medicare population can vary significantly from the commercial population, especially in terms of comorbidities and the risk for complications.

There are many factors for physicians to consider in determining which patients are appropriate for the outpatient setting. CMS has been reticent to define clinical criteria in the past, citing the need to preserve the role of the clinician in determining care. However, defined criteria are needed when CMS determines that a procedure can be safely performed in alternative settings to ensure that hospitals are able to follow clear clinical protocols and maintain compliance with setting of care guidelines. We encourage CMS to provide at least baseline criteria or guidance for providers to consider when determining which services would be appropriate in the outpatient or ASC setting. Establishing a baseline protocol does not limit clinical decision-making, as clinicians are still able to provide supporting clinical documentation to justify inpatient stays for patients that may otherwise be candidates for outpatient surgery. As discussed in greater detail below, **we urge CMS to exempt hospitals that utilize clinical decision support tools from patient status review for the two-midnight policy.**

CMS has recently removed several notable procedures from the IPO List and added procedures to the ASC CPL. We would urge CMS to continue to monitor the effects of these changes on patient care. Additionally, we encourage CMS to consider testing removal of codes in the context of Innovation Center models before expanding nationally. Alternative payment models offer the opportunity to test new payment approaches with minimal impact on beneficiaries as the accountable entities are responsible for the total cost of care and quality. This would afford CMS the opportunity to monitor outcomes of patients and develop clinical appropriateness criteria.

Additionally, CMS should consider adopting additional policies to safeguard patients. For example, ASCs are not subject to physician self-referral prohibitions. CMS should consider adopting a policy that would require physicians to inform beneficiaries of any ownership-interest in an ASC if the procedure meets certain criteria. Additionally, while outpatient coinsurance is capped at the inpatient deductible, no similar cap is placed on beneficiary cost-sharing when the services are furnished in an ASC. CMS should adopt a policy that would require ASCs to inform patients of their cost-sharing obligations in instances where the coinsurance obligations would be higher at the ASC than if the procedure was furnished in an outpatient setting.

Finally, **we continue to urge CMS to proactively monitor changes in site-of-service to determine whether it needs to modify alternative payment models (APMs),** such as CMS Innovation Center models and the Medicare Shared Savings Program (MSSP). As was seen with the removal of total knee arthroplasty (TKA) from the IPO List, changes in site-of-service can have significant effects on whether participants can continue to succeed in models. When this procedure was initially removed in 2018, CMS had indicated that it did not expect the removal to have any significant impact on the Comprehensive Care for Joint Replacement (CJR) model[1]. However, CMS has since revised this conclusion, noting that that nearly 25 percent of TKA procedures in 2018 were performed in an outpatient setting.[2] This led CMS to modify the CJR model to better account for shifts in site-of-care, including expanding the definition of a CJR episode to include TKA and total hip arthroplasty (THA) when performed in the outpatient setting and introducing a new risk adjustment methodology to account for differences in patient case mix across settings.

To ensure participants continued success in APMs, **Premier strongly recommends that CMS take proactive steps to** mitigate the impact of site-of-service changes on benchmarks and target prices used in Innovation Center models and MSSP. As lower acuity patients move to the outpatient setting, the risk profile of the remaining beneficiaries receiving inpatient care will be more complex. The changes in case and cost mix need to be recognized in the inpatient target prices and benchmarks set under these models and MSSP. CMS has historically been reticent to change the composition of target prices or benchmarks due to fee-for-service (FFS) changes on the basis that risk should not be removed from models due to external changes. However, these changes do not reflect changes in provider performance, but rather coverage determinations that place participating providers at financial risk. Without adjustment, it will be extremely difficult for participants to avoid being harmed financially by these policy changes. Providers participating in Innovation Center models and MSSP have made significant investments to lower cost while improving quality of care. As CMS makes changes to its FFS, CMS must ensure its reforms do not hinder the movement to value. Instead it should focus its policies on rewarding those who have adopted value-based care models.

[1] CY 2018 OPPS final rule (82 FR 59384)
[2] Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing (CMS-5529-P)

MEDICAL REVIEW OF CERTAIN INPATIENT HOSPITAL ADMISSIONS

In the fiscal year (FY) 2014 IPPS final rule, CMS established the two-midnight rule (78 FR 50913-50954). Under the two-midnight rule, an inpatient admission is considered reasonable and necessary when the physician expects the patient to require hospital care that crosses at least two midnights. Since FY 2016, CMS has allowed for case-by-case exceptions to the two-midnight rule where the admitting physician does not expect the patient to require hospital care spanning two midnights but documentation in the medical record supports the physician's determination that the patient requires inpatient hospital care.

Procedures on the IPO list are appropriate for inpatient hospital admission regardless of the expected length of stay and are not subject to the two-midnight rule. However, the two-midnight rule is applicable once procedures have been removed from the IPO list. Procedures that are removed from the IPO list are also subject to initial medical reviews of claims for short-stay inpatient admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs). BFCC-QIOs may also refer providers to the Recovery Audit Contractors (RACs) for further medical review due to exhibiting persistent noncompliance with the two-midnight rule.

As part of FY 2020 OPPS rule, CMS finalized a policy to exempt procedures from certain medical review for compliance with two-midnight rule for the two years following removal from the IPO list. During this exemption period, the procedures would not be eligible for referral to RACs for noncompliance. BFCC-QIOs would have the opportunity to review claims to educate practitioners and providers about compliance with the two-midnight rule, but claims identified as noncompliant would not be denied under Medicare Part A. Along with its decision to eliminate the IPO list as part of last year's rulemaking, CMS finalized a policy to exempt procedures from site-of-service medical review until which time they were more commonly performed in an outpatient setting. Given its proposal to halt elimination of the IPO List, CMS now proposes to reinstate its original policy for exempting procedures for two years following removal from the IPO List.

Premier believes the medical reviewers should give significant deference to the physician's judgment when evaluating the decision of where to treat the patient. Clinical decision support tools are useful in providing best practices content for enhanced patient safety. Additionally, these tools can leverage and pull data from evidence-based practice guidelines to provide patient-specific recommendations to ensure patients are receiving the most clinically appropriate care. As noted above, clinical decision support can be a critical tool for hospitals as they navigate the most appropriate setting for their patients. As a result, **we recommend that CMS exempt hospitals that utilize clinical decision support tools from two-midnight review of procedures that were once on the inpatient only list beyond the two-year exemption.**

At a minimum, we recommend that CMS establish a list of procedures that would be exempt from two-midnight review permanently. CMS could use similar criteria as it currently has established for the IPO List. For instance, if a given procedure performed inpatient has an average length of stay of more than a set number of days, deference would always be provided to the physician. Alternatively, if a procedure is performed inpatient more than seventy percent of the time based on data from a recent year, deference would always be provided to the physician.

ADVANCING TO DIGITAL QUALITY MEASUREMENT

CMS articulates its goal of moving to fully digital measurement by 2025. As part of this goal CMS aims to streamline the approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning. Premier appreciates CMS' commitment to advancing digital measurement. We have long been committed to advancing providers' capability to analyze data from multiple sources and to manage the health of their populations. We offer the following comments on advancing digital quality based on experience with supporting providers in advanced data analytics and quality reporting:

- ***Definitions***. CMS defines digital quality measurement as software that processes digital data to produce measures scores. While we support this definition, we caution CMS from creating separate standards or requirements for digital quality measurement software. Many systems such as EHRs, health information exchanges (HIEs), and registries currently meet this definition and are regulated by CMS and the Office of the National Coordinator for Health Information Technology (ONC). Any requirements of these tools should be incorporated into existing regulation in order to reduce inconsistencies in requirements and timelines and alleviate any additional provider reporting burden.

- ***Data Access***. CMS notes that data sources for digital quality measurement may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), HIEs, or registries, and other sources. We appreciate that CMS is broadly considering numerous types and sources of data; however, we note that providers currently have limited real-time access to robust claims and EHR data. Federal efforts are needed to accelerate adoption and consistent implementation of data and interoperability standards, enhance certification of EHRs, require seamless and unfettered provider data access at the point of care and within the workflow, and make claims-data more readily available to providers. As access to existing digital data sources is limited, we ask that CMS speed access to those sources and consider provider access to novel digital data sources (e.g. wearable device) prior to implementing measures that require use of novel data.

- ***Timing.*** We appreciate the commitment to rapidly move to digital quality measurement by 2025. We ask that in setting timelines for the transition CMS consider how digital quality measures timelines align with other implementation timelines, such as ONC's promoting interoperability and CEHRT.

- ***Data Standards.*** CMS notes that its potential action steps are to leverage and advance standards for digital quality and to redesign measures to be self-contained tools. Specifically, CMS discusses using Fast Healthcare Interoperability Resources® (FHIR®) for electronic clinical quality measures (eCQMs) and designing software solutions for digital quality measures to be compatible with any data sources that implement standard interoperability requirements. A holistic approach is needed for data standards whereby standards are developed and adopted for use across care settings. There are at present a limited number of common data elements across inpatient, outpatient, and post-acute care; however, these elements could serve as a starting point for cross-continuum patient assessment. While FHIR® will likely make development and maintenance of measures easier over time, measure developers are just beginning to test measures using FHIR®. We will need sufficient testing and consideration by multi-stakeholder groups such as Health Information Technology Advisory Committee (HITAC) and NQF prior to

wide-spread adoption. A critical component to using FHIR® for eCQMs is the adoption of bulk FHIR® transactions to simplify and speed transmission. In the absences of bulk FHIR® transactions, providers will be unable to support FHIR® implementation. CMS needs to work with ONC to advance the adoption and consistent implementation of data and interoperability standards so that provider data collection and reporting requirements are enabled by health information technology

Meanwhile, we ask that CMS and ONC continue to address some of the underlying data issues. For example, the annual iteration of QRDA-I file standards creates a burden on EHRs to frequently adopt and roll-out the new standards to their customers and this results in many health systems/practices not being able to produce a current-year file through much of the reporting year. The costs of these annual updates are often factored into the pricing of these reporting modules, which can be cost-prohibitive to smaller health systems/practices. Where possible, Premier encourages CMS to promote backward compatibility in both reporting modules and measure development/updates

- ***Data Aggregation.*** CMS discusses actions to better support data aggregation. In addition to EHR oversight, claims data access and promotion of standards. Premier urges HHS to continue efforts to address the need for a national strategy and approaches to improve patient identification and matching to support patient care and facilitate more accurate data aggregation. In the absence of this it is difficult to track patients across a single encounter, rendering it impossible to assess outcomes using numerous types of data.

- ***Measure Alignment.*** CMS notes its continued focus on aligning measurement across reporting programs. Alignment would focus on measure concepts, specifications and individual data elements used to calculate measures. We appreciate the continued focus on measure alignment across CMS programs and the private sector. In aligning measures, we urge CMS continue to continue to address the need for more timely access to robust data.

Hospital Outpatient Quality Reporting (OQR) Program Measure Changes

Measure adoption and removal

CMS proposes removal of two measures beginning with the 2023 reporting period: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3). CMS also proposes to adopt an electronic clinical quality measure (eCQM) related to myocardial infarction, ST-Segment Elevation Myocardial Infarction (STEMI) eCQM. The measure was submitted for NQF endorsement in January. CMS believes the new eCQM is more broadly applicable than the two chart-abstracted measures and that the removal of the two measures will reduce provider burden. **We support removal of the two chart-abstracted measures in favor of adopting a new eCQM measure. However, we urge CMS to not implement the new eCQM until which time it has received NQF endorsement.** The NQF endorsement process provides a critical opportunity for technical experts to consider and address any potential methodological challenges.

CMS also proposes to adopt a new claims-based process measure related to breast screening recall rates, beginning with the 2023 payment determination. This new measure would track the percentage of patients who are recalled for additional outpatient imaging after traditional mammography or after traditional mammography or digital breast tomosynthesis (DBT) screening. **Premier urges CMS to**

submit the measure for NQF endorsement prior to adopting the measure into the OQR Program. As currently specified the measure would not include any exclusions. However, there might be instances where it is clinically appropriate for a patient to recalled for outpatient imaging, such as patients with a family or personal history of breast cancer. The NQF endorsement process offers an opportunity for technical experts to assess whether exclusion or other methodological changes, such as risk adjustment, would be appropriate.

COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

CMS proposes to adopt a new process measure in the Hospital OQR program which would track the percentage of HCP who have received a complete COVID-19 vaccination course. Under this policy, hospitals would be required to collect data from one self-selected week each month and submit the data quarterly through the CDC National health Safety Network (NHSN) web-based survey, beginning in CY2022. CMS plans to report quarterly vaccination coverage rates. CMS has proposed and finalized adoption of this measure across other Medicare quality reporting programs.

Premier recognizes the critical importance of vaccinating frontline workers and that this measure would provide valuable information to the government as part of its ongoing response to the pandemic. **However, we continue to urge CMS to execute caution in adopting this measure into the Hospital OQR and other Medicare quality reporting programs as it could place significant burden on hospital facilities.**

CMS notes that it and the CDC aligned the measure as closely as possible with the specifications for the Influenza HCP vaccination measure, which has received NQF endorsement. However, the COVID-19 vaccine differs significantly from the flu vaccine in several key ways. First, it is still unknown if individuals will need to receive annual COVID-19 vaccines or additional booster shots. As a result, the measure specifications for a COVID-19 vaccination measure are likely to change as the definition of a completed COVID-19 vaccination course changes overtime. Secondly, while facilities have often set-up flu clinics to vaccinate their staff, the rollout of the COVID-19 vaccine has differed across facilities. Some hospitals did set-up clinics to vaccinate their staff as doses became available. Still some personnel may have received the vaccine outside the facility at mass vaccination sites or other healthcare settings. Collecting this data across all personnel could prove burdensome for facilities.

We support collecting this information in a format that is less burdensome to hospitals and would support collection of this data through CDC's National Healthcare Safety Network (NHSN). **However, CMS should not include this measure in the OQR program, which would require publicly reporting data on individual hospital performance.** Rather, CMS could collect the measure through NHSN and provide confidential feedback reports to hospitals. At a minimum, we urge CMS to seek NQF endorsement prior to proposing adoption of this measure in the IQR program. The NQF endorsement process will provide an opportunity for technical experts to consider and work through the various challenges noted above.

Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37a-e)

The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) set includes five measures designed to assess a patient's experience with care following a procedure or operation performed in a hospital outpatient department. CMS first adopted the set into the OQR program during 2017 rulemaking, but subsequently delayed implementation to allow more time to

evaluate operational experience and implementation data from a voluntary reporting program that began in 2016.

CMS is proposing to restart voluntary reporting beginning with the 2023 reporting period, followed by mandatory reporting in 2024. Additionally, CMS is proposing to adopt two additional data collection modes: web-based with either mail or telephone follow-up of non-respondents.

Premier supports adoption of the two additional reporting modes which will provide health systems with more data collection flexibilities. We recommend that CMS begins with voluntary data collection for CY2023 reporting and requests industry feedback prior to implementing mandatory reporting. Specifically, CMS should release additional information on the results from voluntary reporting, including any operational or technical challenges providers faced in reporting the survey measures.

Request for Comment on Adoption of Future Measures

In light of CMS' proposal to reinstate the IPO List, CMS seeks comment on adoption of future measures that assess quality of care for services whose delivery shifts from inpatient to HOPD setting. We appreciate that CMS is exploring adoption of cross-continuum measures, which can be valuable in assessing site of care. **We encourage CMS to work with stakeholders to identify measures that would be appropriate and useful across the continuum and to address reporting challenges before proposing to adopt new measures into the OQR Program.** Additionally, as noted above, there is a limited number of common data elements across inpatient, outpatient, and post-acute care. CMS should work towards standardizing data elements and collection.

CMS is also considering inclusion of the Hospital-Level Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) performance measure as part of the Hospital OQR Program. If adopted, the measure would be respecified from its current inpatient application for use in HOPD setting.

Hospitals participating in the Comprehensive Care for Joint Replacement (CJR) payment model have had the option of reporting this measure since the model began in 2016. Under the model, participants can increase their composite quality score by two points if they successfully reported on the measure. Many model participants have found that the burden of data collection outweighed the potential for bonus points. As a result, completion rates for the measure have been low.

As we have noted previously, introducing the measure to all hospitals may result in even more burden. **CMS should also evaluate and release feedback on the voluntary reported measure under CJR before considering adoption of this measure into either the Hospital IQR or OQR programs.**

Closing the Health Equity Gap in CMS Hospital Quality Programs

Reducing disparities in care and achieving health equity across communities requires a holistic approach to care, shifting the incentives in our health system from sickness-based to wellness-based**. When providers are responsible for total cost of care for their patients and have flexibility to address social determinants of health, providers will be proactive in addressing inequity and disparities.** Addressing the underlying social and economic inequities as well as systemic barriers and biases that drive disparities in care requires (1) data collection and monitoring of key outcomes and health equity measures and (2) shifting the payment system to account for a more comprehensive set of services that address disparities. We appreciate CMS' commitment to closing health equity gaps in the CMS quality programs and look forward to partnering with CMS in this area.

Stratification of Measure Results by Race and Ethnicity

CMS seeks comment on approaches to stratify measures by race and ethnicity. Stratifying measures by race, ethnicity, gender and disability will give providers needed insight into potential disparities. Premier has partnered with HHS' Office of Women's Health to leverage Premier's data and proven performance improvement methodology to scale advancements in care for mothers and infants across the nation. This effort includes stratifying measures by race and ethnicity with the aim of reducing health disparities and scaling standardized, evidence-based practices. We believe stratification of outcomes is one of several useful tools to improve health disparities.

CMS seeks comment on using algorithms to indirectly estimate the race and ethnicity of Medicare beneficiaries to overcome the current challenges with demographic information collection and enable timelier reporting of equity results until other ways to improve demographic data accuracy materialize. The agency notes that indirect estimation techniques do not impose additional data collection burden on hospitals, since these are derived using administrative and census-linked data. **We do not support the use of indirect estimation techniques due to data inaccuracy.** Health systems are currently collecting self-reported sociodemographic data from their populations through a variety of methods. Inaccurate measure stratification can disrupt ongoing efforts to improve disparities in care. **Instead, we urge CMS to rapidly and meaningfully pursue efforts to improve access to directly collected race and ethnicity data from self-reported sources.**

Additionally, **we recommend that all efforts to stratify measures by race and ethnicity begin with confidential reporting and appropriate risk adjustment to account for factors associated with outcomes that cannot be addressed by providers**. We must avoid a perverse cycle, wherein we deny resources in the form of both payment penalties and income by discouraging beneficiaries from using providers that care for patients in marginalized communities, subsequently leading to unequal care for those patients due to lack of equal resources to treat them. It is critical that information publicly shared on disparities in care is accurate and can be understood by consumers. Moreover, while stratification and comparing providers with similar populations helps identify opportunities for improvement, it does not provide hospitals with all the tools necessary to address any underlying factors contributing to health inequities. **These efforts must be combined with a broader set of supports to enable providers to respond to disparities in care**, such as learning networks and data on available community support services.

Finally, we request that CMS also focus on stratifying measures using a broader set of sociodemographic factors, such as income and other social determinants of health.

Improving Demographic Data Collection

CMS seeks input on improving data collection practices to improve capture of demographic elements. We strongly encourage CMS to focus its efforts on driving toward standardization of data capture and measurement, leveraging resources currently available and accessible to providers, and streamlining administrative burden across programs.

Health systems are currently capturing sociodemographic data, but this information is not easily translatable for CMS purposes. For example, despite an available framework for mapping the more than 900 race ethnicity codes provided by the CDC to the OMB, race and ethnicity codes captured in the EHR cannot be consistently mapped. This is a result of lack of use of standard taxonomies—in part by the EHRs and in part by the providers to allow the category selections to align with how their populations

would like to report information. Similarly, there are an abundance of tools to screen for social determinants of health with underlying definitions for certain social risk factors (e.g. food insecurity) significantly varying even when the same tool is used by different providers.

Standardization is vital to providers' success in driving towards health equity, as it will foster the development and sharing of best practices within and among clinical settings, health systems, and delivery system designs. The Agency for Healthcare Research and Quality (AHRQ) has found that one of the biggest barriers most health systems face in improving quality and reducing disparities within their own walls is systematically identifying the populations they serve, addressing the needs of these populations, and monitoring improvements over time. AHRQ further found that the principal challenges in obtaining race, ethnicity, and language data for use in quality improvement assessments include a lack of standardization and understanding of why the data are being collected.

We ask that CMS make a concerted effort to advance standards for the collection of socio-demographic information, using existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7 and FHIR® standards.

REQUEST FOR INFORMATION ON RURAL EMERGENCY HOSPITALS (REHs)

Under the Consolidated Appropriations Act (CAA), 2021, Congress established a new Medicare provider type – Rural Emergency Hospitals (REHs) – effective for CY2023. Under this policy, Critical Access Hospitals (CAHs) and other small rural hospitals will have the opportunity to apply to become an REH, whereby they will only furnish emergency department services, observation care, and certain outpatient services. As part of this year's rulemaking, CMS seeks input on several topics to inform future rulemaking, including types of services REHs should furnish, applicable requirements and conditions of participation (CoP), and quality measurement.

Premier appreciates CMS seeking stakeholder input on the design of the REH provider type. This new provider type could be an essential tool for addressing access issues in many rural communities. As it looks to implement this provider type over the next year, we encourage CMS to take the following recommendations into consideration.

Improving access to specialty care through allowing use of shared space

When establishing requirements for REH, CMS should allow REHs flexibility when sharing space with other providers at distinct times, or sequential shared spaced. Rural communities often lack healthcare specialists, leaving patients with few options but to travel long distances to receive needed care -- often at significant personal cost to the patient through lost wages and incurred travel expenses. Hospitals and other providers have tried to partner with rural providers to bring specialists closer to patients. However, providers have been hindered by a lack of clarity and sometimes inconsistent guidance on when shared space between providers is allowed.

Currently, rural providers have primarily two options when it comes to partnering with other providers to bring in specialists to community: the rural provider, usually a hospital, can contract a specialist from another provider or lease space to the other provider. Both options have their own unique challenges:

- The contracted specialist must be reimbursed at fair market value. This approach can be cost prohibitive for many rural providers, which must weigh several factors such as payor mix and whether there is enough patient volume to offset the cost of contracting the physician.
- Visiting providers also have the option of leasing space from the rural hospital at fair market value. However, based on guidance from CMS Regional Offices, once this space has been leased it cannot be used by the rural hospital. This policy has resulted in an inefficient allocation of space, as most specialists only visit a facility a few times per month. As a result, the space often remains empty the remainder of the month. Additionally, many rural hospitals have limited physical space or resources to invest in extra space. For those who have additional space, survey and certification guidance may make it challenging for rural providers to carve out separate space. For example, guidance has indicated that the space must be clearly demarcated from the hospital and have its own entrance, hallways, bathrooms, and waiting room.

In establishing requirements for REHs, ***CMS should establish clear guidance that would allow REHs to share space with other types of providers.*** Precedents for this type of policy exists. For example, rural health clinics (RHC) and federally qualified health clinics (FQHC) can sequentially share space. These entities are required to clearly state hours of operations for each distinct provider. Practitioners are required to bill under the rate corresponding with the hours of operation (e.g., bill for RHC services when the space is being used as an RHC).

Under the sequential shared space policy, providers would be required to notify patients whether they are affiliated with the hospital or another provider and any cost-sharing implications. CMS should also allow for shared public spaces. For example, the REH and provider leasing a space could utilize the same entrance, public hallways, and restrooms. Finally, CMS should provide guidance on how to reconcile the relevant requirements related to privacy, safety, and infection control that each entity must meet. For example, the policy could default to the more stringent one or each entity would be responsible for using their own requirements.

Application of certain requirements applicable to Critical Access Hospitals

CMS seeks input on certain CoPs and other requirements that are applicable to CAHs and whether they should be applied to REHs.

Currently, CAHs are subject to two requirements related to average length of stay. As a CoP, CAHs must maintain an annual average length of stay (ALOS) of 96 hours or less across all patients. Additionally, as a condition of payment, a CAH must certify that a patient is not expected to require a stay of more than 96 hours. While CMS has generally practiced enforcement discretion around the 96-hour certification requirement and has not listed it as a high priority topic for auditors, the requirements is burdensome for CAHs and generally duplicative of the CoP requiring an annual ALOS of 96 hours or less. The REH statute specifies a similar CoP related to ALOS. Specifically, REHs must maintain an annual ALOS of 24 hours or less. The statute does not include a similar condition of payment for REHs (i.e., certify that each patient treated is expected to require a stay of 24 hours or less) as it does for CAHs (i.e., certify that each patient admitted will be require an inpatient stay of 96 hours or less). **CMS should not adopt a 24-hour certification requirement for REHs**, similar to the 96-hour requirement for CAHs. Additionally, we strongly urge CMS to practice enforcement discretion related to the annual 24-hour ALOS requirement to provide REHs additional time to adjust to requirements for this new provider type. CMS should work with its contractors to educate REHs on ALOS requirements, but should not take punitive action if an REH exceeds an annual ALOS of more than 24 hours.

During the COVID-19 PHE, CMS adopted several waivers to help ensure providers had the necessary workforce and flexibilities to respond to the pandemic. For example, CMS removed the requirements for CAHs that a doctor must be physically present to provide medical direction, consultation, and supervision, allowing CAHs to meet this requirement through a virtual presence. **We encourage CMS to adopt lessons learned from the PHE when designing supervision and other requirements related to workforce**. Allowing for virtual supervision or consultation can be an effective tool at addressing workforce shortages in rural areas.

Improving access to maternity care

Women in rural areas face many barriers to accessing prenatal, perinatal, and postpartum care. Many rural communities lack primary and specialty care; fewer than half of all rural counties have a practicing obstetrician or gynecologist. Rural hospitals that do remain open are often shutting down their obstetric units, leaving fewer than half of all rural counties having such units. There are even fewer community programs to support women who may have chronic conditions, substance use, and mental health issues. As a result, more than 40 percent of women in rural areas must travel between 50 and 100 miles to access care, while another 30 percent must travel more than 100 miles.

Several other barriers may make it challenging for women in rural areas to access appropriate care, including lack of health insurance, high unemployment rates, and lower household incomes. Rural areas also tend to have higher rates of chronic disease, including heart disease, diabetes, and cancer.

CMS seeks input on whether maternal health services would be appropriate for REHs to furnish and how REHs can address the maternal health needs in rural communities. REHs can play a critical role in improving access to health care in rural community, including access to maternal health services. **REHs should be allowed to offer labor and delivery services to the extent that services can be furnished safely.** We are concerned that many labor and delivery services may require stays of longer than 24 hours. As noted above, statute requires REHs to have an average ALOS of 24 hours or less. While this does not prohibit facilities from having stays longer than 24 hours (so long as shorter stays offset the longer stays and keep the facility below the 24-hour average), **we recommend that CMS practice enforcement discretion for facilities that may have average ALOS longer than 24 hours due to providing maternal health services.** As noted above, **we also urge CMS to not require REHs to certify that a patient is not expected to require a stay of more than 24 hours, as a condition of payment.**

In addition to allowing REHs to furnish labor and delivery services, we would also encourage CMS to take the following actions to help improve quality and access to maternal health:

- ***Focus on best practices that address ambulatory care.*** Ambulatory care clinicians particularly in locations where women seek care such as emergency departments, must have the resources and knowledge to recognize and properly modify care for pregnant and postpartum women that present with chronic or complex conditions which contribute to severe maternal morbidity and mortalities. Implementing a standard approach to postpartum discharge education during the hospital stay to provide consistent messaging related to essential post-birth warning signs and teach women and their families how to recognize and respond to signs of post-birth complications. Improve coordination and collaboration among healthcare providers, including obstetrical, primary and mental health professionals ensures that issues are identified early and that patients are referred to needed services as appropriate.

- ***Improve maternal mortality and morbidity data collection through public-private partnership.*** In the United States, we have a limited understanding of why women are dying, or nearly dying, during pregnancy and childbirth. A lack of access to comprehensive clinical data or reliable outcome measures (inpatient and outpatient) makes it difficult to identify the incidence and causes of maternal mortality and morbidity. As a result, there is a focused need to analyze the factors driving maternal mortality and harm, including social determinants, racial and ethnic factors, to identify clear strategies to address them. Premier has partnered with HHS' Office of Women's Health to leverage Premier's data and proven performance improvement methodology to scale advancements in care for mothers and infants across the nation. Premier is also uniting a cohort of more than 200 hospitals across the country – particularly those that serve vulnerable populations – to reduce health disparities; scale standardized, evidence-based practices; and reliably measure associated outcomes. These efforts are generating positive outcomes and needed to be scaled nationwide

- ***Reform how maternity care is delivered and paid.*** Current maternity care models, which are based on fee-for-service reimbursement, are fragmented and ultimately incentivize more care. This not only increases the cost of care, but also lowers the quality of furnished care. There is also considerable variation in perinatal care practices and implementation of known reliable process across the continuum of care delivery. Healthcare organizations lack improvement expertise, resources and support necessary to impact the extensive implementation of reliable care processes and required outcome measurement strategies. CMS can play a critical role by working with States to test and adopt alternatives to fee-for-service payment that transform maternal health care. Additionally, CMS should provide guidance and expedite approval of Medicaid state plan amendments and waivers that implement maternity care alternative payment models. We encourage CMS to include REHs and other rural providers in their design of maternity care payment models.

Designing a REH Quality Reporting program

Statute requires CMS to establish a quality reporting program for REHs, including a process for publicly reporting results. CMS seeks input on the development of quality reporting requirements for REHs, including the types of measures and challenges that rural providers face in reporting measures. In developing these requirements, **we urge CMS to work with the NQF Rural Health Workgroup to develop a set of measures that capture the unique health needs of rural communities**. As part of this, CMS should explore ways to address issues related to low volume reporting, as well as adopt measures that minimize burden on providers.

Incentivizing movement to value-based care

In developing this new provider type, we encourage CMS to explore ways that allow REHs to participates in value-based care initiatives. As we've noted in the past, there are several barriers that discourage or prevent rural providers from participating in alternative payment models, including inability to absorb high discount rates commonly applied under APMs. **We continue to encourage CMS to explore ways of adapting existing APMs to ensure rural providers, including REHs, have the necessary flexibilities and tools to succeed in value-based care.**

RADIATION ONCOLOGY MODEL

The Radiation Oncology (RO) Model focuses on promoting quality and financial accountability for episodes of care centered on certain radiation therapy services. Under the model, CMS will pay participating providers and suppliers a prospective, site-neutral episode-based payment for certain radiation therapy services furnished during a 90-day episode of care. Providers and suppliers located in selected geographic areas will be required to participate. Through earlier rulemaking, CMS randomly selected certain Core-Based Statistical Areas (CBSAs) for participation, representing approximately 30 percent of eligible RO episodes. CMS had originally intended to launch the model January 1, 2021, but subsequently delayed the model as a result of the ongoing COVID-19 PHE. Under the CAA, 2021, Congress mandated that the model could not begin before January 1, 2022. CMS proposes to start the model on January 1, 2022. Additionally, CMS proposes a number of changes to correspond with the new start date and to address concerns raised by stakeholders.

Premier continues to have a number of concerns with the design of the RO model. Most notably we continue to be concerned that the model relies heavily on payment cuts and withholds and offers no meaningful incentive structure that rewards high-value, low-cost care. As currently designed, the model is simply a payment cut to providers. **We strongly urge CMS to make several modifications to the model,** as detailed below.

Create opportunities for upside risk

The RO model constitutes a significant change in direction from previous alternative payment models (APMs) that provide financial incentives for performance and/or funding for practice transformation. The model, as currently designed, is essentially testing the impact of a payment cut to providers and offers no opportunity for providers to take on meaningful risk under the model. The goal of APMs should be to fundamentally change care delivery and improve population health, rather than seeking opportunities to leverage market dynamics to reduce costs.

Premier recommends that CMS incorporate opportunities for upside risk under the model. For example, CMS should allow participants to earn back above their quality withhold based on quality performance. For example, CMS allows participants in the Direct Contracting model to qualify for a bonus above the participant's quality withhold from a High Performers Pool (HPP). Alternatively, CMS should consider setting lower discount rates for high performers. For example, under the Comprehensive Care for Joint Replacement (CJR) model, CMS allows participants to earn back a percentage of the discount applied to the episodes based on quality performance. CMS recently finalized changes to that model, which essentially eliminate the discount applied under the CJR model for the highest performing hospitals.

Lower discounts applied under the model

CMS proposes to reduce the discounts applied under the model – from 4.75 percent to 4.5 percent for the technical component and from 3.75 percent to 3.5 percent for the professional component. CMS notes that its decision to remove brachytherapy as a modality and liver cancer as an included cancer type would reduce pricing variability if finalized. As a result, they are able to propose a lower discount rate and still detect a significant Medicare savings without increasing the size of the model.

While Premier supports CMS' decision to reduce the discount applied to both the technical and professional components, we are concerned that the proposed discounts under the model, when

combined with other withholds and payment reductions under the PFS, will be unsustainable for providers under the model and likely result in access issues for beneficiaries. As a result, we recommend that CMS set the discount rates under the model at no more than 3 percent.

Under the model, CMS will apply additional withholds for incorrect payments, patient experience of care, and quality performance. This corresponds to a 6.5 percent reduction in initial payment with the opportunity to earn back up to 3 percent on the professional component and 2 percent on the technical component. We also note that in the Physician Fee Schedule, CMS is proposing cuts of 8.75 percent across all radiation oncology services under the PFS, as a result of changes in Clinical Labor Pricing Inputs and a 3.75 percent cut due to implementation of E/M changes.

In addition to significant payment cuts, many RO providers and suppliers have seen significant declines in service volume, as a result of patients delaying care under the COVID-19 PHE. One study found that cancer screenings declined between 56-85 percent (depending on cancer type) and that there were significant reductions in utilization for both screenings and treatment during the first half of 2020.[3] In addition to reduced volume, delays in cancer care may result in increased cancer morbidity and higher case mix acuity, which is not accounted for in the current financial methodology.

Significant payment cuts, combined with additional reporting and administrative burden, will place many practices in financial jeopardy and may result in some RO providers and suppliers scaling back services or even closing their doors all together. Ultimately, this could create significant access issues for all patients.

Reducing the discounts to no more than 3 percent will still generate significant savings to the Medicare program and will align the RO model with discounts applied under other APMs. As noted above, we also encourage CMS to adjust discounts based on quality performance, setting an even lower discount rate for high-performing and efficient providers and suppliers.

Allow for an implementation year

There are still several key operational details that are unknown related to the implementation of the model. For example, under the model an episode is triggered when a patient receives an initial RO treatment planning service from a professional (or dual) participant and a technical (or dual) participant furnishes an RO service within 28 days. As a result, in order for a technical participant to know that an episode has been triggered, it would need to know that the professional service has been furnished. However, if the professional and technical participants are not in the same system or network, it is possible that this information may not be communicated, and the technical participants may incorrectly continue billing for services under FFS.

Additionally, there are many factors throughout the episode that could result in an episode being considered incomplete. For example, a beneficiary may no longer meet the eligibility criteria for the model. It is unclear how participants will be notified that an episode has been cancelled and that they should begin billing under FFS again.

[3] Patt D, Gordan L, Diaz M, Okon T, Grady L, Harmison M, Markward N, Sullivan M, Peng J, Zhou A. Impact of COVID-19 on Cancer Care: How the Pandemic Is Delaying Cancer Diagnosis and Treatment for American Seniors. JCO Clin Cancer Inform. 2020 Nov;4:1059-1071. doi: 10.1200/CCI.20.00134. PMID: 33253013; PMCID: PMC7713534.

Knowing whether an episode has been triggered or cancelled is also essential for understanding beneficiary cost sharing. Under the model, beneficiaries are responsible for 20 percent of the episode payment. If an episode is cancelled, then beneficiaries are responsible for 20 percent of the FFS amount applicable for RO services furnished. As a result, participants will need up-to-date information on episode status in order to ensure they do not charge beneficiaries incorrect cost-sharing. Under the current model design, participants will not know until reconciliation whether an episode was incomplete. As a result, **it could be anywhere from several months to more than a year before participants know if they have charged beneficiaries incorrect cost-sharing. Additional information is also needed to understand how participants should reconcile cost-sharing with beneficiaries in the least burdensome manner.**

Additionally, CMS states that it will not be able to provide case mix or historical experience adjustment data until after the final rule is issued, likely in early November. Without this information, providers and suppliers will be able unable to know or calculate their individual episode payments.

While we appreciate the steps that CMS has taken to provide additional guidance to participants through webinars, we are concerned that several key programmatic details remain unknown, despite the anticipated launch of the model in mere months. As a result, **we encourage CMS to establish an implementation year for at least one year or longer if CMS and stakeholders determine more time is needed**. Allowing for a performance year 0 (PY0) would help support practice transformation and ensure providers have the adequate information they need to implement this model. During a PY0, participants could submit no-pay claims for the episode while continuing normal billing. This approach would allow CMS to address complexities in the billing design and allow participants to change workflows to align with the model, utilize performance data from CMS to identify areas for transformation, and receive additional education from CMS on model parameters and meeting objectives. A PY0 would provide further benefit by allowing providers and vendors additional time to operationalize data collection and reporting requirements.

Adopt additional payment adjustments to ensure adequate payment

One of the goals of the RO model is create payment parity across sites of services and treatment modalities. CMS will establish 30 separate bundled payments, based on the type of cancer and whether the provider is furnishing the professional or technical component of the treatment. CMS will establish rates based on a three-year baseline year and will apply a trend factor to account for current trends in payment for RT services and changes under FFS.

We continue to be concerned that the current payment structure does not account for multiple treatment sites and secondary malignancies. For example, an episode may be initiated through treatment for breast cancer, but then a secondary brain metastasis may require radiation therapy. Failure to provide reimbursement for additional clinically necessary treatments may create perverse financial incentives to delay care until after a RO bundle has completed. **CMS should adjust the payment structure to account for multiple treatment sites and secondary malignancies.** This can be achieved through clinical risk adjustment or creating add-on payments for multiple treatment sites.

Additionally, payments will be based on claims data from a fixed three-year baseline. As a result, innovations in treatment and changes in clinical practice that occur after the baseline period may not be fully accounted for in the episode cost. CMS plans to apply a trend factor to base rates to account for payment changes under FFS. However, given data lags in setting FFS rates, it will likely take several years before new technology or treatments are reflected in sufficient volume to impact and be reflected in the FFS rates. As a result, **CMS should establish an add-on payment to account for new**

technologies and advances that improve quality of care. This will help ensure that model participants are not disincentivized from adopting new technologies or treatments that could benefit patients. CMS has adopted a similar methodology in other APMs. For example, in the Oncology Care model, CMS updates reconciliation calculations to compensate for new therapies being administered to patients.

Establish Separate Tracks

CMS proposes to establish two tracks for the RO Model. Professional and Dual participants who meet the RO Model requirements, including use of CEHRT, and who are eligible clinicians on an APM Participation List would fall under "Track One." Professional and Dual participants who did not meet the criteria for "Track One" would fall under "Track Two." All Technical Participants would also fall under "Track Two." CMS anticipates that "Track One" of the RO Model will qualify as an Advanced APM or MIPS APM. **Premier supports CMS decision to establish separate tracks for the RO Model.** Some Professional and Dual participants, especially small or rural providers, may not use CEHRT or meet other requirements under the model. Upgrading their systems just to participate in the RO model would place significant cost and burden on these providers. Establishing separate tracks provides participants with additional options for complying with the model requirements. Additionally, Track One offers radiation oncologists a pathway to APM participation and will support the movement to value for these clinicians.

Clarify application of opt out policy for new entities

Under the RO model, certain providers or suppliers will have the opportunity to opt out of the model if they have fewer than 20 episodes of radiation therapy services across all CBSAs in a given year. To make this determination, CMS will use the most recent year for which claims data is available, which will generally be two years prior to the applicable performance period. CMS proposes to codify that for providers or suppliers who receive new TINs or CCNs, it will use both the new and legacy TINs or CCNs to determine if a participant is eligible for the opt out policy.

We urge CMS to clarify how the opt out policy will be applied to completely new entities or for existing CCNs or TINs that add a radiation therapy service line. In prior communications, CMS has indicated that such entities would not be eligible for the opt out policy since they would have no historical claims to determine if they are eligible for the policy. We urge CMS to establish a process by which new entities or entities adding a new service line that anticipate having low volume in the performance year could apply for the opt out policy.

Additionally, **we encourage CMS to establish a separate process by which rural and small practices that demonstrate financial hardship could opt out of the model**. As noted above, the model will impose significant payment cuts to participants, in addition to the reductions proposed under the PFS. Small and rural providers are less able to absorb such significant cuts in payments, in addition to the costs of implementing the process changes needed to succeed under the RO model. As a result, many small and rural providers and suppliers may close their doors, further exacerbating access issues in these communities.

Modify measures to reduce burden on participants

Under the model, professional and dual participants will be required to report on four quality measures and collect the CAHPS® Cancer Care Radiation Therapy Survey. (Technical participants will also be required to field the CAHPS survey for the RO Model.) Additionally, professional and dual participants will be required to submit clinical data elements. CMS will calculate an Aggregate Quality Score (AQS) based

on a mix of pay-for-reporting and pay-for-performance measures. The AQS will be used to determine the amount of the quality withhold that professional and dual participants can earn back.

The four reported quality measures are not limited to just beneficiaries aligned under the model but would include all patients that meet the measure specifications (e.g., all patients ages 12 and older). **We encourage CMS to explore limiting reporting on these measures to only beneficiaries aligned under the model**. Doing so will minimize burden on providers and will ensure that quality performance reflects care furnished under the model.

Additionally, reporting on clinical data elements will impose significant burden and costs on model participants. In order to receive full credit for reporting clinical data elements, participants will need to report on at least 95 percent of RO beneficiaries. At this time there are several technical challenges that will make it difficult for providers to report this information. For example, clinical data is not easily extracted from EHR systems and linear accelerators. In some instances, participants will need to contract with third party vendors or upgrade systems, resulting in additional costs under a model where participants will already experience steep payment cuts. **We recommend that CMS remove requirements around reporting clinical data elements. At a minimum, CMS should reduce the number of cases that participants must report and make reporting voluntary until which time model participants are more easily able to extract this information.**

Address COVID-19 impacts on model

CMS proposes to adopt an extreme and uncontrollable circumstances (EUC) policy for the RO Model. Similar to other APMs, the policy would take effect if CMS determines that circumstances beyond the control of participants will adversely impact the ability of providers to deliver care and participate in the model. If the EUC policy is enacted, CMS will have the flexibility to amend the model performance period, eliminate or delay certain reporting requirements, or modify the model's pricing methodology. **Premier supports adoption of the EUC policy.**

In the proposed rule, CMS acknowledges that it is currently analyzing the effects of the COVID-19 pandemic on the RO model and will consider removal of the 2020 data from the calculation of applicable baseline periods or trend factors. However, at this time, CMS is not considering exclusion of 2020 from the case mix adjustment because case mix episodes are equally weighted and the adjustment does not rely on the volume of services furnished.

While utilization is not a component of the case mix adjustment, we are concerned that CMS is overlooking additional impacts from the ongoing PHE that may affect the adjustment. For example, the case mix adjustment uses six factors: cancer type, age, sex, presence of major procedure, death during episode, and presence of chemotherapy. None of these factors account for increased acuity of patients during or following the pandemic. As noted above, many patients have delayed diagnosis and treatment due to COVID-19. As a result, they may present with more advanced stage diseases, which will require more expensive radiation therapy treatment. Since the historical experience adjustment is based on a fixed time-period prior the PHE (2017-2019), the additional costs associated with treatment of these patients will not be captured in the payment methodology. **We urge CMS to conduct a more holistic analysis of the impacts of the COVID-19 PHE on the RO model and work with stakeholders to modify the model's financial methodology to ensure participants are not unduly penalized as a result of the pandemic.**

Key Design Considerations for Mandatory Models

As we have noted before, Premier believes that voluntary models are ideal as they allow providers to select participation based on their mission, abilities, and market realities. As CMS evaluates the design of the RO model and considers adoption of future mandatory models, we strongly urge CMS to consider the following key factors:

- ***Provide opportunities for upside financial gains, as well as gradual risk options****.* As noted above, CMS should design APMs that allow for meaningful opportunities to take on two-sided risk. Mandatory models should also offer opportunities for providers to gradually assume risk to ensure all providers have an opportunity to succeed.
- ***Address overlap with other models.*** We urge CMS to work with and provide exceptions for providers already in APMs when existing models overlap with new mandatory models. These providers have voluntarily taken on the work and invested in value transformation. Precedence should be given to the previously established models that are already in testing.
- ***Establish appropriate provider exclusion criteria that recognize the challenges that rural and low-volume providers face with mandatory participation****.* Many rural and low-volume providers cannot absorb the additional costs and potential payment cuts that may result from mandatory payment models. We urge CMS to design appropriate exclusion criteria that protect rural and low-volume providers and help protect access in these communities.
- ***Provide sufficient information in advance of model test starts****,* including making claims data available in advance to allow for sufficient time for data analysis. Additionally, CMS should provide information on waivers and other key policies for implementation, such as the financial methodology and any applicable target prices or benchmarks. Without this information providers do not have sufficient time to prepare for the model start.

We also strongly urge CMS to engage with stakeholders early on the design of mandatory models.

340B DRUG DISCOUNT PROGRAM

Congress created the 340B Drug Pricing Program in 1992 to allow certain safety net hospitals and other healthcare entities (known as covered entities) to purchase outpatient drugs at a discount from drug manufacturers “to stretch scarce Federal resources” and to expand healthcare services to vulnerable populations. For nearly three decades, the 340B program has been critical in helping covered entities expand access to lifesaving prescription drugs and comprehensive healthcare services to low-income, underinsured, and uninsured individuals in communities across the country.

The savings produced by the 340B program have become essential to covered entities in meeting the needs of the communities and patients they serve. Under the program, drug manufacturers are required to offer lower prices on covered outpatient drugs to covered entities (e.g., those with a Medicare disproportionate share percentage of more than 11.75 percent) and other settings, enabling them to reinvest the difference between the discounted price and the amount paid by Medicare in healthcare services for underserved and uninsured patients. The ability to reinvest these savings is more critical than ever as our nation continues to face unprecedented healthcare challenges under the ongoing COVID-19 pandemic.

In the 2018 OPPS rule, CMS adopted a policy to pay hospitals for separately payable, non-pass-through drugs (other than vaccines and those furnished by rural sole community hospitals, inpatient prospective

payment system (IPPS) exempt cancer hospitals, and children's hospitals) purchased through the 340B program at the average sales price (ASP)-22.5 percent, rather than ASP+6 percent. This policy has been subject to ongoing litigation. On December 27, 2018, United States District Court for the District of Columbia concluded the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP-22.5 percent for 2018 (see *American Hospital Association et al. v. Azar et al*). On May 6, 2019, the District Court ruled that the rate reduction for 2019 also exceeded his authority. The District Court remanded the issue to the Secretary to devise an appropriate remedy while also retaining jurisdiction. CMS subsequently appealed this ruling and on July 31, 2020 the United States Circuit Court for the District of Columbia entered an opinion reversing the earlier judgments. Most recently, the United States Supreme Court has agreed to hear the case.

As part of this year's rulemaking, CMS proposes to continue to pay for drugs and biologicals acquired under the 340B program at ASP-22.5 percent. **Premier objects to these cuts as it threatens access to care for the patients who benefit from the much-needed 340B program.** This policy continues to punish hospitals for a policy that is designed to assist safety-net hospitals serving vulnerable patients, including those in rural areas. For the reasons cited below, we strongly urge CMS to drop these cuts.

CMS' 340B cuts harm our nation's most vulnerable patients

Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals in their efforts to build healthy communities. Continuing the policy will harm vulnerable patients by cutting 340B drug savings that hospitals use to provide needed support for outpatient services in underserved areas. This is creating devastating consequences for the patients and communities who rely on this vital program.

As noted above, the Congressional intent of the 340B program was to enable covered entities "to stretch scare federal resources as far as possible," allowing them to reach more eligible patients and provide more comprehensive services. 340B drug discounts help defray the costs that 340B hospitals and other covered entities incur in furnishing medicines to 340B eligible patients at low or no cost; the savings are also used to furnish other healthcare services to the poor, the uninsured, and the underinsured.

The Biden Administration has made equity – including health equity – a centerpiece of its policies. The 340B program is a critical resource for safety net hospitals in providing care to the uninsured and low-income patients and should play a key role in the Administration's health equity agenda. 340B hospitals use the savings they receive on the discounted drugs and reinvest them in programs that enhance patient services and access to care, as well as provide free or reduced priced prescription drugs to vulnerable patient populations. For example, hospitals operate a variety of programs and services that otherwise would not be financially viable:

- Provide financial assistance to patients unable to afford their prescriptions;
- Provide clinical pharmacy services, such as disease management programs or medication therapy management;
- Fund other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- Establish additional outpatient clinics to improve access;
- Create new community outreach programs; and
- Offer free vaccinations for vulnerable populations.

Given the Administration's commitment to addressing health equity, it is unclear why it would choose to continue to punitively target 340B safety-net hospitals serving vulnerable patients. It is possible that this Administration is continuing a policy of the prior Administration while the issue is pending before the Supreme Court. However, even if the Supreme Court upholds CMS' authority to undertake this policy, we urge this Administration to discontinue it on the basis that the policy is inconsistent with this Administration's equity goals.

Our concerns are only heightened by the ongoing pandemic and effects that it will have on our nation's healthcare system. Safety-net hospitals are an essential part of the ongoing fight against COVID-19. However, many safety-net hospitals are already operating on razor-thin or even negative margins and the ongoing pandemic will only further complicate finances for these hospitals. Continuing the 340B cuts will only serve to harm hospitals who are already severely strained by ongoing financial pressures from COVID-19.

CMS' policy justifications are flawed

CMS has previously stated it adopted the payment cut to address rising drug costs. As we have stated before, this policy does not directly address this issue and will have no effect on the price of pharmaceuticals. Instead, the policy targets the assistance provided to 340B hospitals to protect patient access to healthcare.

CMS has also stated its belief that the policy will benefit beneficiaries by lowering coinsurance, contending that a reduction in the payments to 340B hospitals would also reduce beneficiaries' coinsurance as it is a percentage of payments. However, since this policy is applied in a budget neutral manner, the coinsurance obligation would simply shift to beneficiaries receiving other outpatient services as the payment for those services increases. Moreover, if hospitals drop out of the program, CMS only will succeed at reducing access to care or increasing the financial obligation for vulnerable populations. CMS has not provided evidence that this policy, which was enacted four years ago, addresses the rising costs of pharmaceuticals nor protects beneficiaries.

Policy goes against Congressional intent

The goal of the 340B program is to enable 340B covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Report No. 102-384(II), at 12 (1992)). As noted above, 340B drug discounts from manufacturers allow 340B hospitals and other covered entities to furnish medicines to 340B eligible patients at low or no cost. In turn, these entities use savings achieved under the program to furnish other healthcare services to the poor, the uninsured and the underinsured.

That is what Congress intended when it enacted the 340B program; Congress has done nothing since 1992 to change those policy goals. In fact, under the Affordable Care Act (ACA), Congress specifically expanded the number of hospitals that could qualify as 340B covered entities and made other changes to ensure greater availability of the 340B drug discounts so that more individuals in vulnerable populations could get access to medicines and other healthcare services. The ACA neither mandated these payment reductions nor authorized them.

As a result, any change to the fundamental policy goals of the 340B program can only be accomplished by Congress. As Premier has stated before, CMS' ongoing policy to pay differential rates for drug APCs based on 340B covered entity status is inconsistent with current law. **We urge CMS to discontinue its harmful 340B cuts to our nation's safety-net hospitals.**

HOSPITAL QUALITY REPORTING PROGRAM, SAFE USE OF OPIOIDS MEASURE

CMS previously finalized that hospitals will be required to report the Safe Use of Opioids -- Concurrent Prescribing eCQM (NQF # 3316e), in addition to three self-selected eCQMs, as part of the Hospital Inpatient Quality Reporting (IQR) program, beginning in CY2022. CMS is planning to submit the measure for NQF re-endorsement in 2022 and seeks input on potential updates to the measure and whether it should modify its previously finalized policy requiring reporting in 2022. Stakeholders have previously raised concerns with this measure, including concerns that it could alter prescribing practices or disincentivize clinicians from appropriately concurrently prescribing medications in addition to treatment of opioid use disorder.

We encourage CMS to share aggregate data and lessons learned from voluntary reporting. Additionally, CMS should delay mandatory reporting of the measure until which time the measure has been re-endorsed by NQF.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the CY 2022 OPPS proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, vice president, policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance