Atrium Health (GA, NC, SC)

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

Central Florida Health (FL)

Community Hospital Anderson (IN)

Franciscan Missionaries of Our Lady Health System (LA)

Hartford Healthcare (CT)

Kaiser Permanente, Southern California Permanente Medical Group (CA)

SSM Health (IL, MO, OK, WI)

University of Pittsburgh Medical Center (PA, NY)

September 26, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016

Re: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates CMS-1717-P

Dear Ms. Verma,

The Provider Roundtable (PRT) submits the following comments on the CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates, as published in the *Federal Register*.

The Provider Roundtable (PRT) includes representatives from 13 different 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 members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual OPPS policymaking process. We appreciate the opportunity to provide our comments to CMS. 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

PAYMENT FOR HOSPITAL OUTPATIENT VISITS AND CRITICAL CARE SERVICES

III. PROPOSED OPPS AMBULATORY PAYMENT CLASSIFICATION (APC) GROUP POLICIES

APC ASSIGNMENTS OPEN FOR COMMENT

The PRT recommends that CMS adopt the recommendation made at the APC Panel Meeting regarding services represented by HCPCS Code C9755 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed).

Specifically, we recommend that CMS reassign HCPCS code C9755 from APC 5193 (Level 4 Endovascular Procedures EVASC) to APC 5194 (Level 4 Endovascular Procedures EVASC). We also believe that this supports the heightened awareness from CMS regarding ESRD and Kidney Health being noted as a top public health priority.

- **The PRT recommends that CMS reassign HCPCS code C9755 from APC 5193 (Level 4 Endovascular Procedures EVASC) to APC 5194 (Level 4 Endovascular Procedures EVASC).**

III. B. NEW TECHNOLOGY APCs — FRACTIONAL FLOW RESERVE DERIVED FROM COMPUTED TOMOGRAPHY (FFR-CT)

In the 2018 OPPS Final Rule, based on PRT and other commenters' feedback, CMS assigned CPT® 0503T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model*) to New Technology APC 1516, paid at $1450.50.

FFR-CT is a major technological advancement for non-interventional diagnosis and potential treatment pathways for Coronary Artery Disease (CAD). This APC assignment was, and continues to be, appropriate because the invoice cost of FFR-CT alone, as purchased from HeartFlow, is approximately $1500.

As the PRT stated in 2018, FFR-CT can assess CAD more effectively than traditional coronary CT angiography. Approximately half of the patients referred to coronary angiography to evaluate suspected CAD are found *not* to have the condition. Hence, FFR-CT enables the provider to more accurately diagnose patients, select the most appropriate course of treatment, minimize unnecessary procedures, enhance patient care, and reduce overall expenses.

For 2020, CMS proposes to reassign 0503T to APC 1509, with a payment rate of $750.50, stating that is doing so: "in order to adjust the payment rate to better reflect the cost for the service." The PRT believes this proposal makes no sense, considering that the invoice cost to purchase the analytical service remains the same and has not decreased since 2018.

The true issue, which has been noted and discussed at length on many occasions by many stakeholders, is in the claims data received by CMS. This proposed payment reduction highlights a perpetual, fundamental problem with CMS' current process for developing geometric mean costs. It also underscores the importance of the difficulties, inaccuracies, and inefficiencies of the costing (i.e. CCRs) process in developing prospective payments. The fact is, **some providers, for whatever reason (i.e., misinformation, transparency, to name a few), do not appropriately apply markups to costs to represent accurate gross patient charges**.

CMS has provided explicit instruction about this, stating: "*We believe that hospitals have the ability to set charges for items properly so that charges converted to costs can appropriately account fully for their acquisition and overhead costs…"* (see <70 *Fed. Reg.* 68654, 2006 OPPS Final Rule). Nonetheless, it is obvious, based on the claims data, that many providers have not reviewed their internal processes to ensure they follow CMS' guidance. It may be that some providers have a fundamental misunderstanding regarding purchased services ("under arrangement") and fail to apply an appropriate markup to these services.

The PRT strongly recommends that CMS leave 0503T in APC 1516 indefinitely. Doing so will allow the agency to educate stakeholders about how to appropriately develop a gross charge that reflects the full costs of providing this cutting-edge and medically necessary service.
It is the PRT's understanding that HeartFlow has offered CMS numerous clinical and academic studies that highlight FFR-CT's efficacy and benefits. For instance, the use of the technology has resulted in physician's ability to rule out CAD medically (rather than interventionally) and to identify the appropriate patients for revascularization with FFR-CT before the patient goes to the Cath Lab. Data from more than 5,000 patients shows that 70 percent of patients who were sent to the cath lab based on FFR-CT assessment undergo revascularization, compared to 45 percent based on stress testing. This confirms that physicians are effectively able to identify the appropriate patients for revascularization with FFR-CT *before* the patient gets to the Cath Lab.

We refer CMS to the PLATFORM study, where the use of FFR-CT demonstrated a savings of $3,109 per patient at just one year, based on Medicare reimbursement rates and inclusive of a $1500 cost for FFR-CT. These savings were realized immediately via deferral of an invasive procedure.[1] The technology has proven substantial cost savings to both patients and the Medicare program, due to the avoidance of unnecessary invasive diagnostic procedures.

The proposed APC rate ($750.50) is significantly less than the cost of the resources involved in providing FFR-CT. The use and adoption of FFR-CT is in its infancy, and the further adoption of the technology will be significantly limited—if not totally abandoned—if CMS proceeds with its proposal, thereby ensuring inadequate payment for the procedure. CMS encourages and supports

[1] Douglas, P.S., et al., 1-Year Outcomes of FFRCT-Guided Care in Patients With Suspected Coronary Disease: The PLATFORM Study. *J Am Coll Cardiol,* 2016. 68(5): p. 435-45.

the use of the most clinically appropriate and cost-efficient care; the PRT believes that the agency would agree that it is short-sighted to sabotage the adoption of such technology by reducing the payment to half the invoice cost.

- **The PRT recommends that CMS retain 0503T in current New Technology APC 1516.**

IV.A. PASS-THROUGH PAYMENTS FOR DEVICES

Beginning with applications for pass-through payment on or after January 1, 2020, CMS proposes to establish an alternative pathway for one criterion used to evaluate the device. If a medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization (e.g., PMA, 510(k) clearance, or the granting of a De Novo classification request), it will not have to submit information to support the substantial clinical improvement criteria for the purposes of determining device pass-through payment status.

The PRT is pleased to provide comment to CMS regarding this proposal. As hospital providers our main concern is being able to provide the best care possible to the patients in our community and to be paid fairly for those services. We appreciate and support CMS's efforts to "reduce barriers to healthcare innovation." We recognize the duplicative efforts required of device manufacturers to gain approvals through both the FDA and through CMS. We fully support CMS recognizing the FDA's expedited programs to reduce the time and effort required to gain the necessary approvals.

We are very excited CMS is proposing changes to the device approval process. We encourage CMS to investigate the possibility of doing the same for new drugs. We understand that the Administration is concerned about drug prices (appendix A 1.O), and we as providers who purchase those drugs at high prices share the same concerns. We also understand why CMS distinguishes between drugs and devices in these processes. However, it is deeply troubling there is not a way to approve new drugs needed for life saving care in a more efficient manner and address the cost of drugs at the same time. Would drug manufacturers be willing to reduce their price in exchange for not having to go through a duplicative process at the FDA and CMS? The drug manufacturer's expense would be reduced because they would see some economies to scale for FDA approval (or some portion thereof) being acknowledged by CMS.

CMS would be able pay less for a newly approved drug and our friends and family get needed medication at a reasonable cost. Because we do understand the distinction between drugs and devices, it may be that the process for expediting approval of new drugs is not as simple as adopting part of the FDA approval process. If this is the case, the PRT strongly encourages CMS to look for another option to expedite the pass-through application process for drugs.

- **The PRT supports CMS' recognition of the FDA's Breakthrough Devices Program to support the substantial clinical improvement criteria for obtaining pass-through status.**

- **The PRT encourages CMS to consider options to expedite the pass-through application process for new drugs as well.**

V. PROPOSED OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

V.6. CY 2020 OPPS PAYMENT METHODOLOGY FOR 340B PURCHASED DRUGS

CMS is soliciting public input on how to formulate a solution in case a court should, once again, find in favor of the American Hospital Association (AHA) in the case of *AHA et al. v. Azar et al*. The PRT agrees with CMS and the US District Court about the Medicare payment system's complexity. We also agree that finding a solution to correct the payments is extremely difficult. The PRT believes that continuing to pay 340B hospitals average sales price minus 22.5 percent (ASP-22.5%) for another year will only make reaching a solution more difficult. It will, moreover, continue to harm 340B hospitals in the event that the ruling favors the AHA again.

- **The PRT urges CMS to stop making the situation worse by paying 340B hospitals ASP-22.5%. Instead, drug reimbursement should be the same for 340B hospitals as non-340B hospitals starting on January 1, 2020. The PRT also requests that Medicare Advantage Plans be instructed to do the same.**

The PRT also notes that CMS collects interest when hospitals are overpaid—we believe that the reverse should also be true. Hospitals should receive interest when they are owned funds from CMS. Continuing to pay ASP-22.5% only increases the interest that would be owed to hospitals once the situation has been addressed and resolved.

While the PRT does not have specific recommendations about how CMS should repay the funds owed to hospitals, we do have three specific guidelines that CMS should follow when making a recommendation to the court for a remedy:

- **The PRT firmly believes that 340B hospitals should be made whole. The 340B program was intended to provide additional resources to hospitals so they can provide services to the disproportionate number of low-income, vulnerable patients they treat. The program was not intended to be used by CMS to redistribute monies to other entities. The PRT urges CMS to make 340B hospitals whole via one, lump sum payment.**

- **The PRT recommends that 340B hospitals receive interest on the money owed to them. CMS has made an underpayment to hospitals and should pay interest on the amount owed back to the facilities.**

- **Hospitals should not be further burdened in order to obtain monies due to them. CMS should repay funds to providers that used a -JG modifier, which indicates that the drug was purchased under the 340B program. The amount of money returned should be reflective of the number of HCPCS codes submitted with the -JG modifier**

and the associated reimbursement. Providers should not have to resubmit claims or go through additional appeal processes.

CMS also requests comments on what an appropriate payment for 340B drugs should be, moving forward, and suggested ASP+3%. The PRT cannot accept this recommendation, since it is far too low. Reimbursement should be at least ASP+6%. CMS continues to believe that, because hospitals pay less for 340B drugs, the agency should reimburse these facilities a lower amount for these drugs. This view overlooks the fact that the 340B program, which was created with bipartisan support in 1992, exists because Congress intended the program to assist hospitals to care for low-income and other vulnerable patients. The discounts received by 340B providers are related to the care they give to vulnerable populations—it should not be redirected by CMS to other uses.

- **The PRT believes that any payment less than ASP+6% for 340B drugs is unacceptable.**

V. 7.PROPOSED HIGH COST/LOW COST THRESHOLD FOR PACKAGED SKIN SUBSTITUTES

In the CY 2014 OPPS/ASC Final Rule, CMS unconditionally packaged skin substitute products into their respective surgical procedures. Part of that packaging methodology included dividing skin substitutes into two groups: high-cost and low-cost. This assignment into group was determined based on Geometric Mean Costs (GMC) or the Products per Day cost (PDC).

CMS proposes to continue with the high-cost/low-cost categories for CY 2020. CMS' proposal includes assigning all skin substitute products to a high-cost category in 2020 if they were assigned to a high-cost group in 2019, regardless of whether or not the product exceeded the GMS or PDC threshold. The PRT believes that the current high-cost/low-cost methodology incentives vendors to raise prices in order to keep the skin substitute assigned to the high-cost category.

The PRT is pleased to again offer comments regarding a new methodology for payment of skin substitute procedures and services. We understand that the OPPS is a prospective payment system and that CMS desires to move to more episode-based payment under the OPPS. As we have noted in the past, there are many negatives to an episode-based payment structure for skin substitute procedures:

- Wound care is very complex and variable for an episode-based payment methodology;
- Due to the nature of wound care, the definition of an "episode" becomes more complicated when multiple wounds are treated;
- The methodology discourages use of higher-cost products, which could limit new product innovations.

The PRT opposes implementation of an episode-based payment methodology for wound care involving skin substitutes. Our opposition stems from the reasons listed above (and submitted by the PRT in last year's comments), and the fact that CMS has little experience with episode-based

payments for services, which can be lengthy and complicated, as these patients typically have multiple comorbidities.

CMS seeks comments on defining an episode of care as being "between 4 and 12 weeks," and establishing a payment methodology for this time frame. Under this option, CMS would assign skin substitute graft procedure CPT and HCPCS codes to comprehensive APCs with the option for complexity adjustments to account for more resource intensive cases.

The PRT supports the establishment of Comprehensive APCs for skin substitute procedures when the Comprehensive APC is based on a per-encounter, single date-of-service, but **not** over a period of time as an episode. We note that, in establishing single episode C-APC payments for these procedures, the procedure add-on codes would create a complexity adjustment for skin substitute applications by accounting for wound size. The PRT recommends that CMS assign "J1" status indicators to the add-on skin substitute procedure codes as well as the skin substitute product codes. This will result in more accurate payment and also incentivize providers to use the most cost-effective product for the clinical indication.

CMS is also soliciting comments for a future payment methodology that would eliminate high-cost and low-cost skin substitutes, resulting in a single APC for skin substitute application procedures, reported with CPT codes 15271 - 15278. The payment rate would be based on the GMC of all procedures for a given CPT code.

The PRT opposes this methodology for the following reasons:
1. Providers would be incentivized to reduce the use of higher-cost products, which could affect quality of care;
2. Manufacturers would be discouraged from developing innovative new skin substitute products; and
3. Providers would be reluctant to treat more complex wounds, as it would be costlier.

- **The PRT recommends that CMS discontinue the high-cost/low-cost payment methodology. We urge CMS to implement Comprehensive APC payments for skin substitute procedures with complexity adjustments created through the use of add-on codes. We recommend that the C-APC be encounter based rather than episode-based.**

IX. PROPOSED PROCEDURES THAT WOULD BE PAID ONLY AS INPATIENT PROCEDURES

As we have stated in our comment letters for many years, the PRT recommends that the Inpatient Only (IPO) List be eliminated. According to the CY2012 OPPS/ASC Final Rule, CMS created the IPO List to specify services for which CMS believes inpatient admission is required for a Medicare beneficiary, and the hospital is reimbursed only when the services are provided in the inpatient setting. This specification is intended to be based on the procedure's nature, the patient's underlying physical condition, and/or the need for at least 24 hours of post-operative recovery time or monitoring before the patient can be safely discharged.

The decision regarding the most appropriate care setting for a medically necessary surgical procedure is a complex medical judgment made by the physician based on the patient's clinical condition and existing comorbidities. The PRT strongly feels that the appropriate level of care and site for delivering care should be determined based on the *physician's assessment of the individual patient's clinical state*. The physician is best-qualified to make this determination. By requiring certain procedures to be provided on an inpatient basis, CMS removes the physicians' opportunity to personalize patient care to the most appropriate setting (i.e., inpatient or outpatient).

Decisions about patient status should be based upon the physician's clinical judgment and physician's order, not the payment status. Patient status is not necessarily tied directly to the procedure to be performed; rather, it depends upon the patient's clinical condition and the level of post-operative care required by that patient. Further, this would require the physician/practitioner to document the reasons for IP vs. OP status, instead of relying on the IPO list or hospital staff explaining why an IP order is required. This methodology will promote better documentation from the clinicians and encourage consistency across documentation practices/habits.

The IPO List presents an unnecessary administrative burden and financial impact for hospitals. The designation of certain procedures as Inpatient-Only provides numerous operational challenges to hospitals, as well. It requires hospitals to provide extensive education and official guidance to both medical staff and hospital schedulers, using the IPO list (Addendum E). Because the IPO list is not applicable on the professional side, it is very unsettling for physicians and other providers to be told by hospitals that an IP order is needed for the facility to be reimbursed for the procedure. They have a hard time accepting that the procedure is what is driving the patient status.

While hospitals have implemented processes in an effort to identify these procedures in advance, the reality is, not every IPO procedure can be identified prior to surgery because it is events during the procedure that change the procedure to one that is on the IPO list. The physician dictates the operative report for a procedure that, based on the physician's determination for the individual patient, was safely performed as an outpatient. When the record is coded (i.e., after the end of the episode of care and patient discharge), based on the operative documentation, the code that corresponds to the procedure is determined on the IPO List. Because the procedure was performed as an outpatient, based on the physician's clinical determination, there is no opportunity to explain to the physician that the procedure was actually on the IPO list and an inpatient order was required.

For example, CPT 43281 describes a hernia repair without mesh, and is not on the IPO List; CPT 43282 describes hernia repair *with* mesh. During the hernia repair, the physician determines that mesh is needed, the clinical professionals involved in the procedure are unlikely to recognize that this change will have a downstream effect on the patient status and facility reimbursement. CPT codes are assigned to a claim after the patient is discharged and based upon the operative report. In the scenario described, proper coding would lead to denial of payment for a medically necessary procedure provided at the level of patient care determined to be appropriate by the physician, based upon the patient's clinical condition and the physician's medical judgment.

Since CMS does not allow retroactive orders, the hospital will have no opportunity to receive payment for the medically necessary services provided.

- **The PRT urges CMS to eliminate the Inpatient Only (IPO) List.**

X. PROPOSED NONRECURRING POLICY CHANGES

X.A. PROPOSED CHANGES IN THE LEVEL OF SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS

The PRT appreciates CMS's willingness to look at this provider requirement. We do not believe that it is necessary for CMS to define separate levels of physician supervision. As part of the Medicare Conditions of Participation (CoPs), hospitals are required to protect the health and safety of their patients. Hospitals have some flexibility to determine how this requirement is achieved, based on their individual situations. This flexibility allows hospitals to provide safe, local access to care based on their specific situation, the potential risk from the service being provided, the facility's liability insurance requirements, medical staff's bylaws, and the resources the provider has with which to provide supervision. Because the CoPs extend to *all* hospital services—including chemotherapy, radiation therapy and other higher-risk procedures—the PRT does not believe any separate physician supervision requirements are needed.

Technology continues to advance and make procedures safer. We are concerned that, should CMS identify "risky" procedures that require direct supervision (for example, chemotherapy or radiation therapy), a separate process would be required to change these procedures from direct to general supervision in the future, when the technology is available that no longer indicates direct supervision is required.

In addition, if CMS requires some procedures to have direct physician supervision, a two-tiered system of supervision will continue unless issues with availability of providers to provide direct supervision in Critical Access Hospitals (CAH) are addressed. This is exactly the two-tiered system that CMS wishes to resolve.

Also, as CMS noted in the proposed rule, the agency has not received any complaints or concerns about general physician supervision that occurs in CAHs. The PRT believes that having separate levels of physician supervision for different outpatient services creates significant operational issues for providers, increases health system costs, and decreases access to care without providing any benefits to the patient or the quality of care received.

If this proposal is finalized, we urge CMS to explicitly clarify that the *minimum level* of supervision is being changed from direct to general. We recommend that CMS also explicitly clarify that physician supervision is not being eliminated and is still required for outpatient services.

- **The PRT supports CMS's proposal to change the level of supervision from "direct supervision" to "general supervision," but recommend that CMS amend the proposal to state that general supervision is the *minimum* required for all hospital outpatient departments.**

X.B. SHORT INPATIENT HOSPITAL STAYS

Two Midnight Rule; Short Inpatient Hospital Stays

For CY 2020, CMS is proposing to establish a 1-year exemption from Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) referrals to Recovery Audit Contractors (RACs) and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on January 1, 2020.

The PRT appreciates CMS establishing this 1-year exemption from BFCC–QIO referrals to the RACs for review of patient status for procedures that are removed from the IPO list. We propose that CMS establish an alternate progression of review. The first year after a code comes off the IP only list, it is exempt from QIO review as well as RAC. The second year, the exemption from RAC review continues to allow a two-year period for operational changes and complete education of the clinical staff. As already noted, this can be a difficult concept for professionals to grasp because there is no corresponding requirement under the MPFS.

It is important to reiterate our strong belief that the appropriate level of care and site for delivering care should be determined based on the *physician's assessment of the individual patient's clinical state*.

- **The PRT strongly encourages and recommends that CMS eliminate the Inpatient Only procedure list and allow the patient status to be determined by the physician based on the individual patient's clinical condition.**

- **If CMS continues with the Inpatient Only list, the PRT requests that CMS exempt site of service reviews by the QIO for one year and by the RAC for two years to allow time for operational changes and complete education of clinical staff.**

X.C. METHOD TO CONTROL UNNECESSARY INCREASES IN THE VOLUME OF CLINIC VISIT SERVICES FURNISHED IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS (PBDS)

Reduction in Payment for Excepted Off-Campus Outpatient Hospital Visit Code G0463

For CY 2020, CMS announces the continuation of its two-year phase-in of the reduction to payment for Hospital Outpatient Visit HCPCS Code G0463 (with modifier -PO) to 40% of the applicable OPPS APC payment rate. The PRT reiterates our continued, strong opposition to this reduction. We continue to believe that CMS is circumventing Congressional intent (i.e. Section

603 of the Bipartisan Budget Act of 2015) by targeting services provided at "grandfathered" off-campus provider-based departments, under the guise of "volume control." We believe that CMS should reverse course and respect Congress' intentions.

We also note that on September 17th, U.S. District Court Judge Rosemary M. Collyer granted plaintiffs' motion to vacate the 2019 OPPS Final Rule, denied a cross-motion filed by CMS, and remanded the matter for consideration of future remedies. It is now *legal precedent* that CMS exceeded its statutory authority in finalizing this policy. For this reason, CMS *must* halt the phased reduction and instead begin to formulate a plan to reinstate full hospital payments for G0463-PO which according to the court's instructions must be prepared and released by October 1, 2019.

This politically motivated policy suppresses appropriate access to care. It is likely to force hospitals to close off-campus locations altogether, due to the policy's unsustainable financial consequences.

Consistent with CMS' intent, guidance and regulation, off-campus locations were initially developed to bring physician-ordered services closer to the patients we serve. The unfounded reimbursement reduction will force providers to move services back on-campus, which may ultimately hamper patient access to care and force some patients to forgo needed care. It is extremely disappointing that CMS' current leadership, which purports to be an advocate for patients and consumers, is pursuing a decision that sabotages the very services patients need to access in their communities.

- **Based on the U.S. District Court ruling as this being an action outside the scope of CMS' authority, CMS must reverse this payment structure immediately.**

XIV. REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

The PRT congratulates CMS on its 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. We are pleased that CMS has not introduced any new measures in this OPPS Proposed Rule for CY 2020.

The PRT agrees with the proposal to remove OP-33 (External Beam Radiotherapy for bone metastasis). We generally do not support web-based (formerly "chart abstracted") measures, because of their significant impact on operations. In our comments on the CY19 Proposed OPPS Rule, we indicated that we doubted that this specific measure served the broad purpose of analyzing the quality of care provided to oncology patients in the outpatient setting and that Tumor Registry data might serve as a good source for needed data. We recommended removal of this measure at that time, and appreciate that CMS is now proposing to remove it. We agree that

this measure is in alignment with "Factor 8," indicating that costs associated with the measure outweigh benefit of its continued use.

The PRT understands that CMS is proposing to delay removal until the CY 2022 payment determination, rather than conducting more immediate removal for CY 2021 payment determination. CMS notes that it is doing so in order to "be sensitive to facilities' planning and operational procedures."

While we are thankful for CMS's consideration of our operational burden, we very strongly support removal of this measure for the 2021 payment determination. It is unclear why providers should be required to continue reporting this measure for another year when CMS has acknowledged the lack of benefit. No improvement to outpatient quality of care will be gained by continuing the administrative chart-abstraction burden for another year.

In addition, we note that, while intense resources and system programming are required to ADD or REVISE a chart-abstracted measure for reporting, there is only limited burden to STOP reporting a measure.

- **The PRT urges CMS to implement the removal of measure OP-33 for CY 2020.**

The PRT has significant concern about the proposed measures being presented for future consideration.

"Patient Burn"; "Patient Fall"; and "Wrong Site, Wrong Side, Wrong Procedure, Wrong implant" were previously used in the ASCQR program, but the NQF removed their endorsement for these measures in the ASCQR program. CMS actually suspended collection of data on these measures in the ASCQR program due to the agency's concerns about the complexity of the data submission method.

It is unclear why CMS is now proposing to add these measures to the OQR program, when the issues in ASCQR program have not been resolved?

- **The PRT urges CMS not to implement these measures for CY 2020.**

In the Proposed Rule, CMS seeks comment on data submission methods, while also clearly acknowledging that the proposed, alternate submission measures "*would add burden*" for providers. The PRT suggests that CMS identify a less burdensome data collection method, then test the method in the Ambulatory Surgery Center (ASC) program—where the measures still exist. Only after the data collection method is assessed and found to be adequate, should it be considered for addition to the OQR.

- **The PRT recommends that CMS first identify and test data collection methods in the ASC setting, before applying them to the OQR.**

The most concerning of the proposed measures is the "All-Cause Hospital Transfer/Admission" measure. This measure may make sense for an ASC, which have a specific list of procedures that may be performed and, by nature of the ASC environment, 100% of the procedures are expected

to remain outpatient. If that expectation was not valid, the physician would not be performing the procedure in the ASC setting. However, this same concept does not apply to hospital outpatients. While patients are regularly admitted as inpatients (IP), it does not always occur as a result of complications, as suggested in the Proposed Rule. Some patients are admitted after hospital outpatient surgery for monitoring, while others have a clinical diagnosis that cause them to meet IP criteria.

Hospitals are also subject to the Inpatient-only List, which is not applicable in an ASC. If a patient is originally scheduled to have an outpatient procedure but, it changes once the procedure begins due to clinical conditions and/or findings, the procedure that is actually performed may be on the Inpatient-only List—in this case, the patient must be admitted as an inpatient. This in no way suggests that anything adverse occurred; only that the procedure actually performed is on the Inpatient-only List.

CMS "*adopted this measure for ASCs because the transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error, or other unplanned negative patient outcome*" and that "*acute intervention may be necessary*."

This measure seems very appropriate and logical for the ASC setting, since those facilities are not connected to a hospital—but is <u>not</u> reasonable for hospital outpatients. In the hospital outpatient setting, CMS would never obtain these data, since an OPPS claim would never be submitted. If a patient who is undergoing a hospital outpatient surgery is admitted as an IP post-operatively, the outpatient encounter would be rolled into the inpatient stay.

- **The PRT recommends that CMS not implement the "All-Cause Hospital Transfer/Admission" measure for hospital facilities.**

The PRT once again voices our opposition to measures for which the quality of submitted data is unreliable and the data are, therefore, meaningless. Several of these measures are open to interpretation, and the provider community lacks clarity on the definitions within the measures. The PRT recommends that CMS educate providers on the appropriate use. We urge CMS to carefully review the following measures:

<u>OP-22 Left Without Being Seen</u>

The PRT continues to be concerned with this measure due to the differences in record-keeping practices at facilities for patients who leave prior to being seen. At many facilities, if a patient leaves prior to registration, there is no official medical record for that patient. If CMS maintains this measure, we recommend that the agency define "being seen." At what point would a patient be considered "left without being seen"—before or after triage? The PRT notes that there are data integrity issues with reporting this measure due to variability in interpretation.

<u>OP-29 Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients</u>

The PRT believes the large number of colonoscopies being performed results from the age of the Medicare population, rather than over-utilization. Since these data are already collected through

PQRS #320, the PRT objects it being maintained as a hospital indicator. Surgeries and endoscopies are scheduled and controlled by the surgeon and his or her office staff. This indicator is a measure of quality of the physician, not the facility where the procedure is performed.

In addition, the initial and/or follow-up colonoscopy may occur in the physician office-based endoscopy suite and not in the hospital's outpatient department. In the Proposed Rule's section discussing the removal of OP-33, CMS acknowledges, *"Hospital Outpatient Departments do not have access to physician billing data, and so it is not operationally feasible*." This same issue exists when hospitals attempt to comply with measure OP-29. The lack of access to physician medical records prohibits hospitals to have the data necessary to determine follow-up intervals.

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. The patient does not return to the hospital 90 days post-surgery. As discussed above, hospitals' do not have access to physician's office records and obtaining this information is impossible and inappropriate. It is unclear how or why a hospital would gather data regarding the patient's visual acuity showing improvement within 90 days after surgery. This outcome is a measurement of the surgeon's skills, but does not reflect in any way on the quality of care provided by the hospital. The measure is already included as a physician quality indicator (PQRS #192) and should not be used to measure hospital quality.

- **In summary, the PRT recommends CMS remove measure OP-33 for CY 2020, and not implement the following measures: "Patient Burn;" "Patient Fall;" "Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant;" "All-Cause Hospital Transfer/Admission;" OP-22 (Left Without Being Seen); OP-29 (Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients); and OP-31 (Cataracts: Improvement in Patient's Visual Function within 90 Days following Cataract Surgery).**

Finally, the PRT appreciates the continued delay of OAS CAHPS Survey Measures. We remain concerned about the operational burden and repetitive nature of this extensive and complex outpatient survey.

- **The PRT urges CMS to allow only voluntary reporting through the upcoming calendar year.**

XVI. PROPOSED REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES

Beginning January 1, 2019, hospitals were required to publicly report a listing of standard charges, via the Internet in a machine-readable format. From the PRT's perspective, this initiative was largely ineffective. Despite the enormous amount of media hype and political rhetoric that surrounded the effort, patients today are no closer to understanding the hospital

revenue cycle than they were before the requirement to publish this information.

In response to the *Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First* (June 24, 2019), CMS now proposes to greatly expand requirements for facilities to post their standard charges.

There are two key aspects of CMS' latest proposal: a public disclosure requirement, and requirement for a consumer-friendly display of 300 shoppable services. We describe our concerns with these, below.

1. Public Disclosure Requirement

CMS proposes to require hospital providers to publish a single, comprehensive, machine-readable master list of all "items and services" provided by the hospital to a patient in connection with an inpatient admission or outpatient department visit for which a standard charge is established. (The term "items and services" includes both individual line-item charges and "service packages.") CMS defines two types of "standard charges" that must be made public: "gross charges" and "payer-specific negotiated charges," along with various coding data elements. Each third-party payer's name and the associated negotiated amount for each payer for each item, service, or "package," for both Inpatient and Outpatient services must be displayed. The PRT strongly believes that the Proposed Rule's provisions are overly prescriptive, complex, and burdensome.

Many of the coding elements and concepts CMS describes do not exist in, or are not maintained in, hospital chargemasters (i.e. they may flow to posted charges or bills via mechanisms such as interfaces from other ancillary systems). Each and every proposed data element will add complexity to the file structure. Each and every one of these data elements will also have to be carefully and fully explained to the consumer.

The PRT member hospitals estimate that these file constructs could quickly reach more than several hundred columns: a column for each of CMS's required data elements, plus a column for each third-party contract, for both inpatients and outpatients. We also estimate that line-item charge or "service bundles" data will need to be populated in more than 100,000 rows. This file construct may result in tens of millions of data element fields. Our own group of experts can envision many variations or nuances of file constructs other than the example above that may be interpreted (or misinterpreted) by hospitals.

It will be virtually impossible for providers to build a file of this size and complexity, as it will necessitate a manual, labor-intensive process. And, navigating a file of this size and complexity is certain to quickly overwhelm consumers. We also believe that such enormous files are likely to crash the consumer's computer and/or the hospital's website.

CMS states that only a few "clicks" should be involved in reaching the proposed standard charge listing. But, no number of "clicks"—either 1 or 50—will simplify or solve the fundamental problem, which is the complexity inherent in attempting to compare hospital services.

In fact, creating truly comparable files is *only* possible if CMS launches and manages (or subcontracts) its own data portal with file constructs that are tightly defined and maintained so that every provider submits consistent information. This type of national repository, similar to Hospital Compare, is the only reasonable way to ensure that the comparison CMS desires for consumers actually happens. No matter how much instruction CMS gives, comparing files across individual hospital websites, hospital by hospital, is a challenge no ordinary consumer will be able to accomplish. Sadly, the comparison is inevitably going to be performed by sophisticated insurance company analysts or software companies that are eager to gain some sort of competitive advantage, using information they do not fully understand. This scenario will be detrimental for patients, clinicians, hospitals, and CMS.

CMS further proposes to restrict any attempt to register site users by prohibiting the collection of personal, identifying information from those accessing the public disclosure information. We find it noteworthy that CMS's own website (*Medicare.gov*) requires visitors to provide personal, identifying information (such as date of birth) when reviewing options for Medicare health plans. It is ironic that CMS objects to hospitals' obtaining the very information that the agency itself requires in order for consumers to compare health plan prices.

The PRT is also troubled by the proposal that hospitals that employ their physicians must report both the physician's and the hospital's charges and payer-specific charges. Not all facilities employ their physicians, so some of the public disclosures will include physician services, while others will not. This may create an unfair disadvantage for facilities with employed physicians, since their disclosure information will appear to be more expensive the information provided by hospitals that do not employee physicians.

2. Consumer-friendly display for 300 shoppable services

CMS' second reporting requirement concerns 300 "shoppable services." CMS proposes a requirement that hospitals display, in tandem, all associated usual and customary ancillary service charges (including "payer-specific negotiated charges") that are—or can be—provided in conjunction with the primary shoppable service.

CMS leaves it to hospitals to interpret what this means; our understanding is that CMS expects facilities to break the information in the "master file" down into hundreds of unique files organized by CPT/HCPCS or DRG. All of the complexities we describe above are applicable here and are amplified.

The PRT notes that there are several codes in the list that are not reported by hospitals, making this proposal untenable. We also strongly believe that the list of 300 services is unworkable in the extreme.

Health care is complex, dynamic, a matter of life and death, and simply ill-suited for implementing service estimations as a common commodity. Compare hospital services to services and repairs to an automobile. When you receive an estimate on car repairs, it is reasonable to be told, up-front, the expected costs. If something changes, work stops while the consumer is notified that additional services are needed, and permission to proceed is granted by the consumer. A car can "wait" until the owner is notified and approves (or declines) the repairs.

But, with healthcare, it is not always possible to predict everything that may happen during the course of care. For example, a patient who is under anesthesia having an abdominal laparoscopy cannot be brought out of anesthesia to tell him/her that he/she has a bowel adhesion and small cyst and will need additional services, including release of the adhesion, cyst removal, pathology review of the cyst, etc. Patients can be counseled up-front about common complications via the consent process, but it is impossible to predict every possible clinical scenario that could occur. Moreover, patients will not want to pay out-of-pocket "up-front" for services that may or may not be needed. All of these factors add to the complexity of the healthcare revenue cycle communication and management.

Most hospitals strive to offer patients clear and accurate information about the patient's potential out-of-pocket costs. This includes patients who are asking about costs prior to a procedure and patients who have scheduled services at the hospital. It certainly is in the hospitals' best interest to do so, because hospitals are committed to improving and providing accurate estimates of patient liability. Many information technology vendors and hospitals are currently developing sophisticated tools that interact electronically with the major insurance payers to provide current information about a patient's out-of-pocket maximums and unmet deductibles. This information is *only* available from the health insurers. Without this critical information, hospitals cannot provide accurate information about what the patient will actually owe. This is the case because hospitals are unlikely to know: 1) what other healthcare services have been sought at other locations/facilities, 2) whether or not family members' healthcare counts toward a patient's out-of-pocket maximum, and 3) how much the patient still has "open" toward the out-of-pocket maximums.

When information from insurers is coupled with hospital information about the clinical plan of care, hospitals are increasingly able to assess the financial picture for a specific course of care, and accurately estimate what patients can expect to owe from that one provider. Even still, there will always be caveats of unforeseen complications that may not have been part of the original plan of care. Moreover, the hospital has *no* information about costs from other providers, such as post-acute care, pharmacy, therapy, etc.

The Regulatory Impact Analysis estimates that publishing both the comprehensive file and the shoppable file(s) will require only "12 hours" of additional hospital administrative time. This estimate is simply laughable. The PRT organizations have already spent **hundreds** of collective hours trying to decipher how to comply with CMS' convoluted proposal.

We suspect that CMS does not understand that the information in the prescribed file formats is not readily available to hospitals in a single location or repository. Hospitals will have to gather these requirements from various information systems, such as pharmacy systems, patient accounting systems, contract management systems, supply chain systems, etc. Then the information must be analyzed to comply with the requirement that all 'service sets' be reported together. This requirement alone will duplicate the reporting of various line items over and over.

For example, consider a transplant episode, which could include infusion charges. In addition to being part of a transplant episode, infusion charges would be listed as a separate line item in the CDM, and are also likely to be included in a perinatal episode, and in a joint replacement bundle,

and on and on. Based on the way CMS describes the file format, services like infusion therapy would be repeated throughout the file numerous times. How are consumers and patients going to be able to understand this? We think patients will find this information very confusing.

Given the lack of actual patient response to this first year of public listing (2019), we conclude the proposal is unlikely to help provide patients with information that is important or useful to their making informed healthcare decisions. If finalized, hospitals would be using extensive resources to create data that are neither usable to patients nor further hospitals' ability to provide meaningful financial counseling to patients. This represents significant risk to hospitals, because they will have to invest significant resources to comply with these requirements without generating any positive results for consumers.

And, of note, this proposal runs completely counter to CMS' efforts to "Reduce Administrative Burden." It will impose an inordinate amount of more bureaucratic "red tape" and significantly worsen the complexity and burden of hospital reporting.

A Better Alternative

CMS seeks comment on "whether and how there may be different methods for making such information available to individuals who seek to understand what their out-of-pocket cost obligations may be in advance of receiving a health care service."

The PRT believes that it is far preferable for CMS to encourage hospitals to invest resources in providing "*information of greatest relevance to patients*," which is an estimate of the patient's specific financial obligation given their insurance plan, status, deductible, cost sharing, etc. For patients without insurance, it is an estimate of the cost, any discounts to be extended to the patient up to and including 100% write-off under financial assistance policies.

New electronic tools that interact between providers and payers that are being developed offer the **best opportunity** to ensure patients can access customized, patient-specific information about specific services. Providing patient-specific estimates is already in place at many hospitals. For PRT member hospitals, activity related to these custom patient-specific estimates continues to increase and is far more useful than a one-size-fits all process like the one CMS is proposing.

One PRT member hospital estimates that it provides more than 104,000 patient-specific estimates annually (more than 86,000 telephone estimates and more than 18,000 in-person estimates). Another PRT multi-hospital system estimates that it generates nearly half a million patient-specific pre-service estimates every year, along with fielding thousands of patient-initiated price estimate queries. A third, smaller PRT member hospital estimates that it provides nearly 10,000 patient-specific estimates. The popularity of these customized estimates continues to grow because patients find them useful. Hospitals are responding to demand by contacting each patient's insurance to assess costs.

The PRT recommends that CMS encourage this important activity by exempting hospitals that invest resources in providing and improving patient-specific estimates from the publishing rules that the agency is proposing. CMS could require hospitals to attest to the process of providing customized estimates to patients, or could make this activity a condition of participation. Either

approach would allow hospitals to avoid the inevitable patient confusion and probable competitive risk that will result from publishing prices on the hospitals' website.

Payer-Specific Negotiated Rates

CMS specifically requested stakeholders' input on whether visibility into competitor price arrangements poses a legitimate risk for unintended consequences. We wish to highlight for CMS that providers enter into legally binding private contracts that contain confidentiality clauses related to disclosure of contract rates. For this reason alone, we urge CMS to remove these provisions before publishing the Final Rule.

Furthermore, we question whether CMS even has the right to compel publication of information that is irrelevant to the populations of patients served by CMS. A key phrase in the June 24th Executive Order is "…propose a regulation, consistent with applicable law…" But, there is, in fact, *no law* with which CMS' proposal is consistent. The only authority CMS has regarding standard charges stems from the Public Health Service Act. In the Proposed Rule, CMS purposely mischaracterizes "negotiated rates" as "negotiated charges." We believe this language was used so the agency could invent a way to go after confidential, proprietary, trade-secret information that it actually has *no authority* to require be made public.

CMS has direct experience with this situation, from the Protecting Access to Medicare Act of 2014 ("PAMA") reporting requirements—i.e. the "gag rule," wherein Congress protected confidential payer-specific reimbursement information from being reported discreetly. In establishing the PAMA reporting regulations for lab services, Congress prescribed confidentiality protections.

If Congress had to grant CMS *specific authority* regarding confidentiality and lab pricing, then it stands to reason that CMS has *no* right to require the publication of payer-specific rates without similar, specific Congressional direction. At a minimum, if CMS proceeds, it must do so in the same manner as with lab rates under PAMA and require only blended/blinded information. CMS simply does not have the authority to codify mandatory publication of payer-specific rates.

CMS is supremely mistaken in its characterization of "payer-specific negotiated charges" and the PRT rejects the definition outright. No such information is contained in any chargemaster. Furthermore, "payer-specific negotiated charges" are one in the same with standard gross charges. Providers do not negotiate charges with payers; they negotiate payment methodologies and payment rates. Providers bill *all payers* consistently with gross charges, and payer-negotiated rates are adjudicated at the *claim* level – not the chargemaster level.

CMS need look no farther than its own MCE (IPPS) and I/OCE (OPPS) claims processing systems logic to understand the myriad ways that payers structure and adjudicate providers' claims.

Third-party payers have processing systems that determine allowables, adjustments, payments, patient responsibility, etc. and that address unique plan design constructs (at the employer's discretion) based on each unique contract. For example, some contracts include mechanisms for quality and/or value. The variations are endless and it is *impossible* for an accurate estimate to be

"published in a file," due to all of the factors and machinations necessary to generate anything like true patient-specific out-of-pocket costs.

The Role of Payers

Finally, the PRT questions where payers are in CMS' proposal. It is unclear to the PRT why payers were not involved in this discussion and requirement, since the contract that matters most to patients is the one between the payer and the patient? Ensuring that patients have accurate information about their costs should be the responsibility of *payers* to their members. We do not believe the current proposals will provide patients with *any* useful information or assistance. For Medicare Part C and other commercial insurances, each insurer is in the best position to provide their beneficiaries with the most accurate information based on what is in

their individual plan; the discounts negotiated with in-network providers in the beneficiary's market; negotiated allowables; year-to-date out-of-pocket payments already made by the beneficiary; and in- and out-of-network providers of associated ancillary services such as pharmacy, post-acute care, durable medical equipment, and therapies.

When providers furnish financial counseling, they must obtain the information from the insurer, so the information provided is accurate and up-to-date. Because insurers may receive additional claims prior to the provider's service, this amount often changes. So, even when it is obtained directly from the payer, the information is often outdated by the time it is provided to the patient.

This is merely one reason that the PRT believes *insurers* are best equipped to handle questions and information regarding what a person's individual out-of-pocket costs will be for the services in question, and to assist with comparisons to other in- and out-of-network providers in the patient's area.

Conclusion

It is impossible to address all of the proposed definitions and data elements in the short time allotted for public comment. For this reason, we stress that the PRT's lack of comment on any particular definition or data element does *not* imply endorsement or agreement with CMS' proposal. In fact, we strongly disagree with CMS' definitions and believe they contradict existing definitions in other CMS sub-regulatory guidance.

CMS' proposal is complex, questionable, riddled with mischaracterizations and misunderstood assumptions, and should be withdrawn entirely.

We strongly believe that the proposal will neither meet patients' needs nor address CMS' challenges and concerns. This mandate will merely confuse and frustrate patients as they attempt navigate the healthcare system to determine their out-of-pocket costs.

The PRT urges CMS *not* to finalize the expansion outlined in the Proposed Rule. We strongly recommend that CMS leave any further legislation or mandates to individual states and encourage hospitals that have not already done so to improve price estimates and financial counseling. The agency should work with hospitals, insurers, consumers, and other stakeholders

to identify ways to provide meaningful information that patients can use to better understand their true out-of-pocket costs for hospital care.

We also recommend that insurers be held accountable through Administrative Simplification Act transaction requirements to provide their patients with the information they need.

If CMS blatantly moves forward with this misguided proposal, the PRT believes that an implementation date of January 2020 is completely impossible, for all the concerns articulated here. Providers will require MUCH more time than the 12 hours CMS' estimate in order to put this single file together—if they are able to compile it at all. The PRT expects a delay of two years, at a minimum.

Furthermore, if CMS finalizes this proposal, the PRT strongly recommends that hospital providers that attest to CMS that they have a mechanism to respond to patient queries **be exempted** from publishing provider-specific negotiated rates, the comprehensive items and services list, and "300 shoppable" services files. (Suitable mechanisms for addressing patient queries include Price Estimate Software, Price Estimate "Hotline", web-based applications or calculators, or compliance with state-specific transparency requirements, etc.)

The PRT once again offers our recommendations for improving price transparency in the manner that is most important to the individual patient:

- **Hold insurance plans responsible for educating and informing their members on the out-of- pocket costs in advance of elective services, comparing across sites of care as well as in-network and out-of-network providers.**

- **Continue to require hospitals to publicize how and from whom patients seek price estimates and financial counseling.**

- **Work with stakeholders, such as individual providers, the American Hospital Association (AHA), and the Healthcare Financial Management Association (HFMA), to investigate and publish best practices currently in place at various hospitals around the country for price estimates and financial counseling.**

XIX. CLINICAL LABORATORY FEE SCHEDULE: POTENTIAL REVISIONS TO THE LABORATORY DATE OF SERVICE POLICY

In the CY 2018 OPPS/ASC Final Rule with comment period (82 FR 59393 through 59400), CMS established an additional exception at § 414.510(b)(5) for the date of service (DOS) for molecular pathology and Advanced Diagnostic Lab Tests (ADLTs) furnished to hospital outpatients. CMS has subsequently delayed enforcement of this provision, which was effective January 1, 2018. These enforcement delays have been published only days before the enforcement dates, meaning that most hospitals and laboratories had already spent significant resources revising processes to comply.

Payment for molecular pathology tests and ADLTs whether billed by a hospital "under arrangement" or by the actual hospital or freestanding performing lab are paid via the Clinical Lab Fee Schedule (CLFS) and excluded from the OPPS packaging policy.

Under the new date of service (DOS) exception, the DOS of the test must be the date the test was performed when it meets the following criteria:

1. The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
2. The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
3. It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
4. The results of the test do not guide treatment provided during the hospital outpatient encounter; and
5. The test was reasonable and medically necessary for the treatment of an illness.

CMS has heard concerns from some providers regarding this DOS exception and is asking for comments about possibly changing the criteria again. We believe that the DOS exception should remain, with the exception of a provision for blood banks. We explain our concerns regarding each option presented by CMS below.

<u>Option 1 – Eliminating the Exception Necessitating that Hospitals Bill Molecular Pathology and ADLTs Under Arrangement with the Specimen Collection Date as the DOS</u>

We do not recommend that CMS change the policy back. Most hospitals and labs have incurred significant administrative cost to make changes to comply with the policy; it would literally be a waste of significant time and resources to have to change back at this point.

For many hospitals, the current DOS exception actually alleviates administrative burden because it relieves hospitals from having to contract with many different independent labs to perform these specialized tests, which may only be ordered by physicians on a sample taken from a hospital outpatient on an occasional basis. Furthermore, it alleviates hospitals from the need to operationalize the Molecular Diagnostic HCPSC (Z-codes) and apply to obtain these codes in order to bill for tests they do not actually perform.

For hospitals that are willing to incur the burden for billing for these tests, however, the PRT recommends that CMS make the billing requirement associated with the DOS exception optional. An optional process allows those hospitals and labs that prefer the "under arrangement" billing scenario to continue to bill Medicare. Because these tests are paid separately under the CLFS, this process would not result in any payment changes for CMS regardless of the entity that submits a bill. CMS could simply retain the DOS policy as it exists and clarify that either the lab or the hospital can bill with the DOS being the date the test is performed.

The PRT does not support this option.

Option 2 – Requiring the Physician's Order Regarding the Tests to Direct the Billing of the Test

CMS proposes an option that revolves around the ordering physician determining that the test results are not intended to guide treatment either during the hospital outpatient encounter when the specimen was collected or during a future hospital outpatient encounter. The physician would document this determination and the DOS service for the test would be the date of test performance. In this scenario, the test would not be considered a hospital service and the performing laboratory would be required to bill for it.

This proposal is not practical and should be abandoned altogether because it would add unnecessary burden to treating physicians. It is essentially asking them to predict future sites of service for care that is unlikely to be planned when the time the specimen is collected and to document this on the test order. For hospital outpatients, these tests are actually run and analyzed *after* the hospital outpatient encounter during which the specimen was obtained. These tests do not affect the clinical care during the encounter. Nor are the tests going to be part of medical decision-making during a subsequent hospital encounter, because the decision relating to the test result(s) have already have been utilized by the practitioner(s) between visits in order to determine the next steps in clinical care.

For several years CMS has been "prioritizing patients over paperwork" and eliminating unnecessary administrative burdens. This proposed option runs counter to CMS' objectives in this area, and would place *additional* unnecessary burdens on both hospitals and physicians.

The PRT does not support this option.

Option 3 - Limiting the Laboratory DOS Exception to ADLTs

In the CY 2018 OPPS/ASC Final Rule, CMS agreed with commenters that limiting the new laboratory DOS exception to only include ADLTs (and not molecular pathology tests) would be inconsistent with the OPPS' packaging policy. It would, moreover apply to very few ADLT tests. Not many hospital laboratories perform molecular pathology testing compared to freestanding laboratories, and most hospitals rely on independent and other hospital reference laboratories to perform these tests. As CMS asserts, both hospital laboratories and independent laboratories can perform molecular pathology testing, whereas ADLTs, by definition, are solely performed by a single lab.

Prior to the DOS exception, these tests were billed with the specimen collection date that equated to the date of a hospital outpatient encounter, billed "under arrangement," and paid under the CLFS. This process was problematic because it obscured the lab tests' actual price, since performing labs could seek payment from hospitals for any amount they desired. Hence, the amount the lab billed the hospital may have no relationship whatsoever with the lab's actual costs. Most hospitals will appropriately mark this amount up, in order to accurately reflect to CMS what the test's actual costs are for the hospital. (Note, two states prohibit purchased services from being marked-up; this is likely to further skew the data because, if CMS applies the hospital's CCR to calculate costs based on charges, the costs will be significantly understated.)

Today, the DOS is the date that the test was performed; the performing lab, regardless of whether it is a freestanding lab or a hospital lab, bills Medicare directly for its payment. Payment is still made under the CLFS, but the price billed is the price of the test from the performing lab. This provides more transparent pricing information compared to the prior DOS policy.

If CMS removes the DOS exception, hospitals will have to request that physicians delay ordering tests on a specimen until at least 14 days after the patient is discharged from the hospital outpatient department—as they still must do for hospital inpatients—if they do not want the tests to be billed under arrangement.

The PRT does not support this option.

Option 4 – Exclude Blood Banks and Blood Centers

Certain blood banks and blood centers have raised concerns regarding billing requirements and having to enroll as a Medicare provider. Typically, these entities do not perform molecular pathology tests as diagnostic tests that could drive patient care determinations. They usually provide molecular pathology testing as part of processing blood products for release into the blood supply.

CMS proposes that an exception could be provided for these specific entities, so they could continue to allow those tests to be billed under arrangement by hospitals. CMS benefits from this option, as there would be no need for the agency to completely exclude all molecular pathology tests from the DOS exception.

- **The PRT supports this option as a viable compromise for blood banks, blood centers, and CMS.**

XX. PROPOSED PRIOR AUTHORIZATION PROCESS AND REQUIREMENTS FOR CERTAIN HOSPITAL OUTPATIENT DEPARTMENT (OPD) SERVICES

CMS proposes to initiate a nationwide prior authorization program for five quasi-cosmetic procedures when they performed on a hospital outpatient. The five are: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. CMS reports that there have been increases in the volume of these services, but does not state whether the increase has occurred in all sites of service, including physicians' offices and Ambulatory Surgery Centers (ASCs). CMS implies that the volume increase means that the services are not medically unnecessary.

The PRT is puzzled by this assumption. There is no evidence that CMS has used its considerable resources and outreach capacities to educate physicians who perform these services about medical necessity requirements. There is no information available that either CMS or the Office of Inspector General (OIG) have conducted audits and issued reports on this issue. Has CMS conducted audits for each of these services? If so, where can we find published results about the results of those audits?

If CMS' assertion that an increased volume of services truly indicates a rise in medically unnecessary services, then the agency should implement program integrity controls for these services *to all settings*—not solely hospital outpatient departments. Since physicians determine both the procedures' necessity *and* setting, CMS should implement education and controls directly to physicians, in all settings. Only by doing so will the agency be able to ensure that Medicare Part B does not pay for cosmetic services.

It is premature for CMS to conclude that a prior authorization program is needed when the agency has not used all of the existing program integrity resources at its disposal, including:

1. Establishing a National Coverage Determination (NCD) spelling out the circumstances for coverage of these procedures in all settings which they can be performed;
2. Instructing MACs to follow the new Local Coverage Determination (LCD) process and establish LCDs reflecting local practice for these procedures;
3. Publishing articles in the Quarterly Medicare Compliance Newsletter that illustrate documentation practices and the and circumstances that support medical necessity;
4. Suggesting the MACs engage in Targeted, Probe and Educate audits for these procedures in all settings;
5. Requiring Recovery Auditors to implement pre-payment or post-payment review programs for these procedures in all settings; and
6. Mandating that providers affix modifier KX to attest that the procedures meet medical necessity requirements; CMS can then conduct sample audits to verify.

The PRT acknowledges and agrees that it is appropriate for CMS, in its fiduciary role for the Medicare program, to establish program integrity controls for services or circumstances of concern. However, it would be much less costly and just as effective for CMS to administer one or more of the program integrity controls listed above rather than implementing a costly prior authorization program. CMS would also learn a significant amount from the above activities, which will help determine whether a prior authorization program would be effective or not. Specifically, a 100 percent pre-payment review would be much more effective than a prior authorization program.

As CMS accurately describes, prior authorization is provisional and does not guarantee either coverage or that payment is valid. Under a prior authorization program, hospitals would carry the risk of a clinician providing documentation prior to a procedure to achieve provisional approval, only to later document the actual procedure in a manner that does not support medical necessity. Hospitals already experience denials from commercial and Medicare Advantage payers with prior authorization programs. Hospitals experience denials after obtaining a valid prior authorization, because the clinician actually performs and documents something other than what was authorized. The hospital's claim is denied by the payer because billing is based on the coding from the actual operative/procedural report documentation that details what was performed—while the clinician bills his or her professional fee that reflect the codes for authorized services, and receives reimbursement. This is a very real and serious program integrity consequence of prior authorization programs. For these reasons, the PRT doubts that a prior authorization program will have the result CMS desires.

Physicians determine the medical necessity of these procedures and the care setting, so it is curious that CMS did not discuss either the procedures or the proposed program in the Medicare Physician Fee Schedule's (MPFS) Proposed Rule for CY 2020. If the prior authorization program are only implemented for hospital outpatient procedures, CMS states that the professional fee would not be paid if the provisional authorization was not sought and granted. If the proposal is implemented only for hospital outpatient settings, performing physicians could simply bypass the burden of the prior authorization requirement and perform the services in freestanding ASCs or their offices. If CMS is sincere in its concerns about these procedures, then the agency must implement the prior authorization program in *all settings,* not just in hospital outpatient departments.

The PRT suggests that, if CMS truly wants to address this issue, the agency should implement a 100 percent pre-payment review. This would place the responsibility on the *performing physician* to ensure that the procedure is medical necessary, and that the actual procedure performed and documented supports this assurance. Such a pre-payment review requires that physician documentation support the coverage requirements, since the procedure documentation would be used to validate coverage and payment for both entities, rather than the physician's reporting the authorized codes. It also places responsibility on the hospital to ensure the appropriate documentation to support medical necessity is complete, accurate, and clearly evident in the hospital's medical record. A 100 percent pre-payment review program across all settings would ensure compliance for the ASC and office settings, as well, and provide a consistent message to performing physicians regardless of where care is delivered.

If, after trying the program integrity initiatives listed above, CMS still believes more controls are necessary, the agency could consider making changes to its hospital Conditions of Participation (CoP) for utilization review of these procedures. Changes to the CoP would create the regulatory support hospitals need to require performing physicians to provide medical record documentation in advance when scheduling the procedure. This enables the utilization review staff to confirm medical necessity and coverage prior to the procedure being performed. Many hospitals have tried to implement this type of program voluntarily but have been challenged by their medical staff about the hospital's "authority" to make such a requirement. Having formal CoP would give hospitals the supportive authority they need to implement utilization review processes prior to performance of these procedures. CMS can always conduct audits to verify the effectiveness of the hospitals' determinations.

- **The PRT asks CMS to abandon its proposal for a prior authorization program. Instead, the agency should implement one or more of the existing program integrity controls to ensure these procedures are medically necessary when paid under Medicare Part B.**

- **The PRT urges CMS to apply the prior authorization requirement to all settings of care.**

XXI. COMMENT SOLICITATION ON COST REPORTING, MAINTENANCE OF HOSPITAL CHARGEMASTERS, AND RELATED MEDICARE PAYMENT ISSUES

The PRT thanks CMS for raising questions about these topics and beginning an important national dialogue. We note that the cost reporting rules governing the CDM and gross charges have not changed materially since their inception around 1967 in the early days of the Medicare program. The structure of the healthcare industry is highly dependent upon these rules, which have created a variety of challenges, including charge compression.

Our comments address the importance of stakeholder engagement regarding any changes as well as the need for significant lead time and detailed instructions and direct communication to hospitals. We also discuss the relationship of the cost report to chargemasters in response to CMS' questions and offer some suggestions for changing cost reporting and payment methodologies in the near term.

Stakeholder Engagement

Hospital finances and payment from Medicaid programs are two critical areas that are wholly dependent on the longstanding cost report rules. These mandatory rules define important concepts that underpin hospital finances, including the distinction between ancillary and routine services; how pricing structures are set; and requirements around posting gross charges for items and services to all patients, not just Medicare patients. Cost report principles require that services must be charged and posted to all patient accounts at the same value as services are rendered, regardless of payer. The Administrative Simplification Act (ASA) rules require that claims are billed in a HIPAA-compliant manner to all payers.

It simply cannot be overstated that cost reporting is a very significant component of hospital operations and, therefore, that stakeholder engagement regarding any changes is one of, if not the most, critical component to the success of any changes made to the methodology. For this reason, any and all changes CMS proposes must first be carefully vetted with hospitals, state Medicaid programs, and other industry stakeholders.

Due to the complexity of cost reporting and the operational processes upon which it is based, the PRT recommends that only a small number of changes be implemented at any one time, and that the agency provide detailed instructions and sufficient time for implementation for each change proposed. It is important to account for the fact that not all entities have fiscal years on the same cycle. For this reason, any changes will have to allow enough time for each hospital to implement the changes at the beginning of its own specific fiscal year. In order to do that, hospitals need at least one full year prior to the fiscal year of implementation in order to make any changes to their general ledgers/chart of accounts and accounting practices to undergird the cost reporting change.

CMS must also recognize that cost reports that reflect these changes would be filed five months after the end of the fiscal year of implementation; the HCRIS changes that allow CMS to see the results arrive at an even later date. The PRT believes that any changes must be a three- to four-year process and we are worried about conclusions that may be made when too many changes

are made simultaneously—especially if those changes impact the reporting of both expenses and revenues in the same cost center—CMS and other stakeholders, for example, may not be able to understand the outcome of cost-to-charge ratios (CCRs). This could lead to problems worse than the original problems the changes were intended to correct. Extreme caution is mandatory in order to prevent unintended consequences and cause a domino effect, and to maintain stakeholders' ability to support, implement, and comply with any changes made.

Instructions and Communication to Hospitals

Any cost report changes must be accompanied by very clear and detailed instructions. As part of this process, CMS may wish to consider piloting certain changes with a group of volunteer hospitals that can help develop instructions and statistics for proper allocation, as well as provide audit verification. Such a pilot group is the best vehicle to ensure that the subsequent roll-out to all hospitals results in consistent information.

In addition, a pilot group could provide information to evaluate the impact(s) of changes through the entire process, facilitating the identification of unanticipated and unwanted impact before all hospitals implement the changes. New instructions can be issued and webinars conducted and recorded, in which the volunteer hospitals step through their chart of accounts and other operational changes made to effectuate appropriate cost report changes. MACs could work with the pilot group to determine audit procedures for the changes as well. This would also be a good demonstration of CMS' willingness and desire to work with stakeholders throughout the process.

The PRT wishes to clarify that "clear instructions" means *detailed instructions*. We cannot overstate how important it is for instructions to be detailed and thorough. An illustrative example of how important this is is provided by CMS' decision to exclude hospitals' data from OPPS rate-setting if facilities use square footage to allocate costs for major movable equipment. CMS excluded these hospitals for five years in order to provide an opportunity for them to update their allocation method and use either dollar value or direct assignment, both of which are more accurate than square footage. CMS reports that only about 15% of the hospitals that needed to make the change did so, however. Hospitals' failure to correct their allocation methodology illustrates the need for CMS' communication with hospitals to be direct and specific.

CMS absolutely must help hospitals understand the details of how these changes will affect them, and why the changes must be made in a timely manner. Despite CMS' best intentions—and its activities to make rules, issue transmittals, and conduct dialogues with professional associations to utilize those communication channels—the agency was unable to influence hospitals to change cost accounting and cost reporting practices.

Like many others in this age of information-sharing, hospitals are simply drowning in information. The result is that certain types of information risk not being prioritized until the stakes are raised. For example, when cost reports resulted in a year-end settlement, hospitals finally paid more attention to the process.

The PRT is not suggesting that hospitals "ignore" instructions, especially instructions regarding the cost report. We are merely noting that, for whatever reason, CMS' communications via traditional methods have been ineffective in reaching hospitals en masse. Yet, successfully

reaching hospitals is *critical* for CMS to achieve its desired results with respect to rate-setting. This is another benefit of establishing a group of volunteer hospitals that can speak to other facilities and share the operational impacts of any changes made.

Once changes are determined, CMS needs to communicate directly with hospitals by sending a letter *to each individual hospital and their MAC*, alerting them about the change(s) and describing how to make the change(s). MACs must audit each individual hospital for implementation of the applicable changes. And, hospitals must not only be responsible to their MACs if they do not make the recommended changes but also be required to explain why they neglected to make the changes.

The PRT supports the use of explicit instructions followed by audits. The recently created standard cost centers for implantable devices, MRIs, catheterization lab, and CT highlight the importance of such a process, since a review of the HCRIS files indicated many hospitals had aberrant CCRs in these newer cost centers.

We suggest that CMS publish tables comparing CCRs for standard cost centers by hospital, by geographic area, and by hospital size and type, and highlight the outlier hospitals. We also suggest that CMS release audit findings when MACs identify inappropriate cost report practices that distort either expenses or revenues in these cost centers that create inappropriate CCRs. Both practices will provide CMS with clear data regarding the actual impact when hospitals do not make the prescribed changes.

On the revenue side, CMS should enforce HIPAA transaction sets that preclude MACs from denying revenue codes for certain services. For example, MACs continue to refuse to accept drug administration CPT codes when they are billed with the revenue code that best reflects the department incurring the expense (such as 0450 for ED or 0510 for clinic). MACs are, instead, mandating that hospitals report these services with revenue code 0260. These MAC practices are improper. CMS should work with the MACs to make it easier for hospitals to report services when the MACs reject and/or deny claims submitted following HIPAA transaction sets. This principle should also apply when claims submission follows any guidance that results in improved cost reporting.

To truly get hospitals' attention, CMS should send individual letters to hospitals regarding any of their claims and CCRs that had to be trimmed from the rate-setting methodology. This would provide hospitals with specific feedback that *their* claims were specifically trimmed, and would draw attention to the need to potentially correct and/or amend their cost reports. In other words, hospitals that are educated about when their CCRs and/or charges are outliers are more likely to make needed changes to align their cost report and pricing practices with other hospitals'.

<u>Cost Reports and Chargemasters</u>

CMS' definition of "charges" at PRM1 Section 2202.4 states that *"[c]harges should be related consistently to the cost of the services.*" (Cost includes actual acquisition cost as well as operating costs and overhead.) Yet, the published national average CCRs of the 19 cost groups used in IPPS rate-setting suggests that most gross charges are no longer reasonably related to the cost of services. The PRT believes they are not consistently related to cost, either.

The PRT and many others believe that gross charges have become extremely distorted from actual costs. For example, the national CCR for drugs is noted to be 0.189 for FY 2020. This means that, for every $1.00 in charges for a drug, the actual drug cost and all allocated overhead and associated operating costs is 0.19 cents. This does not appear to be "reasonable."

Low CCRs are due, in part, to the fact that some hospitals do not understand that payment rates under CMS' OPPS and IPPS payment systems are *prospective rates* and are paid by the agency regardless of billed charges. Many hospitals use a standard to set prices because commercial payers often use a payment structure that applies a "lesser of charge or payment" methodology. Payers often describe this structure as a DRG or APC payment system despite the fact that it is not a true DRG/APC methodology. This standard is applied even when a true DRG/APC payment is made for a line item service but, in that case, the payment rate includes payment for all of the other items and services that must be separately billed on the claim (e.g., drugs, supplies, and ancillary tests).

Unlike other payers, however, CMS does not apply a "lesser of payment rate or billed charges" methodology when the charges billed on a claim are lower than the payment rate. So, in an effort to receive appropriate payment from non-Medicare payers, the "standard" may apply a specific percentage mark-up to the APC payment rate, and also separately charge all services as mandated by HIPAA transaction sets.

The PRT urges CMS to clarify in its manuals that a "lesser of charge or payment" methodology *directly conflicts* with prospective payment systems. Prospective payment systems, by definition, package payment for individual items and services into an overall payment, such as a case rate or a *per diem*. The focus on the "lesser of" methodology used by non-Medicare payers purportedly using a DRG or APC-based payment method creates the perception that gross charges must always exceed the payment rate in order for hospitals to receive fair and equitable payment. CMS could help eliminate commercial payers' application of a "lesser of" methodology by providing education and materials on this issue.

CMS has an opportunity to educate hospitals about how to truly relate charges to cost. Facilities would benefit from additional education regarding hospital cost centers that include services provided to both outpatients and inpatients. Outpatient department services often have a lower cost than inpatient department services for several reasons. CMS has an opportunity to help hospitals understand that setting lower charges for the outpatient services compared to the inpatient services is appropriate, so long as the outpatient charges are appropriately "grossed up" in the cost center for cost reporting purposes.

Many hospitals do not understand that prices may be set lower for a unique outpatient cost center that provides services with lower operating costs compared to a different outpatient cost center. For example, an outpatient infusion cost center would have no cost for emergency services or 24/7 hours of operation, but an Emergency Department would have those costs. The outpatient infusion center could have lower costs for physical location expenses, because it provides scheduled services. The drug administration service codes would be reported in each cost center, but the line item charge would be different because the overhead is different.

Education from CMS could help increase hospitals' awareness and understanding of legitimate steps they can take to lower gross charges; doing so will help remove uncertainty hospitals face when they do not understand the appropriate options.

Suggestions for Changing Cost Reporting and Payment Methodologies

The PRT offers several areas where CMS' payment methodologies could rely on more accurate data and move away from reliance on cost reports. This would help balance accurate payment with actual cost in those places where CMS has better information, while the agency continues to rely on cost report data in areas with no alternative. An advantage of CMS making these changes is that it would not require any changes to hospital cost reporting practices.

High cost drugs is one area where CMS could make such a change. CMS and providers have long agreed that charge compression causes significant issues, and that payment and payment rate-setting based on CCRs only perpetuates and exacerbates these problems. The PRT suggests that, when new drugs receive new technology approval, CMS could utilize the drug's average sales price (ASP) instead of the CCR and billed charges in order to determine cost for its reimbursement calculations. CMS need only to ask hospitals to supply the NDC of the selected drug on the inpatient claim. Furthermore, CMS could develop an alternative for outlier payment whereby CMS defines a formula that is not dependent on billed charges that are reduced to a calculated cost using CCRs.

Another suggestion, which does involve changes to the cost report itself, is to develop CCRs based on separating the actual acquisition expense from CCRs that include the allocated overhead. This process might involve changing the cost report to separately calculate CCRs for actual acquisition cost for drugs, implants, and other supplies, and to separately calculate any allocated overhead, handling, and other operating expenses. CMS would then have actual expense data to use to ensure that payments developed from CCRs do not result in payment amounts lower than the individual item's actual cost. This could encourage increased efficiency by highlighting overhead and handling that deviates significantly from the norm. This process would necessitate exploring whether hospitals could eventually bill the actual acquisition costs for purchased drugs, supplies, implants, and services purchased "under arrangement" and then receive a separate payment for overhead and handling. The PRT is interested in whether such an approach would improve data transparency.

These are just a few of the PRT's suggestions regarding this topic. Again, we appreciate that CMS is facilitating dialogue about the topic's many interrelated issues and to help the industry make needed change and modernization.

- **The PRT encourages CMS to collaborate with hospital providers to improve the cost reporting methodology and process to the eventual benefit of the agency, providers, and individual beneficiaries.**

- **The PRT recommends that CMS pilot individual changes with a group of volunteer hospitals that can help develop instructions, statistics, and communication of the changes.**

- **The PRT urges CMS to adopt the use of explicit instructions, audits, and individualized communication to facilities.**

- **The PRT suggests that CMS abandon the use of CCRs in areas where the agency has more accurate data.**

Provider Roundtable: c/o Community Hospital Anderson, Anderson, IN
Attention: Terri Rinker, MT (ASCP), MHA, Revenue Cycle Director
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Provider Roundtable

Attachment A: Provider Roundtable Members

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