Atrium Health (NC, SC, GA, AL)

Avera Health (IA, MN, NE, ND, SD)

Community Health Network (IN)

Erlanger Health System (TN)

Franciscan Missionaries of Our Lady Health System (LA)

Hartford Healthcare (CT)

Oregon Health & Science University (OR)

SSM Health (IL, MO, OK, WI)

University of Florida Health Shands (FL)

University of Pittsburgh Medical Center (PA, NY)

Ms. Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
PO Box 8016
Baltimore, MD 21244-8016

September 15, 2021

Re: *CMS-1753-P: 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 Hospitals*

Dear Ms. Brooks-LaSure,

The Provider Roundtable (PRT) submits the following comments on the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, as published in the *Federal Register*.

The PRT includes 15 representatives from various health systems, serving patients in 19 states. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services by CMS, but do not have any specific financial relationship with vendors.

The past 18 months have been incredibly difficult for providers and, we are sure, for CMS as well. In addition to the pandemic's obvious stress on health care providers, we have seen our respective organizations under significant financial stress, lost co-workers to COVID-19, and experienced exponential increases in our workload, as the rules under which we operate were (understandably) changing on a daily basis.

The PRT truly appreciates CMS's efforts to keep providers informed through the After Hour Calls during the early months of the PHE. In the past, the members of the PRT have collaborated to provide substantive comments with an operational focus that we hope CMS staff would consider during the annual OPPS policymaking process. We have always felt that our comments made a difference in the process—even when CMS did not agree with us or adopt our recommendations, we feel that the agency listened. Because of the ongoing Public Health Emergency and the increase in work at our jobs, we have not been able to comment on as many topics as normal, or provide as much detail, as we normally do and would have liked.

We appreciate the opportunity to provide our comments to CMS and hope next year we will all be able to meet in-person at the Hospital Advisory Panel for Outpatient Payment (HOP) meeting and contribute more in-depth comments on a wider variety of topics. A full list of the current PRT members is provided in **Attachment A.**

Please feel free to contact me at 765-298-2110 or via email at: *trinker@ecommunity.com*.

Sincerely,

Terri Rinker, MT (ASCP), MHA
PRT Chair and Revenue Cycle Director
Community Hospital Anderson, Anderson, IN

Visits and Critical Care

OPPS Payment for Hospital Outpatient Visits and Critical Care Services

The PRT requests that CMS make a technical change to the definition of HCPCS G0463 by inserting the word **"or"** between the words outpatient and clinic. That is, define HCPCS G0463 as "*Hospital outpatient or clinic visit for assessment and management of a patient*." Many payers are erroneously categorizing G0463 as a clinic-only E&M code. In other words, payers are refusing to pay for G0463 because, in their assessment, it only represents services provided in a provider-based department/"clinic" where the hospital also employs the physician and is split-billing for both the professional and technical component.

As CMS is aware, there are legitimate instances in which hospitals report G0463 for an outpatient evaluation visit only, on the order of and under the supervision of physician (but not necessarily an employed physician where the hospital would bill the professional component). CMS' historical guidance to hospitals is to report G0463 if there is no other appropriate CPT or HCPCS code to describe the service provided.

- **The PRT requests that CMS make a technical change to the definition of HCPCS G0463 by inserting the word "or" between the words outpatient and clinic.**

Hospital Price Transparency

As CMS is all-too-aware, the United States is in the midst of a nationwide increase in COVID-19 cases driven by the Delta variant. Hospitals in many parts of the country are experiencing tenfold increases in COVID-related admissions; there are literally no beds available at many hospitals in many states. Ambulances wait in ED bays for hours due to the scarce to no bed availability in overcrowded Emergency Rooms.

The current state marks a new—yet eerily familiar—period in the COVID-19 pandemic. Hospitals are back to dealing with critical staffing shortages, working to decompress EDs and urgent cares, postponing non-urgent procedures, and generally dealing with overwhelming operational issues. We also know that Delta will not be the last surge—further variants are inevitable.

In light of this dire and overwhelming situation, CMS should not—rather MUST NOT—implement *any* changes or promulgate *any* additional rulemaking on Hospital Price Transparency until the PHE is over. In fact, CMS should delay any action until at least one year AFTER the end of the PHE, so the agency has sufficient time and opportunity to assess payers' compliance with the Transparency in Coverage Final Rules (TiC). The PRT cannot stress this strongly enough.

It is dismaying that, at the same time that CMS announced a delay for certain aspects of enforcement of Payer Transparency and Surprise Billing, the agency is doubling down on hospitals regarding enforcement, civil monetary penalties, and looking for ways to expand and implement additional penalties in this unprecedented time. In CMS' own rationale for delaying aspects of the Payer and Surprise Billing delay, there are areas of additional overlap and

redundancy with the Hospital Price Transparency (HPT) requirements. Both of these factors make it incomprehensible to the PRT why CMS is proceeding with the HPT requirements.

CMS' stated objectives on price transparency cannot be achieved in a hospital-specific vacuum; success will require hospitals and payers to work simultaneously under the same rules with common objectives and accountabilities. On August 20, 2021, CMS announced to payers that:

> *"with respect to plan or policy years beginning on or after January 1, 2022, as an exercise of enforcement discretion, the Departments will defer enforcement of the requirement to make public the machine-readable files for in-network rates and out-of-network allowed amounts and billed charges, until July 1, 2022."*

The PRT is alarmed that CMS is not extending the same enforcement discretion for hospitals as it is for payers. Hospitals are on the front lines of fighting this ongoing pandemic where the care of patients is of the utmost importance and where all resources are focused (as they should be). CMS should continue to acknowledge this as hospitals' top priority and at the very least, provide the same delays as they proposed for other payers. Any future enforcement should be considered for hospitals and payers together and should be balanced between hospitals and payers, including any Civil Monetary Penalties (CMP).

Despite the PHE and the inequitable enforcement between payers and hospitals, CMS proposes to increase HPT CMPs– however because CMS has not yet publicized non-compliant hospitals nor issued any penalties, the industry does not know if the current penalties are sufficient. Hospitals and Health Systems that have not received letters of non-compliance from CMS do not know what types of issues or deficiencies the agency is communicating. Organizations that consider themselves to be compliant have no official CMS benchmark with which to compare.

- **For these reasons, the PRT urges CMS to not implement any changes proposed concerning the HPT Civil Monetary Policies.**

The PRT would like to reiterate that the Price Transparency policies are unlikely to achieve the goal of providing beneficiaries and their families with useful information with which to make health care decisions. The PRT's member organizations are fully committed to providing our patients with actionable information, and we expend significant energy in creating information and communication processes that enable them to do so. What we oppose is the overly broad use of machine-readable files that have no capacity to provide an individual patient with detailed information related to their specific payer's potential reimbursement for a particular treatment.

If CMS insists on moving forward with the proposed changes to Civil Monetary Penalties, the PRT offers the following recommendations:

- Providers must be afforded sufficient time to rectify purported deficiencies.
- CMS must clearly and specifically explain reason and rationale for noncompliance.
- CMS should direct non-compliance letters to the authorized official as documented on the 855A.
- In general, we offer no better proposal regarding application of CMPs than that of Table 63 in the proposed rule.

- We suggest using the number of licensed beds for those who are not Medicare-enrolled. This would be more equitable and would enable CMS to utilize each state's facilities division information on licensed beds.
- With regard to additional scaling measures, no more than half of the penalty should be related to each of the two major components (i.e., the Shoppable Services/Online Price Estimation Tool).
- The concept of "scaling" needs to be revised. Since CMS has not prescribed a specific format, there is no way to "scale" based on perceived one-off deficiencies; everyone is posting different things. There is no way to equitably scale specific "deficiencies" because they vary from provider to provider.
- Minor infractions should not invoke full penalty or any penalty that is defined based on the five types of standard charges. A full penalty should only be considered based solely on the presence or absence of payer-specific negotiated charges.
- **CMS alone should be the arbiter of compliance, and the agency should forcefully denounce any non-governmental or general media "study" or reporting of purported compliance.**

With regard to CMS' concerns about Online Pricing Estimator tools, the PRT submits that at this point in time, it is not fully or completely possible to automatically obtain an individual's benefit information directly from the insurer when CMS has not yet enforced HIPAA transaction sets that require payers to provide current deductible, co-payment, co-insurance, and out-of-pocket maximums to hospitals via the eligibility code sets (i.e., 270/271). In addition, most price estimator tools are not integrated with eligibility transactions of hospitals and cannot initiate a 270 eligibility request to obtain a 271 response that includes up-to-date beneficiary financial obligations. Once created, this information must be "read" by the tool and applied to the hospital's estimate for the services. A beneficiary would receive more useful information by going to the payer's website, and keying in their identification number. Using the payer's information regarding the beneficiary's individual contract, the hospital selected by the beneficiary, and the services selected, the payer can provide the beneficiary with up-to-date financial responsibility, including costs related to any services beyond the hospital, such as physicians who bill separately for their services.

- **Therefore, until CMS fully enforces HIPAA transactions and code sets, and technology that incorporates this information is developed, advancing CMS' aspirations for online price transparency tools is virtually impossible.**

Additionally, CMS requests comment on the definition of "Plain Language." If CMS pursues an initiative to adopt standard naming conventions in the future, we urge CMS to convene a group of stakeholders (to include, for instance, AMA, AHA, and PRT) to determine an appropriate pathway for standardization. Any future changes should not impose an undue burden on hospitals to deviate from usual or normal chargemaster (CDM) naming conventions.

Regarding the question of publishing Hospital Exemplars, the PRT recommends that CMS delay thinking about this for an indefinite period of time. This is particularly critical, given the issues stated above and the (delayed) pending implementation of Payer Transparency and Surprise Billing.

Regarding ideas for potential standardization of the CMRF, the PRT has the following recommendations:

- The standardization must be simplified; there is no conceivable way to publish consistent information unless it is significantly pared down. For instance, CMS could simplify this by limiting it to each hospital's Top Ten Plans (defined by gross revenue book of business).
- CMS should remove the requirement for de-identified Min/Max; if these data are truly meant for data scientists and data developers, then these subject matter experts can calculate the Min/Max.
- For Medicare Advantage/Managed Medicaid, if hospitals are contracting based on traditional Medicare/Medicaid, they should be allowed to simply publish the negotiated percent of Medicare/Medicaid rates. These are public rates; for APC-based contracts there is really no way to publish payment detail on those due to claim-level adjudication.
- CMS *must* work with, or at least consider the input of, hospital financial system vendors (e.g., Epic, Cerner, etc.) as well as proprietary vendors (e.g., VitalWare, Craneware). Many hospitals rely on base files or output from their contract management systems as the basis for publishing their rates.

- **In summary, the PRT urges CMS not to implement *any* changes or promulgate *any* additional rulemaking on Hospital Price Transparency until at least one year after the end of the PHE.**

Proposed Payment Changes for 340B Drug Payment Policy, Including in Off-Campus PBDs

CY 2022 Proposed 340B Drug Payment Policy

For CY 2022, CMS proposes to maintain payment rates at ASP minus 22.5 percent (ASP-22.5%) for 340B-acquired drugs and biologicals. This rate includes drugs furnished in nonexcepted off-campus PBDs that are paid under the PFS.

For 340B providers, continuing this payment reduction would be devastating. 340B providers have endured reimbursement reductions ever since CY 2018, with significant and negative financial impacts. Worse, as reimbursement has decreased, the operational burdens of administering the program have increased. (One example is the requirement of the "JG" modifier, which indicates that the drug was purchased under the 340B program.) In a time when clinical and support staff challenges continue, especially in the light of the COVID-19 pandemic, the continue reduction of payment is troublesome, to say the least.

The PRT firmly and unequivocally believes that 340B hospitals should be made whole. CMS is erroneously assuming that, because hospitals pay less for 340B drugs, the agency should reimburse these facilities a lower amount for these drugs.

- **PRT has previously requested that drug reimbursement should be the same for 340B hospitals as non-340B hospitals: ASP +6%. PRT confirms our strong opposition to the continued CMS 340B reimbursement policy of ASP-22.5%.**

Congress and HRSA intended the 340B program to provide additional resources to hospitals so the facilities could, in turn, provide services to the disproportionate number of low-income, vulnerable patients they treat. The current CMS outpatient reimbursement conflicts with this intent. Frankly, it is egregious for CMS to continue its policy, which robs funding for covered entities, and to potentially redistribute those funds through a budget neutrality mechanism that includes non-covered entities.

As in the PRT's past comments, we note that CMS has underpaid hospitals with the 340B reimbursement reduction over the past four years. We continue to recommend that 340B hospitals receive interest on the money owed to them. Specifically, CMS should repay funds to providers for line items that were reported a -JG modifier. The amount of money returned should be reflective of the number of HCPCS codes submitted with the -JG modifier and the associated reimbursement to reflect ASP+6%. Additionally, hospitals should not be further burdened to obtain monies due to them. Providers should not have to resubmit claims or go through additional appeal processes to regain these funds.

- **The PRT urges CMS to make 340B hospitals whole and requests the agency to instruct Medicare Advantage Plans to do the same.**

The past four years of 340B reimbursement reduction have validated previous PRT concerns submitted in our comment letters. As predicted, the drastic reimbursement reduction has resulted in less funding being available for vital patient assistance programs and other support for the vulnerable beneficiaries.

By its own admission, CMS does not understand where these monies are being utilized. Hospitals have made significant efforts to reduce cost to make more services available to underserved; yet, for every effort made, there are significant reimbursement decreases. This defeats providers' efforts to serve these patient populations. CMS states that it recognizes

> *"the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients."*

Hospitals provide a variety of free services for patients who need them, including housing; transportation; and meals. Hospitals also use 340B savings to support charity and free care funds; offer discounted medication to underinsured and uninsured patients; and purchase equipment for clinics. Hence, the savings realized through the 340B program allow providers to expand the scope of charitable services they offer to their communities. These provider assistance programs are jeopardized by decreased reimbursement.

The PRT wishes to highlight activities by many essential hospitals about which CMS be unaware. Many providers provide 340B savings directly to beneficiaries by establishing patient assistance programs where patients pay the exact cost of the 340B drug at hospital pharmacies that act as contract pharmacies. For example, extending these savings has allowed patients to purchase life-saving insulin for $20 rather than the previous $100. As another example, a PRT member facility noted that its trauma patients (who are often indigent and/or uninsured) can get anticoagulant therapies for under $25, vs. being charged hundreds of dollars. Access to these immediate and lifesaving therapies (e.g., insulin and anticoagulants) enable patients to be discharged vs. having to stay in the facility.

One PRT member notes that the facility's assistance program allows many of its patients to afford and adhere to their therapies, and prevents them from having to return to the hospital later with health problems caused by financially-related nonadherence with treatment.

We recognize that CMS is only interested in the monetary savings to the Medicare program, but the target of these services includes Medicare beneficiaries, who often have out-of-pocket costs related to self-administered drugs, including insulin. This use of the 340B savings allows all patients, regardless of insurance status, to have the same reasonable cost for insulin when purchased at these contract pharmacies related to a hospital. With the continued reimbursement of ASP-22%, the manufacturers are removing their 340B pricing from contract pharmacy participation, which has the domino effect of preventing hospitals from extending the 340B savings to their patients. Hospitals must then contact each manufacturer individually and request an individual exception to this removal—time will tell if this is effective or not. The continued ASP-22% reimbursement will affect Medicare beneficiaries, who will no longer to able to access lower-priced medications from contract pharmacies, creating a clear and direct loss of benefit for these beneficiaries.

The PRT believes this is completely against the intention of the 340B program initiated by Congress; the ability to directly impact beneficiaries in a way that decreases cost should be highest priority for CMS

- **CMS should re-establish 340B drug reimbursement at ASP+6%.**

The PRT strongly disagrees with CMS' assertion that no 340B hospitals argued in prior rule-making comments that ASP-22.5% was incorrect. Several of our member hospitals participate in the 340B program and have voiced their disagreement and provided supporting reasons in formal comments ever since the proposal was first made.

CMS noted that:

> *Based on feedback from stakeholders, we stated that we believed maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs was appropriate to maintain consistent and reliable payment for these drugs both for the remainder of the PHE and after its conclusion to give hospitals some certainty as to payments for these drugs. We explained that continuing our current policy also gives us more time to conduct further analysis of hospital survey data for potential future use for 340B drug payment. We also noted that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.*

The PRT supports CMS' statement that any changes to current 340B policy would be adopted through required notice and comment rulemaking as that is a federal requirement. The PRT disagrees that the current policy is supported by stakeholder feedback; providers have individually and collectively told CMS that the current policy is detrimental to the hospital providers in general and in specific ways and goes against the integrity of the 340B program. The PRT also submits again that the survey data were gathered at a time when hospitals were inundated with COVID-19 and had no resources to respond to the survey; CMS then used the "default" value prescribed in their survey. While CMS had no control over the PHE, the timing of the survey was horrible, at best.

The CY 2022 OPPS proposal includes extensive review of the legal proceedings related to 340B cuts to reimbursement. The PRT strongly disagrees with CMS' statement that ASP-22.5% *more closely aligns the payment rate with the resources expended by 340B hospitals to acquire such drugs compared to a payment rate of ASP plus 6 percent, while also recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients.*

- **The PRT supports continued pursuit along all appropriate legal challenges to this erroneous reimbursement policy that has real time beneficiary impact.**

In closing, the PRT reminds CMS that:

- 340B hospitals treat a large share of low-income, Medicare, and Medicaid patients while being traditionally underpaid. Based on the intention of the 340B program, hospital providers have followed the regulatory requirements and integrity of the 340B program and should not be punished with this continued reduced payment policy.
- Savings from these programs enable facilities to offer specialty services to meet specific needs of a specific patient population or location (e.g., rural areas). Hospitals use these savings to create easy access for patients by meeting them in their community setting. The 340B cuts **must** be rescinded and 340B providers made whole to continue to provide these needed services.
- By maintaining the current 340B reduction policy, CMS is taking vital savings for these safety net health centers and ignoring the legitimate, specific recommendations of providers, which is contrary to the process intended for public comment and rulemaking and specifically is detrimental to the patients across many communities in need.

Inpatient Only List: Proposed Services That Will Be Paid Only as Inpatient Services

The PRT has long called for the elimination of the Inpatient Only (IPO) List. While the PRT appreciates and shares CMS' concern about the safety of Medicare beneficiaries, elimination of the IPO List would not, in our view, negatively impact patient safety in the hospital setting.

Our opposition for the IPO List stems from the enormous operational issues that it creates for providers, and the unnecessary costs it causes to beneficiaries (because inpatient care typically carries higher patient responsibility portions than outpatient care). Regardless of patient status, a patient treated in a hospital is being provided hospital level of care and there is no difference in the requirements, infrastructure, or capabilities that surgical suites have just because the doctor decides to treat the patient as an outpatient status vs. inpatient.

Eliminating the IPO List would allow hospitals more flexibility and beneficiaries more choice in the type of care they receive, placing the determination of choice in the hands of the physician and individual beneficiary rather than enforcing a standard based on patient population.

Our opposition to the IPO List does not mean that the PRT is suggesting that *all* procedures can or should be performed on an outpatient basis. Rather, our consistent position has been (and

continues to be) that scientific and technological advances enable procedures to be provided safely to patients on an outpatient basis. This allows many patients to receive the procedure under outpatient orders and to be discharged without hospital-level of care for two nights, or extraordinary hospital care for one night—which is CMS' two-midnight requirement for Part A coverage. We also continue to believe that physicians should be the ones making the clinical determination about the best site of care (i.e., inpatient vs. outpatient) rather than CMS.

CMS lists several criteria for determining when a procedure code can be removed from the IPO List. We agree with all but two of these criteria, which are described below.

The first criterion we oppose is CMS' requirement that the procedure is being performed on the Medicare population in numerous hospitals on an outpatient basis. CMS looks at claims data for this assessment; yet many hospitals do not bill for an IPO procedure if it is performed as an outpatient procedure (OP). All PRT member hospitals and health systems have processes in place to ensure that a scheduled IPO procedure is not performed or billed as an OP. The processes include methodologies to request an inpatient order from the physician when the planned procedure is on the IPO list. Occasionally, the planned procedure becomes unexpectedly more involved during the surgical case, and the procedure is more extensive. Neither the physician nor the hospital anticipated this based on the individual beneficiary's presenting clinical scenario. The change to a procedure on the IPO List occurs intra-operatively and is not known by either party until the operative procedure documentation is reviewed and coded. Then, the hospital is faced with an IPO procedure having been performed on an OP basis.

When this happens, the scenario is costly for the hospital. Facilities spend significant time investigating what happened, could this have been known prior to the surgical procedure starting, and how to mitigate the scenario in the future. We also note that the process and resulting payment implications affect only the hospital. There is no methodology under the Medicare Physician Fee Schedule (MPFS) for physicians to not be reimbursed for a procedure on the IPO list when performed as an outpatient. This is one reason it is very difficult for these scenarios to be mitigated—the only negative impact is to the hospital, and the patient already received the care. In addition, many facilities have a process in place to not submit a claim for an IPO procedure when performed on an OP basis. These facilities have internal mechanisms that flag the claim and prevent the claim from being billed to Medicare. The PRT submits that this is one reason that CMS sees very few OP claims for many IPO procedures – the claims are never submitted so there is no data for CMS to review.

The second criteria we disagree with is CMS requiring that the procedure can be safely performed in an ASC. CMS seems to be conflating hospital capabilities with those of an ASC, but they are very different. While both are classified as outpatient sites, hospitals have many more resources to safely recognize and care for an outpatient if there is a change in the patient's condition and/or unforeseen complications arise. Hospitals have advanced imaging on-site (such as CT and MRI), as well as blood banks. The hospital pharmacy has a bigger inventory than an ASC pharmacy. Hospitals also have numerous caregivers such as Respiratory Therapists, ECHO technicians, and Registered Nurses who are experienced in providing needed critical care treatment. The hospital also has the capability of admitting a patient as an inpatient post-operatively should these types of circumstances arise. Requiring a procedure to be safely performed in an ASC just because a hospital can safely provide the service on an outpatient

basis is unfair, not only to the hospital but also to the individual beneficiary. The review of a procedure coming off the IPO list and its being safely performed in an ASC are two ***entirely different*** considerations.

Rather than utilizing these two criteria, the PRT recommends that CMS look at claims data for IPO cases that are less than a two-midnight stay. These claims and procedures would be an acceptable proxy for determining if a procedure may be eligible to be performed on an outpatient basis, based on the requirements of the Two-Midnight Rule and also based on CMS' clinical advisor review. We believe this is a more useful criterion for determining procedures that are suitable for removal from the IPO List rather than looking for outpatient claims data.

As noted above, our organizations investigated situations when an IPO-List procedure is performed on an outpatient. Because this shift in status would not be identified until *after* the patient is discharged and the operative report documentation is coded, we recommend that CMS help providers avoid this complication by allowing providers to append a modifier that indicates that the scheduled procedure was an outpatient procedure, but the situation changed intraoperatively. A modifier similar to the CA modifier would be appropriate for this use. Or, CMS could change the description of modifier CA from "Procedure payable only in the inpatient setting when performed emergently on an outpatient who expires prior to admission" to accommodate these scenarios. For example, "*Procedure payable only in the inpatient setting when performed during surgery scheduled as an outpatient case, or emergently on an outpatient who expires prior to admission or is transferred*." These scenarios would be supported by documentation in the medical record as well as the clinical scenario that presented itself during the actual operative procedure.

- **The PRT asks CMS to strongly consider revising the claims data the agency utilizes to determine whether a procedure is suitable for removal from the IPO List and allowed for coverage and payment under the OPPS.**

- **We also strongly recommend removing the criterion requiring that a procedure can be appropriately and safely performed in an ASC when deciding whether to remove a procedure from the IPO List.**

- **The PRT also asks CMS to allow the CA modifier (with a description update) or create a new modifier that allows IPO procedures to be billed and paid when an outpatient procedure is scheduled, and the procedure changes intraoperatively to an IPO procedure due to the individual beneficiary's clinical condition.**

CMS also stated its interest in stakeholders' viewpoints on the financial impact of removing services from the IPO List.

Hospitals have experienced unprecedented costs over the last 18 months—and will likely continue to do so as long as the pandemic continues. For this reason, *anything* that impacts our finances is a significant concern. While we support eliminating the IPO List on principle, we are concerned about the financial impact it would have, specifically if the OPPS payment rates are not appropriate and fail to adequately cover our costs on average.

We have two overarching questions that we hope CMS will consider with respect to removing procedures from the IPO List.

1. What impact will the decrease in inpatient days have on DSH and IME?
2. Will items removed from the IPO List be appropriately reimbursed without strong claims and cost data?

- **We recommend that CMS consider using a concept similar to new technology APCs: procedures that come off the IPO List would be assigned to an APC using concepts of clinical and resource homogeneity without automatically being placed into an existing C-APC or APC.**

These APCs could be titled "Procedures removed from the IPO list" and would allow CMS to collect actual outpatient cost data for two to three years in order to make an appropriate APC assignment.

Another approach CMS could consider would be to pay the higher of a percentage of the MS-DRG rate to which the procedure was assigned, or utilize a cost-based claim reimbursement methodology where hospital charges are reduced to cost using the overall operating cost-to-charge ratio. Either of these types of assignment and/or payment methods is likely to be less than the MS-DRG amount, but more than placing procedures in similarly related, but not clinical/resource homogenous APCs.

CMS also solicited public comment on several other questions and topics.

First, CMS asked if the agency should maintain the longer-term objective of eliminating the IPO List. As stated above, the PRT continues to support elimination of the IPO List, because clinicians should make patient status determinations, not CMS. If CMS does retain the IPO List, it should be used only for primary procedures that are appropriate for inpatient status orders pursuant to CMS' two-midnight policy for coverage of inpatient hospital care. CMS has special claims processing logic in the Integrated Outpatient Code Editor (IOCE) for procedure codes on the IPO List that are designated by AMA as "separate procedures." These procedures are not primary procedures; the IOCE logic will line-item reject only the line with the IPO procedure and the primary and other procedures reported on the claim will process and be paid under OPPS. Unfortunately, as noted above, many hospitals do not bill an outpatient claim containing an IPO procedure code. As a result, CMS does not receive these claims. Further, many hospitals do not know that under the IOCE logic, the line item with the "separate procedure" CPT code would be rejected, while the remainder of the outpatient claim would process and receive OPPS payment. Therefore, these "separate procedures" should either be removed from the IPO List or (at a minimum) CMS should create a separate status indicator that alerts hospitals to the special OPPS treatment for these procedures.

Second, CMS asked if the agency should maintain the IPO List but continue streamlining the services that remain on it. The PRT recommends that, if CMS maintains the List, it continues to streamline it and remove services on a regular basis.

Third, CMS also asked about the effect that scaling back the IPO List would have on safety and quality of care. The PRT strongly believes that there are no differences, within a hospital setting, in safety for an IP or an OP. The care provided is based on what a physician deems to be

medically necessary; orders for treatments and diagnostic services for a particular patient determine the care, not the clinician's IP vs OP status order. Both inpatients and outpatients are treated in licensed departments of hospitals including routine, specialty care (e.g., ICU) and ancillary departments.

Fourth, CMS asked if the clinical evaluation of the safety of service for a procedure in the OP setting should consider the safety and quality of care for the typical Medicare beneficiary or a smaller subset of Medicare beneficiaries for whom the OP service may have fewer risk factors. The PRT recommends that CMS should consider clinical safety guidelines for the smallest subset possible. Because beneficiaries have individual clinical scenarios, and medicine is individualized, it makes more sense to allow an individual determination for an individual patient; basing guidelines on the description of *an average* beneficiary will lead to increased costs overall.

Fifth, CMS asked if stakeholders believe services that were scheduled for removal from the IPO List in CY 2021 meet the longstanding removal criteria and should not be included in the IPO List. CMS also asked for evidence that supports the conclusion. The PRT regrets that we do not have the clinical expertise to provide evidence nor, during the PHE, do we have the capacity to obtain the information from others in our organizations. The PRT would like, once again, to request that the following services *not* be included on the IPO List. These procedures were scheduled to come off the List and can all be safely performed in a hospital on an outpatient basis (we do not know if they can be safely performed in an ASC, however). We have previously asked for these codes to be removed from the IPO List and suspect that CMS has evaluated these codes to some extent already. The agency is likely to have some historical analysis and data to assist with rate-setting and appropriate APC assignment.

The PRT asks that the following codes be removed from the IPO List so they may be performed in a hospital as an outpatient (we make no comment on the safety of performing these procedures in an ASC):

- 35372 Thromboendarectomy, including patch graft, if performed, deep (profunda) femoral
- 35800 Exploration for post op hemorrhage, thrombosis of infection, neck
- 37182 TIPS procedure
- 37617 Ligation, major artery, abdomen
- 38562 Limited lymphadenectomy for staging (separate procedure), pelvic and para-aortic
- 43840 Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury
- 44300 Open jejunostomy following a diagnostic laparoscopy
- 44314 Revision of ileostomy, complicated (reconstruction In-depth) separate procedure
- 44345 Revision of colostomy, complicated (reconstruction In-depth) separate procedure
- 44346 Revision of colostomy, with repair of paracolostomy hernia (separate procedure)
- 44602 Suture of small intestine accidental laceration

- 49010 Exploration, retroperitoneal area with or without biopsy(s) separate procedure
- 49255 Omentectomy, epiploectomy, resection of omentum
- 51840 Anterior vescourethropexy, or urethropexy (eg. MarshallMarchetti-Krantz Burch), simple
- 56630 Vulvectomy, radical partial
- 61624 Transcatheter permanent occlusion or embolization, percutaneous any method central nervous system

Changes to Beneficiary Co-insurance for Certain Colorectal Cancer Screening Tests

The PRT wishes to thank CMS for not only recognizing the confusion this coinsurance causes for beneficiaries but also making adjustments to address the confusion. Our organizations have heard from many beneficiaries who are upset because they do not understand why they owe coinsurance when they had a screening test that was supposed to be covered at 100%. Many times, the beneficiary says something to the effect that, had they known about the coinsurance, they would not have had the screening done because the polyp that was removed turned out to be benign.

The PRT is concerned that Medicare patients will now hear that the coinsurance is being eliminated and one of two things will happen:

1. The beneficiary will hear there is no longer a coinsurance but will *not* hear that there is still a partial coinsurance due from patients until 2030, and then will be even angrier when they get a bill for their portion, and they call the provider and find out the details of the phased in elimination of the coinsurance.
2. The beneficiary will understand they may still have coinsurance and will chose to delay this important screening exam, with potentially life-threatening results.

Some health care providers would like to waive the coinsurance to avoid either of the two situations above. Compliance experts, however, have differing viewpoints about whether that is possible. Some consider the waiver to be an inducement and will not allow it to happen. Others feel that, if the waiver is not advertised, then it cannot be considered an inducement; they believe that it is better to waive the copayment than to have angry patients calling and trying to understand what is happening. The latter situation also requires staff time and resources that would be far more costly than the payment received from the coinsurance.

- **The PRT supports CMS' proposal to eliminate the coinsurance. We request, however, that CMS allow providers to waive coinsurance even earlier than 2030 if they elect to do so.**

- **We also request that CMS explicitly address this situation fully in the Final Rule so providers that do want to reduce the coinsurance at a faster pace than CMS can do so without fear of violating any CMS rules.**

Outpatient Quality Reporting Program (OQR)

The PRT congratulates CMS for the agency's efforts to promote consistent delivery of higher-quality and more efficient health care for Medicare beneficiaries under the OQR program. We acknowledge and appreciate CMS' efforts to manage and alleviate the OQR's maintenance costs and administrative burdens under the Meaningful Measures Initiative. We appreciate the limitation of measures to those that are truly "meaningful" and improve care for the Medicare population.

Request for Information: Advancing to Digital Quality Measurements

CMS is seeking comments on Digital Quality Measures (dQM).

- **The PRT continues to oppose CMS having *direct access* to a facility's EHR for data, whether electronically or digitally.**

We note that a requirement to submit data digitally may be premature; we have little confidence that health care providers are prepared to do so with great accuracy. We doubt that significant advancements in data standardization have occurred while facilities struggle through the global public health emergency. The technological challenges, burden, and cost of reporting dQM data still exist and are all exacerbated by the impact of the PHE.

CMS' solicitation of comments also discusses the benefit of "near real-time" quality measure scores. Documentation is so dynamic and ever-changing, the PRT has difficulty imagining how the agency intends to gather actionable, high-quality information from the electronic medical record on an outpatient basis. Having such "real time" alerts about quality measures seem likely to add to administrative burdens without providing confidence in the scores.

CMS also requests input regarding the incorporation of emerging data sources including "patient reported outcomes and patient-generated health data." We ask that CMS take caution in proceeding with this new concept. In previous rules, CMS has acknowledged the difficulty patients encounter in deciphering data that are published as publicly reported data. We believe the challenges in understanding complex health care quality measures will result in unreliable and inconsistent data and reporting. We question the reliability of the data to measure outcomes (specifically with respect to Total Knee and Total Hip Replacements) when derived directly from patient-reported data, without ensuring that the measures are stated in a way that a beneficiary can easily understand.

- **The PRT does not support the incorporation of emerging data sources as proposed without specific details. The PRT does not support utilizing patient-reported data without CMS' creating very detailed explanations of each quality measure in a simplified manner that beneficiaries can easily understand.**

Requirements for the Hospital Outpatient Quality Reporting Program

COVID-19 Vaccination Coverage Among Health Care Professionals

CMS proposes to adopt a new measure: "COVID-19 Vaccination Coverage Among Health Care Professionals (HCP)." While we recognize the significance the vaccination rate plays on mitigating COVID-19, the PRT is concerned about implementation of this quality measure. Specifically, we are concerned that the proposed measure is not supported by Measure Application Partnership (MAP), stemming from the fact that the NQF has not endorsed the measure. We agree with the issues brought forth by MAP in their assessment of this measure.

While we appreciate CMS's recognition of the burden of requiring weekly reporting of HCP vaccination data for every week of each month, there is significant provider burden in requiring monthly reporting, which is a duplication of the information that is already being provided to the Centers for Disease Control and Prevention (CDC). Many of our organizations are currently in the process of implementing vaccination mandates for our health care professionals. The PRT submits that CMS should obtain this information from the CDC and not from our institutes, given that the latter creates a duplication of effort.

We also note that the proposed definition of "population" for this measure is confusing. We understand that this measure defines HCP as staff "eligible to work at hospital for at least 1 day." Within the measure specification section, hospitals are instructed to include HCP who are physically working in a location that is considered as any part of the on-site acute care facility that is being monitored and refers us to the National Healthcare Safety Network specifications. On the CDC's National Healthcare Safety Network's website, HCP is defined as "The entire population of healthcare workers working in a healthcare setting." The population of employees to be included remains unclear.

- **The PRT requests that CMS seriously evaluate the impact on the health care industry of its proposed duplicative measure. Rather, CMS should obtain the information as already reported to the CDC.**

STEMI eCQM

CMS seeks comments on replacing the current STEMI chart-abstracted measures (OP-2 Fibrinolytic Therapy Received Within 30 minutes of ED Arrival, and OP-3 Median Time to Transfer to Another Facility for Acute Coronary Intervention) with a new ECQM measures. The CMS proposal allows retrieval of data directly from the EHR using patient-level data.

As noted in our previous comments, the PRT agrees that EHRs' evolution and infrastructure increase the capacity for electronic reporting of measures and creates opportunities to replace the burdensome chart-abstraction data submission method.

- **The PRT supports the concept of using data collected from EHRs, but we continue to oppose CMS having *direct access* to a facility's EHR for data abstraction.**

We believe that specific data submission from the EHR could be developed in order to provide necessary information electronically without increasing hospital burden. We would support

access within our facility system firewalls to data in the EHR only when it specifically addresses the quality measure.

We do not support the use of a direct portal for CMS to have open access to all data within a patient's electronic health record. We encourage the development of systems to enable hospitals to submit only specific data elements in an electronic format. We approve of the terms in the EHR incentive program that provides a foundation for hospitals to send—and for CMS to receive—quality measures through electronic submission.

The PRT understands that CMS's position on implementing quality measures is not contingent on support from NQF; however, we are concerned that this proposed measure is not supported. Furthermore, we have questions regarding the exclusion of patients from this measure if the patient has a contraindication to fibrinolytic therapy. Capture of this type of contraindication is not a discrete data element in the electronic health record; the PRT requests that CMS clarify how the agency intends to determine exclusion using electronic data.

OP- 37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare

The PRT understands the need for a standardized assessment of a patient's overall experience for surgeries or procedures performed within a hospital outpatient department. CMS proposes to implement voluntary reporting beginning in CY23, followed by mandatory data collection and reporting beginning with CY24.

CMS notes that hospitals will be required to contract with a CMS-approved vendor to collect survey data and report these data to CMS on behalf of the hospital. This contracting is an additional expense for hospitals. The inpatient version of this measure (HCAHPS) uses a self-administered survey.

- **The PRT requests that CMS clarify why the outpatient version of this (very similar) survey does not use same administration method.**

The MAP notes that these measures are also included within other programs. The PRT supports MAP's recommendation that CMS consider how these measures are related to other, existing ambulatory surveys in order to ensure that patients and facilities are not overburdened by multiple surveys.

- **In consideration of the on-going PHE, the PRT requests that CMS continue to delay the implementation of OAS CAPHS. We remain concerned about the operational burden and repetitive nature of this extensive and complex outpatient survey and urge CMS to implement only voluntary reporting for upcoming calendar years.**

OP-31 Cataracts: Improvement in Patient's Visual Function within 90 Days following Cataract Surgery

The PRT continues to strongly object to this quality measure for the simple reason that hospitals *do not see the patient* 90-days post-surgery. CMS seems to insinuate that limit of access to physician's office records has been ameliorated. PRT remains firm in our position that

access to data measuring visual function before and after surgery, especially when these measurements occur outside of the hospital's EMR, is unavailable.

It is unclear how the hospital would have the data to know if the patient's visual acuity had shown improvement at 90 days. Patients return to physician's office for post-operative care—not the hospital OP department or surgery area. The PRT continues to assert that this is a measurement of the surgeon's skills and has no reflection on the quality of care the hospital provides. This is already included as a physician quality indicator (PQRS #192) and should not be used to measure the quality of the hospital.

- **The PRT does not support implementation of this measure.**

Inclusion of Hospital-Level, Risk-Standardized Patient Reported Outcome Measure

As stated previously, the PRT is concerned about the emergence of patient-reported outcomes. We encourage CMS to proceed with this new concept very cautiously. Determining clinical improvement after Total Knee replacements (TKR) or Total Hip replacements (THR) is best determined by the orthopedist who is caring for the patient both pre- and post-procedure.

The agency seems to have expected that a larger volume of TKR and THR procedures would have shifted to the HOPD setting due to the removal of these procedures from the IPO List. We note that, although allowed in the outpatient setting, the volume of these complex procedures being performed as outpatient surgeries in the Medicare population is at the discretion of the surgeon who best understands the clinical needs and risks to the patients for whom they care. The mere fact that a procedure has been removed from the IPO List is not the determining factor in the selected setting for the procedure. We, as an industry, do not anticipate increased shift to the outpatient setting.

In summary:

- The PRT opposes this measure because just because a patient did not improve as he/she expected after surgery does not mean the patient did not receive quality care from the hospital. There are many factors involved when a patient does not see improvement as he/she expected.
- The PRT submits that CMS has not seen any increases in the number of TKR and THR procedures in the outpatient arena as these are mostly elective surgeries, which were put on hold for most of CY 2020 due to the Covid-19 PHE. CMS must also take into consideration that just because a procedure is removed from the IPO list does not automatically equate to its being performed as an outpatient procedure. This is beneficiary and physician determination driven.

Efforts to Address Health Equity in the Hospital OQR Program Setting

The PRT is pleased that CMS acknowledges the impact of a patient's socio-demographic status (SDS) and social risk factors on providers' ability to successfully comply with OP Quality measures.

We support CMS continuing to explore how best to account for social risk factors in the OQR program, including the effect of lack of income, education, social support, and community

resources. Patients with these risk factors often require more intensive social services to achieved improved outcomes.

The PRT appreciates that CMS continues to stratify readmission measures group scores and proposes to factor in social risk factors. The PRT has indicated frequently in our prior comment letters that the socio-economic status of our patients has a *direct* impact on the ability to manage readmissions. The impact on individuals specifically from the COVID-19 pandemic has only added to the socio-economic disparity and the resulting effect on a beneficiary's ability to manage chronic conditions, comply with care needs, and control the recurrence and exacerbation of health conditions. Beneficiaries who have social risk factors may be at higher risk for noncompliance that can significantly and negatively impact their outcomes. Unfortunately, many contributors to health inequities and related disparities are outside of the control of the health care system.

- **The PRT recommends that CMS consider factoring the SDS into the measure calculation method, for those measures where patient behavior (i.e., compliance with medical advice) impacts his or her outcomes.**

In the Request for Information, CMS solicited responses relating to data collection of social risk factor information on hospital encounter claims data (i.e., to include race, ethnicity, sex, sexual orientation, gender identity, primary language, and disability status). As the agency indicates, any such change must be made thoughtfully, with consideration for the administrative burden on providers and impact on patient experience. It is important to ensure there is enough time for providers to comply with changes and to implement data collection efforts in a way that is both considerate and non-intrusive for patients.

The PRT is concerned with the proposed "indirect estimation" concept introduced in the proposed rule. In cases of missing race and ethnicity data, CMS proposes to estimate race and ethnicity on language preference, first and last name matched to validated list of names correlated to specific national origin groups, and radical and ethnic composition of surrounding neighborhoods. We believe this "indirect estimation" method is not a reliable way to identify the race and ethnicity of a patient.

- **We encourage CMS to evaluate alternative methods that could capture this data and avoid increasing administrative burden.**

For example:

1. Utilize HIPAA transaction sets for data fields important for understanding social risk factors, such as race and ethnicity, sexual orientation, and gender identity. This would require updates to transaction and code sets by standards maintenance organizations. For example, data on race and ethnicity are typically collected during patient admission, during which eligibility transactions are made (such as 270/271). This self-reported data could be made a part of those transactions. The common working file (CWF) could be updated with this data (in the same manner as the file is currently updated for dates of each hospital admission for patients) thereby making this information available in subsequent eligibility transactions.

2. Collect this information from the beneficiary when he/she applies for Medicare coverage. This information can be updated if the information changes, but typically this information does not change. This could then be added into the Common Working File at the initiation of Medicare coverage and be available to all providers.

These approaches minimize the impact on both Medicare beneficiaries and providers.

In summary,

- **The PRT recommends that CMS either exclude records missing this vital demographic information from the risk-stratification or use an alternate method of capturing the patient demographics.**

- **The PRT encourages CMS to evaluate an alternative that could avoid increasing administrative burden: utilizing HIPAA transaction sets for data fields important for understanding social risk factors, such as race and ethnicity, sexual orientation, and gender identity.**

Proposal to Use Electronic File Submissions for Medical Record Requests

CMS proposes to make changes in the method and timeline for submission of records to CMS' Clinical Data Abstracting Center (CDAC). Health care facilities are accustomed to submitting records electronically for other CMS auditing initiatives (RACs, MACs, etc.), so the proposal to require electronic submission of the medical records is reasonable.

We do not, however (particularly during these trying times in health care delivery) support the proposal to reduce the submission time from 45 to 30 calendar days.

- **We request that CMS continue to allow 45 days for submission of medical records to CDAC.**

<u>OPPS Payment for Devices</u>

Expiration of Transitional Pass-Through Payments for Certain Devices

Under the OPPS, a category of devices is eligible for transitional pass-through payments for at least two years, but no more than three years. There currently are 11 device categories eligible for pass-through payment. Of these 11, the pass-through payment status of the device category for HCPCS code C1823 is scheduled to expire on December 31, 2021.

In response to the PHE's impact on data, and the proposal to use CY 2019 claims data for rate setting, CMS proposes to use its equitable adjustment authority to provide separate payment for C1823 for 4 quarters of CY 2022, ending on December 31, 2022. This change will allow CY 2021 claims data to inform CY 2023 rate-setting for the procedure reported with C1823.

The PRT appreciates CMS' recognition of the interrupted pass-through payment cycle and resulting efforts to close that gap by extending the time-frame due to the unforeseen PHE.

- **The PRT fully supports the additional year of pass-thorough status for HCPCS code C1823. The additional year of claims data will ensure adequate payment or services using this device when pass-through status expires.**

Proposed Pass-Through Payment for Devices

The PRT fully supports all of CMS' efforts to facilitate payment for the innovative delivery of care, including the most recently established an alternative pathway for device pass-through payments. Under this pathway, a medical device that is part of the FDA's Breakthrough Devices Program and has received marketing authorization (e.g., PMA, 510(k) clearance, or a De Novo classification request) will not have to submit information supporting the substantial clinical improvement criteria to determine device pass-through payment status.

CMS received eight applications for device pass-through consideration that are discussed in the 2022 OPP/ASC Proposed Rule. CMS needs to ensure that pass-through payment amounts adequately cover the cost of the device in order to ensure that Medicare beneficiaries have access to innovative services and reduce facilities' economic burdens. We noted that, many times, the cost of these new and innovative devices exceeds the current APC payment for the procedure alone.

- **The PRT fully supports CMS' approval of pass-through status for the Alternative Pathway Device Pass-Through applications received:**
  - RECELL
  - Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter)

- **The PRT fully supports CMS' approval of pass-through status for the Traditional Device Pass-Through applications received:**
  - AngelMed Guardian® System
  - BONEBRIDGE Bone Conduction Implant System
  - EluviaTM Drug-Eluting Vascular Stent System
  - CochlearTM Osia® 2 System
  - Pure-Vu® System
  - Xenocor Xenoscope™

- **The PRT requests that CMS not include these devices in the off-set payment. Often the device costs to hospitals exceed the current APC payment for the procedure alone.**

Device Edit Policy

In the CY 2015 OPPS/ASC Final Rule, CMS finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs is reported on the claim. In the CY 2016 Final Rule, CMS modified the policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. CMS also created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C code. CMS is not proposing any changes to this policy for CY 2022.

- **The PRT fully supports the continuation of the Device Edit Policy.**

Continuation of the policy will ensure that CMS has claims that fully reflect the cost of performing services. As these devices are often very costly, the omission of charging for these supplies will impact future rate setting.

The PRT continues to be concerned, however, that the removal of the edits requiring specific device codes be reported with specific procedure codes has the potential to cause device-to-procedure code mismatches, thus resulting in CMS not receiving accurate data. We believe that device offsets that are close to 100% of the procedure cost signal an erosion of the accuracy of data used for device-intensive procedure rate setting. We are also unclear how CMS uses C1889 on claims for rate setting. Therefore, we continue to request CMS re-establish specific device to procedure and procedure to device edits.

The PRT understands, from a previous HOPPS Panel meeting, that CMS' concern was about maintaining the edits when certain procedures do not have an associated device HCPCS code. We note that CMS has resolved this issue by creating an unspecified device HCPCS code and that there should not be barriers to implement more specific edits.

- **The PRT requests that CMS revert to the specific device-to-procedure edits to ensure accuracy of data that are reported by hospitals and captured by CMS.**

Effective for dates of service beginning on or after January 1, 2019, providers were able to bypass the claims-processing edit that requires a device HCPCS for the procedure. For certain device-intensive procedures that describe situations in which a device may not be required, providers may bypass the claims processing edits that require a device by reporting modifier "CG." CMS has not discussed if the agency intends to exclude these claims from rate setting in similar fashion to excluding claims with token charges. The PRT believes these claims should be excluded and not averaged into the claims with devices used to establish the APC payment rate for the procedure.

- **We ask CMS to exclude claims with the "CG" appended to a procedure from rate-setting.**

Radiation Oncology Model

The PRT offers the following high-level comments on the Radiation Oncology Model (RO Model). Many of our members are being impacted by the most recent natural disaster, Hurricane Ida, and all are in critical operational modes due to COVID-19's Delta surge. For these reasons, we must be brief in our comments; we simply cannot address all of the proposed changes to the RO Model.

- **First and foremost, the PRT urges CMS to delay implementation of the RO Model.**

We foresee an immediate state of jeopardy for both providers (from a financial standpoint) and

patients (from an access standpoint) if the RO Model proceeds in a mere four months. Even with the previous delays and further refinements CMS proposes, the RO Model still contains too many unresolved issues and provider risks to move forward with it in January, 2022. We implore CMS to defer the start of the RO Model until the calendar year following the end of the COVID-19 Public Health Emergency (PHE). All of the mandatory participants are dealing with unprecedented operational deficiencies and challenges stemming from the PHE, and simply should not be subjected to this.

- **If CMS does move forward, we urge the agency to do so with only a small voluntary group before rolling this out mandatorily to 30% of providers in the country.**

Regardless of when CMS moves forward, we appreciate and support the proposed removal of Liver Cancer from the cancer types included in the model. We also support the proposed removal of Brachytherapy from the services that are included in the RO Model.

The PRT additionally supports CMS' Extreme and Uncontrollable Circumstances (EUC) policy for the RO Model. (This policy would allow the agency to revise the model's performance period; grant certain exceptions to RO Model requirements to ensure delivery of safe and efficient health care; and revise the RO Model's payment methodology.) The proposal would support the PRT's earlier request for a launch delay during the PHE and any future surges. The entire country should be considered an "emergency area" during an "emergency period."

One of the unresolved issues is whether or not RO Model participant hospitals' data will be included in future OPPS rate-setting processes. If ROM payments are no longer OPPS payments, then CMS should exclude participant hospitals' data for the agency's APC payment rates for radiation oncology services. If that is the intent, the PRT requests that CMS address the potential for such an exclusion introducing unanticipated bias. Alternatively, if RO Model participants' data are not excluded from OPPS rate-setting, we request that CMS clarify whether the agency plans to use the no-pay claims to impute OPPS payment.

Additionally, the PRT requests CMS to clarify whether these model payments are considered OPPS payment, and whether they will be used during the RO Model period to recalibrate OPPS. We do not believe this would be appropriate as this is a "model" to test a new payment methodology. Until the methodology is made a permanent part of OPPS, the reduced payments to Model participants SHOULD NOT impact the radiation oncology payments made to all other OPPS providers.

- **The PRT requests that CMS clarify the numerous and unresolved questions about rate-setting and the RO Model's impact on the OPPS.**

We would also like to provide commentary on information presented during the August 24, 2021, RO Model Coding, Billing and Pricing Methodology Webinar.

To be paid the RO Model payment rates, hospitals are instructed to bill outpatient claims (Type of Bill 131) with the RO Model's HCPCS codes and the start and end of episode modifiers. The PRT is concerned about CMS' instructions on slide 27, which directs providers to ensure that the charges on these episodic claims equal or exceed the RO Model payment rate. This appears to imply that CMS will impose a "lesser of" payment methodology, which is inappropriate for a

prospective (i.e., non-fee schedule) payment rate. We believe that the true charges should only be present on the no pay claims, and that providers should report token charges for the SOE and EOE claims.

- **The PRT recommends that, instead, CMS instruct RO Model hospital participants to submit claims using token charges for the ROM HCPCS/Episodic modifier codes.**

- **We recommend that CMS allow the first and last episode services on the no pay claim to have different dates of service than the service month submission. Alternatively, CMS could allow hospitals to submit services charges as a second claim in addition to the SOE and EOE.**

We believe that, for proper charging and cost apportionment, providers should maintain their "pure charges" for the date-of-service specific CPT-code specific line-item charges and that those charges only be submitted on the no-pay claims. Any additional reporting of "artificial charges" to generate episodic payment will overstate, duplicate, or overinflate total Medicare charges, thus subsequently and inappropriately reducing providers' CCRs (not to mention violating the Provider Reimbursement Manual Part 1 instructions at Section 2202.4).

- **Finally, the PRT offers its support to the comments on the Proposed Rule that have been submitted by the American Society for Radiation Oncology (ASTRO) and the American Hospital Association (AHA).**

Attachment A: Provider Roundtable Members

Jennifer L. Artigue, RHIT, CCS
Corporate Director,
Health Information Management (HIM)
Franciscan Missionaries of Our Lady Health System
Baton Rouge, LA

Kathi L Austin, CPC, COC, CCP
Regional Director, Revenue Integrity
Audit – StL/SIL
SSM Health
Richmond Heights, MO

Kathy L. Dorale, RHIA, CCS, CCS-P
VP, Health Information Management
Avera Health
Sioux Falls, SD

Erika Hardy, RHIA, CCS, CDIP
Director Coding
Franciscan Missionaries of Our Lady
Health System
Lafayette, LA

Carole Hokeah, MS, RN, CPC, CCS, CSSGB
Senior Revenue Guardian
University of Florida Health Shands
Gainesville, FL

Vicki McElarney, RN, MBA, FACHE, COC *
Consultant
Craneware
New Brunswick, NJ

Kenneth Mitchell, BSBA, MM
Manager, Medicare and Medicaid Billing
and Compliance
Oregon Health & Science University
Portland, OR

Kathy Noorbakhsh, BSN, CPC, COC
Director, Corporate Compliance and
Revenue Analysis
University of Pittsburgh Medical Center
Pittsburgh, PA

Terri Rinker, MT (ASCP), MHA (Chair)
Executive Director, Revenue Cycle Performance
Community Health Network
Indianapolis, IN

Valerie Rinkle, MPA *
Regulatory Specialist
HCPro
Medford, OR

Anna Santoro, MBA, CCS, CCS-P, RCC
Director of Revenue Integrity
Hartford Healthcare
Newington, CT

John Settlemyer, MBA, MHA, CPC
Assistant Vice President,
Revenue Management / CDM Support
Atrium Health
Charlotte, NC

Angela Simmons, CPA
Vice President,
Finance – Revenue and Reimbursement
Vanderbilt University Medical Center
Nashville, TN

Denise Williams, COC, CHRI *
Senior Vice President of Revenue
Integrity Services
REVANT SOLUTIONS
Cane Ridge, TN

Julianne Wolf, RN
RI Charge Integrity and Pricing Manager
Erlanger Health System
975 E. Third St
Chattanooga, TN 37403

* *Non-voting past PRT member*

Updated July 2021