September 19, 2018

Atrium Health (NC, SC)

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

Baptist Health South Florida (FL)

Community Hospital Anderson (IN)

Franciscan Missionaries of Our Lady Health System (LA)

Hartford Healthcare (CT)

Hardin Memorial Hospital (KY)

Kaiser Permanente, Southern California Permanente Medical Group (CA)

SSM Health (IL, MO, OK, WI)

University of Pittsburgh Medical Center (PA, NY)

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

Re: CMS-1695-P

Dear Ms. Verma,

The Provider Roundtable (PRT) submits the following comments on the 2018 Outpatient Prospective Payment System (OPPS) Proposed Rule, as published in the *Federal Register*.

The PRT includes representatives from 13 different health systems, serving patients in 20 states. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services under the OPPS, 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 (Chair)
PRT Chair and
Revenue Cycle Director
Community Hospital Anderson
Anderson, IN

I. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

Proposed CY 2019 Packaging Policy for Non-Opioid Pain Management Treatments

CMS proposes to provide separate payment for certain non-opioid drugs when they are administered in the ASC setting, and provide separate payment for non-opioid pain management drugs that function as a supply when used in a surgical procedure performed in an ASC. The drug that is currently utilized in ASCs that CMS proposes for separate payment is Exparel (bupivacaine/lidocaine injected at the surgical site), which is reported with HCPCS code C9290.

CMS states that separate payment is warranted because the agency believes that packaged payment is a barrier to access to care. CMS' proposal is intended to encourage the use of Exparel over opioids for pain management. CMS is also requesting comment concerning other non-opioid pain relief options. The PRT is pleased to offer comments on this area.

The PRT submits that packaged services present a barrier to the provision of some items for *all* providers, not just ASCs. It is also clear that the nation's dangerously excessive number of opioid prescriptions is a concern across all sites of care, not just in ASCs. For these reasons, the PRT recommends that CMS apply this proposed methodology across all sites of service in order to improve access to care and reduce the prescribing of opioids.

CMS has requested comment regarding specific options that, similar to Exparel, are non-opioid-based but are effective for pain management. The PRT submits the following for consideration based on our facilities' experiences and outcomes. The "On-Q" pain relief system is a portable pain system that provides non-opioid local anesthetic medication to the site of the pain. Its purpose is the same as Exparel's: to deliver relief at the site of the pain rather than by a systemic pain reliever. It also prevents the side effects that many people experience from oral medications. Other medications that should be considered are IV Ibuprofen and Ofirmev (IV Acetaminophen), and THC oil applied topically. Polar ice devices use ice and water for post-operative pain relief after knee procedures. In addition, therapeutic massage, acupuncture, and dry needling procedures are very effective both for post-operative pain and for long-term and chronic pain.

While the PRT understands and acknowledges that self-administered drugs are excluded from payment based on statute, we believe that Congress should revisit this exclusion. CMS would then be able to apply this methodology to other scenarios and impact the opioid crisis on an even larger scale. For example, if Congress revisits the exclusion, CMS could consider incentives to physicians and other practitioners who utilize non-opioid alternatives for pain control in any situation. These providers are the *only* professionals who can order and prescribe these medications. CMS should consider establishing a HCPCS G-code to be reported by a practitioner who prescribes a non-opioid option for pain management. There could even be an add-on payment structure for practitioners who make a conscious effort to utilize other options.

Neurostimulators

The PRT appreciates that CMS is considering separate payment for the HCPCS codes C1822, C1820, and C1767, representing neurostimulators utilized for the long-term control of chronic

pain. The PRT encourages CMS to review its coverage policies regarding the length of time that must pass before beneficiaries are eligible to receive these devices. The current coverage determinations require all other means of pain control (including opioids) to be exhausted before a neurostimulator is viable for coverage under the Medicare program. Softening this requirement would save money for both beneficiaries—in terms of the cost of the neurostimulator versus oral medication and pain management injections—and the Medicare program. The PRT requests that as part of the opioid crisis management, CMS liberalize the coverage time frames before a patient is eligible for coverage of a neurostimulator. It is very possible that many patients with chronic pain could experience relief from a neurostimulator, and avoid having an opioid prescription entirely. While a neurostimulator is not the first-line treatment for pain management, the longer people take medication for chronic pain, the more tolerant they become to the medication and the more likely to seek stronger medication to control the pain.

New Quality Measure

In concert with these recommendations, we encourage CMS consider a Quality Measure on opioid versus non-opioid medications. This measure would be driven by physicians, since they are the prescribers. The resulting data would enable CMS to identify what settings and which providers are working with patients to utilize non-opioid medications to control their pain, and make a positive impact on the number of opioid prescriptions. This is especially pertinent to post-operative pain management, but would also apply to other environments, as well, such as Emergency Departments.

Additional Settings

The PRT recommends that CMS not limit its consideration of opioid prescriptions to the ASC environment and immediate post-operative pain control. These are not the only drivers of opioid use. Patients who experience non-surgical injuries and visit the Emergency Department may also be prescribed an opioid for pain control.

Summary

The PRT recommends that CMS:

- Allow separate payment for Exparel (HCPCS code C9290)) across all sites of service in order to improve access to care and reduce the prescribing of opioids.
- Include the On-Q pain relief system, IV ibuprofen, and Ofirmev for unpackaging.
- Include therapeutic massage, acupuncture, dry- needling procedures, Polar ice devices, and THC oil as covered services for pain relief.
- Liberalize the coverage time frames for neurostimulators being covered for chronic pain relief.
- Consider a Quality Measure on opioid versus non-opioid medications.

II. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

CMS is proposing for CY 2019 and subsequent years, to continue providing an additional $10 payment for radioisotopes produced by non-HEU sources. CMS intends to reassess this payment policy once conversion to non- HEU sources is closer to completion or has been completed.

We appreciate CMS' commitment and consistency for the past five years concerning the additional payment to cover alternative methods for producing TC-99m without HEU, and the due diligence in re-evaluating this additional payment annually.

Based on the information cited from a 2016 report from the National Academies of Sciences, Engineering, and Medicine, the industry anticipates the conversion of Tc-99m production from non-HEU sources will not be complete until at least the end of 2019.

CMS noted in the CY 2013 OPPS/ASC Final Rule that the agency lacks the authority to create a special payment to cover rising costs of TC-99m at the industry or manufacturer level. Typically, the normal OPPS payment methodology creates the adjustment in that: as costs rise, those costs are passed on globally to hospitals, reflected in hospital charges adjusted to costs and, therefore, ultimately reflected in the prospective payments. This add-on payment merely ensures equitable payments to hospitals through the transition period where non-HEU sources are not uniformly distributed; the established OPPS mechanisms ensure that the total cost of any new sources are incorporated into final payments year by year.

- Since the transition has not been completed and there has not been an increase in this additional payment since CY 2013 but costs have increased, the PRT recommends that CMS increase the payment amount of the add-on code Q9969 to $30.00 as a continued method of making equitable payments to hospitals through this transition.

III. Biosimilar Biological Products

For CY 2019, CMS is proposing to continue the policy from CY 2018 to make all biosimilar biological products eligible for pass-through payment. In addition for 2019, CMS is proposing to pay for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. The PRT agrees with the proposal that biosimilars should be paid based upon the ASP of the biosimilar instead of the reference product.

IV. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2019, CMS is proposing to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. Specifically, for CY 2019, CMS proposes to continue to pay all non-pass-through, separately payable therapeutic radiopharmaceuticals at

Average Sales Price plus six percent (ASP+6%). The PRT agrees with the proposal to continue to pay all non-pass-through, separately payable therapeutic radiopharmaceutical at ASP+6%.

V. Comprehensive APCs (C-APCs)

Proposed Additional C-APCs for CY 2019

For CY 2019, CMS proposes three additional new Comprehensive APCs (C–APCs). The proposed new C–APCs are: C–APC 5163 (Level 3 ENT Procedures); C–APC 5183 (Level 3 Vascular Procedures); and C–APC 5184 (Level 4 Vascular Procedures).

CMS selected these APCs on the basis of their similarity to other C–APCs. CMS states that these APCs include primary, comprehensive services, such as major surgical procedures, which are typically reported with other ancillary and adjunctive services. CMS also indicates that, similar to other APCs that were converted to C–APCs, there are higher APC levels within the clinical family or related clinical family of these APCs that have previously been assigned to a C–APC.

The PRT is generally supportive of the C-APC methodology as it allows more claims to be used for rate setting and as a result, better incorporates packaged costs into the payment rates. Consistent with our support of C-APCs, the PRT suggests that CMS study this methodology for skin substitutes, as described below.

The PRT recommends that CMS:

- Proceed with the three new C-APCs as proposed.
- Continue to study other services that lend themselves to the C-APC payment methodology.

VI. Skin Substitutes

Since CY 2016, CMS has used the high-cost/low-cost status for each skin substitute product, based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold.

For CY 2019, CMS proposes to continue to assign skin substitutes to the high/low-cost categories and retain a high cost product in the high cost category for at least two years even if the cost data shows that the product should be reassigned to the low cost category. CMS states that its goal is to promote payment stability for skin substitute products and their related procedures. The agency notes that price stability allows hospitals that use such products to more easily anticipate future payments associated with them.

For 2020 and beyond, however, CMS is soliciting comments on future payments methodologies including the following:

- *Establish a lump-sum, "episode-based" payment for a wound care episode.* Under this option, a hospital would receive a lump-sum payment for all wound care

services involving procedures using skin substitutes. The payment would be made for a wound care "episode" for one wound (i.e., 12 weeks).

- *Eliminate the high-cost/low-cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products.* This option would reduce the financial incentives to use expensive skin substitutes and provide incentives to use less-costly skin substitute products that have been shown to have similar efficacy treating wounds.

- *Keep the high-cost/low-cost skin substitute categories, but change the threshold used to assign skin substitutes in the high-cost or low-cost group.* Consider using other benchmarks that would establish more stable thresholds for the high-cost and low-cost groups.

- *Allow for the payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 cm2 and 99 cm2 and substantially over 100 cm2.* Under this option, payment for skin substitutes would be made more granularly, and be based on the size of the skin substitute product being applied. This option also would reduce the risk that hospitals may not use enough of a skin substitute to save money when performing a procedure. CMS states the belief that such granularity could conflict with prospective payment systems, which is based on a system of averages. Specifically, it is expected that some skin graft procedures will be less than 25 cm2 or around 100 cm2 and will receive higher payments compared to the services' costs. Conversely, services between 26 cm2 and 99 cm2, or those substantially larger than 100 cm2, will receive lower payments compared to the cost of the services, but the payments will average over many skin graft procedures to an appropriate payment rate for the provider.

With regard to these options, the PRT strongly objects to episode-based payments and does not recommend that CMS advance any episode-based methodology under OPPS until much more data related to packaged payment are available, and an analysis of packaging policies has been performed.

Rather than any of the options proposed by CMS, the PRT asks CMS to consider C-APCs as a methodology for skin substitute procedures and products. The PRT recommends that CMS evaluate adding skin substitute procedures into new comprehensive APCs. The PRT notes that many of the wound care (debridement) procedures are already in a comprehensive APC. CMS can evaluate the different skin substitute product codes with the procedures as well as the add-on procedure codes for complexity adjustments. In this way, CMS would have more wound care claims and total claim cost data to use in the development of the C-APC payment rates and we believe this would result in more accurate payment while also incentivizing providers to use the most cost-effective product for the clinical indication.

- The PRT recommends that CMS evaluate creating new C-APCs for skin substitute procedures and evaluate each skin substitute product code and add-on codes for complexity adjustments.

VII. Exclusion of Procedures Assigned to New Technology APCs From the Comprehensive APC Policy

CMS states that services and procedures assigned to New Technology APCs are typically new procedures that lack sufficient claims history to establish an accurate payment for them. CMS' current policy allows for sufficient claims data for New Technology APCs for assignment to an appropriate clinical APC. This policy allows CMS to gather two years of claims data before reassigning a New Technology APC.

When a procedure that is assigned to a New Technology APC is included on the claim with a primary procedure (identified by OPPS status indicator "J1"), payment for the new technology service is typically packaged into the payment for the primary procedure. Because, in this scenario, the new technology service is not separately paid, the overall number of single claims available to determine an appropriate clinical APC for the new service is reduced. This is contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable CMS to assign the service to an appropriate clinical APC.

CMS seeks to address this issue and ensure there are sufficient claims data for services assigned to New Technology APCs. CMS' proposes to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599, and APCs 1901 through 1908) from being packaged when included on a claim with a "J1" service assigned to a C–APC.

Some of the Medicare Administrative Contractors (MACs) have established Local Coverage Determinations (LCDs) regarding new technology services, under which the new technology CPT codes are denied. Often, in order to have the claim processed for the other services on the bill, hospitals may remove the charges associated with the new technology procedure. This practice can exacerbate the problem of not having enough claims data to review.

- The PRT agrees with CMS and asks that the agency exclude the packaging of New Technology APCs into C-APCs so that appropriate payments are made and data collection can occur for use in future rate-setting.
- The PRT requests CMS provide more guidance on the coverage of new technology CPT codes to the MACs as an additional effort to obtain better data on these codes.

Data on Packaging Included in APCs

The PRT understands that packaging is a central concept of a prospective payment system and that CMS has significantly expanded packaging since the inception of the OPPS. CMS publishes annual policy files with each year's OPPS Final Rule, which includes the APC Offset File. The PRT understands that this file includes the amount of packaged payment in every APC for the following categories: drugs above the packaging threshold, policy packaged drugs and biologicals, and packaged devices. However, there is critical packaging information that is not included in the Offset File which includes the amount of packaged payment associated with clinical laboratory tests and other ancillary services. The PRT submits that these services are very similar to the aforementioned items/services and should also be detailed. The PRT is very concerned about the lack of complete information, which, were it available, providers would be

able to perform accurate and complete analyses of the actual costs packaged into an APC's payment rate. Because CMS' packaging principle is central to the OPPS methodology and impacts all APC payment rates, including this information will allow stakeholders to provide more robust and meaningful comments and analyses to CMS.

The PRT recommends that:

- CMS publish detailed packaging data by specific packaging category (e.g., clinical laboratory and ancillary services) in the annual APC offset files as is currently published for packaged drugs and devices.
- CMS publish this data annually with the Proposed and Final Rules.

VIII. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

Additions and Deletions from the List

In the 2019 OPPS/ASC Proposed Rule, CMS proposed removing two procedures from the Inpatient-only (IPO) list: CPT 31241 (Nasal/sinus endoscopy, surgical: with ligation of sphenopalatine artery), and CPT code 01402 (Anesthesia for open or surgical arthroscopic procedures on the knee joint: total knee arthroplasty). The PRT agrees that these two procedures should be removed from the IPO list.

CMS also proposed adding one code to the IPO list: HCPCS Code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel). The PRT agrees with this addition and thanks CMS for making this change.

Split Status Indicator "C" into "C1" and "C2"

The PRT requests that CMS refine the status indicator used to identify the IPO list of procedures from the current status indicator "C" into two status indicators (i.e., "C1" and "C2") in the interest of improved clarity and transparency. This methodology is very similar to the way CMS has split status indicator "E" into indicators "E1" and "E2."

While we understand that the "separate procedure" designation is determined by the AMA and indicated in the CPT description, vendors and other "edit writers" look to the CMS Addenda for concise information regarding status indicators that are applied in the I/OCE logic, and utilize these addenda as the primary source of information. Our request is that CMS create a unique status indicator to easily identify IPO procedures that are considered as separate procedures We believe this change will foster both transparency and clarity for providers in understanding that they should bill CMS in instances when an IPO procedure is a separate procedure, and that the I/OCE logic will be applied. That logic states that:

> *Inpatient-only procedures that are on the separate-procedure list are bypassed when performed incidental to a surgical procedure with Status Indicator T, or effective 1/1/2015, if reported on a claim with a comprehensive APC procedure (SI = J1). The*

line(s) with the inpatient-separate procedure is rejected and the claim is processed according to usual OPPS rules.

The presence of a unique status indicator will ultimately assist providers in insuring that their claims processing system edits are set up to bill these scenarios on an OP claim to CMS, and CMS will benefit by having more accurate claims data submitted. This will also increase the number of claims available for capturing cost data and utilizing for future rate setting.

The PRT notes that many providers do not submit outpatient claims to CMS when an IPO procedure was performed, because the current claim edits indicate that these claims cannot be submitted or paid. Based on the I/OCE logic, noted above, These providers and their vendors would benefit not only from CMS clearly explaining this logic but also from having a way to identify the IPO procedures that will be processed in this manner.

- The PRT requests that CMS identify IPO procedures that are on the separate procedure list with a unique status indicator such as "C1."
- The PRT also requests that CMS reiterate the I/OCE logic regarding IPO procedures that are classified as a separate procedure (e.g., SI = C1) are a line item rejection and do not cause the entire claim to be rejected.

Modifier –CA

It is important that claims assigned with modifier -CA (for patients who die or are transferred to another setting) can process appropriately because they contain information that identifies the specific IPO line item as being appropriately reported on an outpatient claim. While CMS provided guidance regarding the intent of modifier –CA, the agency has not updated the modifier description, verbiage to the I/OCE, technical documents, HCPCS Manual, or the Claims Processing Manual. The PRT believes that providers will benefit from having more explicit information about the purpose and use of modifier –CA.

- The PRT requests that CMS update the I/OCE, technical documents, HCPCS Manual, and the Claims Processing Manual with the revised description of modifier -CA, clarifying the application of IPO codes when the patient expires or is transferred before being admitted as an inpatient.

Eliminate the IPO List

The PRT notes that it is very complex for hospitals to administer the IPO list correctly in order to be reimbursed for delivering care. For this reason, we applaud CMS' reiteration that procedures not listed on the IPO list may be reimbursed *either* as inpatient or outpatient services. Beyond these actions, however, the PRT recommends — as we have for many years — that CMS eliminate the IPO list.

According to the CY2012 OPPS/ASC Final Rule, the IPO list specifies services for which the hospital is paid 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 PRT believes that the decision about the most appropriate care setting for a given surgical procedure is a complex medical judgment that is most appropriately made by the physician.

The PRT strongly feels that the appropriate level of care, and care delivery site, should be determined by the *physician's assessment of the individual patient's clinical state*. The physician is the entity that is best qualified to assess the specific patient's conditions and co-morbidities and determine the appropriate setting for that unique patient. By requiring certain procedures to only be provided on an IPO basis, CMS has removed the physician's ability to personalize patient care to the most appropriate setting (i.e., inpatient or outpatient).

Patient status is currently assigned based upon the physician's order for that patient. Decisions about patient status should be based upon the physician's clinical judgment — not the payment status. In fact, 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, hospitals perform procedures in the operative suite that is best-equipped for that specific procedure, regardless of whether the patient is classified as inpatient or outpatient. And, the same resources are available to perform the procedure, regardless of the patient's status.

The PRT has long held that the IPO list presents an *unnecessary administrative burden* and financial and operational challenges for hospitals, with little impact on physicians or benefit for patients. It requires hospitals to provide extensive education and official guidance to both medical staff and hospital schedulers using the IPO list (Addendum E). If CMS maintains the IPO list, we urge the agency to allow exceptions when the physician determines them to be in the beneficiary's best interests.

- The PRT recommends that CMS eliminate the IPO list and any payment restrictions.
- If CMS maintains the IPO list, the PRT urges the agency to allow exceptions when the physician determines them to be in the beneficiary's best interests, subject to medical review and that physicians adhere to the same IPO list criteria as hospitals are required to follow.

IX. Site-Neutral Related Topics

Below, the PRT presents our comments on three topics:

1. Reduction in Payment for Excepted Off-Campus Outpatient Hospital Visit Code G0463
2. Expansion of Services at Existing Non-Excepted Off-Campus PBDs
3. Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

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

CMS hypothesizes that the reason for the increased outpatient hospital visits is a result of hospitals' practice of purchasing freestanding physician practices and converting them to off-campus provider-based departments (PBD). CMS asserts that a motivation for the increase in off-campus PBDs is that payment under OPPS is higher than payment under its other payment systems (i.e., MPFS, CLFS, drugs at ASP +6%) and allows for payment under both OPPS and IPPS. CMS states that outpatient hospital E/M visits increased by 22% on a per beneficiary basis between CYs 2012 and 2015.

CMS did not detail the analysis that led to its statement that E/M visits increased by 22%. For example, CMS did not clarify whether its analysis excludes Type A and Type B emergency visits, which generally do not represent hospital acquisition of freestanding physician offices. CMS has not conducted any other analysis or offered any other rationale to use a "volume adjustment" authority to reduce the OPPS payment for G0463 by 60 percent.

CMS has also not conducted an analysis to assess whether these visits include a separately billed professional E/M service, which is a main reason the agency cites for its current proposed policy. CMS has yet to conduct and present any analysis of the effect the previously implemented 40 percent payment adjustment has had on clinic visit volume in nonexcepted off-campus departments. It is premature to conclude that applying this reduction to excepted off-campus departments would not harm beneficiaries' access to care.

The PRT recommends that CMS conduct analyses to understand whether all outpatient hospital visits represent both a facility component and a professional component. There are a significant number of outpatient hospital visits that are ordered by physicians to occur at outpatient hospital departments for which there is not a professional claim on the same date for the same encounter. For example, wound care, monitoring of Coumadin/warfarin, congestive heart failure, and COPD therapies, as well as other services are rendered by hospitals as ordered by treating physicians, and billed with outpatient hospital E/M codes when the services do not meet the definition of another therapeutic HCPCS code, the service is medically necessary, and meets outpatient hospital "incident to" coverage criteria.

In fact, at the Hospital Outpatient Panel (HOP) meeting on August 20th, the panel members noted that the outpatient hospital visit is one of the most important tools in the toolbox for treating Medicare beneficiaries who have co-morbid conditions, avoiding ED visits, and minimizing inpatient readmissions. CMS itself has encouraged and incentivized models of care that rely on these outpatient hospital visits to bridge patients from inpatient discharge to the time they can see their primary care or specialists in the office settings. More beneficiaries have co-morbid conditions that require these services and offices are not equipped with the specially trained nurses, technologists and pharmacists who render the services. We believe that CMS needs to better understand that outpatient hospital visits are a natural evolution of ACO and other alternative payment models seeking innovative ways to better manage patients that are high utilizers and require complex management.

Therefore, before making any payment reduction, CMS must better understand the nature of outpatient hospital services, particularly outpatient hospital visits. We request that CMS define another modifier for hospitals to use with HCPCS code G0463 to indicate a physician ordered

service that will not result in a separate 1500 professional claim. These services are provided by hospitals upon order and direction of the treating clinicians.

- The PRT recommends that CMS conduct analyses to explore whether all outpatient hospital visits include both a facility component and a professional component.
- The PRT requests CMS to define another modifier for hospitals to use with HCPCS code G0463 to indicate a physician ordered service that will not result in a separate 1500 professional claim.

Unintended Consequences

The PRT agrees that it is important for CMS to assess and seriously consider payment policies' consequences in its different payment systems across sites of care. These consequences may be intended *or* unintended. For example, we draw attention to the 2019 MPFS Proposed Rule, in which CMS proposes a four-year phase-in to update direct input resource costs for the practice expense component of numerous procedures. An analysis of these services shows that many have a facility NA indicator, meaning that the service is either performed in an office setting or performed by ancillary personnel in a facility setting. CMS generally does not pay clinicians under the MPFS if a facility place of service code is used on claims. Another way to think of these services is that clinicians choose whether to provide the service in their office settings or order patients to receive them in outpatient hospital and other facility settings.

The practice expense reduction in payment to these services begins at just 25 percent of the reduction in 2019 and will continue to be phased-in over the next four years. The PRT is concerned that, as physicians understand this reduction, they will respond by ordering Medicare patients to receive services at the community hospitals. In fact, the closest locations may be the excepted off-campus locations. Paradoxically, CMS is simultaneously *reducing* payment for these services in offices, to which clinicians may respond by ordering patients to receive the services at the hospital, and CMS is considering these same services to be expanded services at the hospital locations that are best able to perform the services for patients. This is how CMS' payment policies interact between different settings and why CMS should be evaluating the change in site of service over time.

It is important for CMS to understand that it is impossible for *hospitals* to order services; only clinicians can either perform services at their offices, or order patients to receive services at the hospital. This remains the sole responsibility of the treating clinician. Therefore, we ask CMS to pause and to consider all the policies it is implementing in MPFS, IPPS and OPPS and to develop analyses to thoroughly understand the impact of those policies across settings prior to using its authority to further reduce payment to hospitals. We ask CMS to not assume that hospitals are solely responsible for increases in hospital outpatient services and to better understand unintended consequences of their policies.

- The PRT requests that CMS actively consider how its payment policies interact and analyze the policies' impacts across settings before the agency uses its authority to further reduce payment to hospitals.

Expansion of Services at Existing Excepted Off-Campus PBDs

Throughout the 2017 OPPS Proposed and Final Rules, which implemented section 603 of the Balanced Budget Act of 2015, CMS referenced the provider-based regulations found at 42 CFR 413.65. These regulations define a department of a provider as follows:

> *Department of a provider* means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility.

This existing definition is consistent with how hospital departments operate. Indeed, the requirements for provider-based status are designed to ensure integration with the main hospital and states that provider-based departments (PBDs) are specifically designed to furnish health care services of the same type as the main provider.

This is also evidenced by CMS' preamble discussion with the initial PBD regulations, which states: "*[W]e emphasize that the provider-based rules do not apply to specific services; rather, these rules apply to facilities as a whole. That is, the facility in its entirety must be a subordinate and integrated part of the main provider."* (See 67 FR 50088.)

The concept of the department as a whole having PBD status and not the individual "items and services" has been in place since the beginning of PBD determination. The PRT strongly believes this must be maintained, as is, because it is foundational to how hospitals operate and deliver health care. This is how the PRT member hospitals deliver care in their departments to treat all types of outpatients.

Items and services furnished at the main provider evolve over time, as the clinical and community needs of its patient population evolve. Pursuant to the definition of all PBDs, those on- and off-campus items and services at these PBDs also evolve in step with the main provider. The main provider is comprised of individual departments that provide routine and ancillary services. These departments happen to be co-located where the main provider's inpatient beds are located. PBDs are ancillary departments of the same type as the main provider's, but may be located at individual on- and off-campus PBD locations. Therefore, once a location that is either an on- or off-campus department is determined to meet PBD requirements and bills under the hospital's CCN prior to 11/2/15, all prior, current, and future items and services provided at that PBD location would be excepted *by CMS' own definition* in 42 CFR 413.65 and 67 FR 50088. As shown above, the services are required to be "of the same type as those furnished by the main provider."

CMS' proposal to limit expansion of clinical services at excepted off-campus PBDs from those services billed as of a baseline period of 11/1/14 to 11/1/15 is untenable for hospitals and well beyond the statutory intent of Section 603. CMS' proposal to limit excepted off-campus PBDs to certain services is tantamount to treating these PBDs as if they are frozen in time; such an

approach does not allow any evolution of services to align with the evolution of evidence-based medicine. This "frozen in time" concept simply fails to recognize how medical care continues to change, and creates a very real possibility that innovation will be stifled and beneficiary access to care reduced. Indeed, CMS itself uses the concept of evidence based-medicine's evolution as the basis for expanding the list of covered Ambulatory Surgical Center (ASC) procedures in this very same Proposed Rule. CMS relies upon this logic to expand coverage and payment at freestanding ASCs, while using this same logic to reduce payment to hospital PBDs.

As the CPT codebook states:

> *It is equally important to recognize that as techniques in medicine and surgery have evolved, new types of services, including minimally invasive surgery, as well as endovascular, percutaneous, and endoscopic interventions have challenged the traditional distinction of Surgery vs Medicine. Thus, the listing of a service or procedure in a specific section of this book should not be interpreted as strictly classifying the service or procedure as 'surgery' or 'not surgery' for insurance or other purposes. The placement of a given service in a specific section of the book may reflect historical or other considerations (e.g., placement of the percutaneous peripheral vascular endovascular interventions in the Surgery/ Cardiovascular System section, while the percutaneous coronary interventions appear in the Medicine/Cardiovascular section).*

Therefore, as AMA changes existing CPT codes, deletes codes, and/or creates new codes for evolving services, codes may be grouped into different APCs. This occurs not because they are new services, but because the *nature* of the service has changed and AMA determines the service should be placed in a different section of the CPT Manual.

CMS should not continue with this misguided policy. Furthermore, the PRT does not believe it was Congress' intent to limit the expansion of all outpatient off-campus hospital services. Rather, Congress intended to slow or limit the conversion of existing freestanding physician practices to new outpatient hospital off-campus PBDs. This is critically important because the site-neutral policies that Congress and MedPAC have been focused on, by definition, should be limited *only* to those services that can be performed in a physician practice. If the services cannot be performed in a physician practice (or are rarely performed in a physician practice), then, when a hospital determines — based on increased physician orders and patient-population needs — to change the services provided at an existing excepted off-campus PBD, the hospital should not be penalized with reduced payment. (This would occur pursuant to the Section 603 payment policy of the site-of-service-specific (SoSS) form of the physician fee schedule [i.e., 40% of the OPPS payment rate]).

CMS proposes that hospitals track whether services provided at an excepted off-campus PBD are "expanded" after 11/2/15 based on running a per-PBD location analysis of the clinical families performed in a baseline period. The PRT questions whether this analysis is to be performed on *all* patients who receive services at this location, or only Medicare patients? We question what happens if a patient was 64 years of age as of 11/1/15, then turned 65 and became eligible for Medicare on 11/2/15. Providing services to this individual does not constitute an "expanded service" for the PBD, since the patient previously received services at the location. But, if the

analysis is just on the Medicare patient population, the services could possible fall into a new clinical family for just that one Medicare patient.

If services are considered to be "expanded" at that PBD, then they would no longer be payable under OPPS. The hospital would be expected to append modifier -PN to trigger the change from OPPS payment to the SoSS MPFS payment (i.e., 40% of the OPPS rate). This will result in modifier -PN being used on services at both non-excepted PBDs and excepted PBDs. As a result, CMS will no longer be able to solely associate modifier -PN with a location that is truly non-excepted as defined by Section 603 and should be delineated on the hospital's 855A enrollment form. CMS would no longer be able to accurately enforce the original intent of Section 603: to identify the actual PBD locations that are non-excepted.

In addition, CMS will not be able to apply the edits it outlines in the August 5, 2016 Transmittal R1704OTN, CR9613, February 2, 2017 Transmittal R1783OTN or CR9907 and in the Special Edition article SE18002 that outlines requirements to report location on claims. Section 603 is not intended to apply to items and services provided to excepted PBDs. Therefore, should CMS persist in this ill-advised policy, the PRT strongly objects to the use of the -PN modifier and asks that a unique and separate modifier be created.

CMS proposes to determine "expanded" services based on APC-based clinical families. As previously stated, hospital "departments" deliver all forms of services of the same type as that furnished in the main hospital. Often the same equipment and personnel are used to deliver services that may not have been performed at a particular PBD location yet, but which can be delivered upon a moment's notice to meet a patient's clinical needs. Indeed, this is the *intent* of the direct supervision coverage requirement for outpatient hospital therapeutic services.

For example, if an excepted off-campus PBD performs advanced imaging services, but a patient needs a drug administration service for a clinical condition at the encounter for the imaging test (not integral to the imaging service and therefore, separately billable), the supervising physician and nurse would be able to perform that drug administration service. This service may not have been billed prior to 11/2/15. CMS' proposal would not allow the drug administration service to be payable under OPPS, since it would be considered an "expanded" clinical service at that excepted off-campus PBD location.

CMS' current proposal means that it is possible that a single medical service needed by a patient and furnished with the same equipment and personnel at the PBD would be an "expansion" and no longer payable under OPPS. This service has nothing to do with the concern about the hospital purchasing a formerly freestanding physician practice and adding those services to the excepted PBD. CMS' proposal is a significant over-reach and not appropriate to how hospitals render services based on physician's orders most often directing the location and site of care. If CMS is concerned about hospital acquisition of physician practices, CMS should mandate provider-based attestations going forward to determine the location of services related to this practice.

Furthermore, using the 11/2/15 statutory effective date for determining new off-campus PBD services as the date to effectively "freeze" the type of services provided at an excepted off-campus PBDs ignores the importance of delivering the right care at the right time. Taken to the

extreme, it is possible that, after 5 or 10 years, all services at excepted off-campus PBDs could be deemed to be "expanded clinical services" simply because the health care services either have new CPT/HCPCS codes or new APC assignments that result in changed clinical families from those defined as of 11/2/15. How does CMS intend to update this policy annually? For example, Table 32, which lists the APCs by clinical family, includes APC 5525, which does not exist in the CY 2019 Proposed Rule. Would procedures that were formerly grouped to this APC be considered an "expansion?"

The PRT also seeks clarification whether it is CMS' intent that, after a period of time, *no* excepted off-campus PBDs would exist that are payable under OPPS. This would occur because, as services evolve and have new and/or different HCPCS codes grouped to new APCs, these would all be "expanded," since they may well change clinical families. This is the logical progression of CMS' proposal—clearly, however, it is not the logical progression of Congressional intent with Section 603 legislation.

The PRT also notes that new technology APCs are not included in the clinical families. What does this mean? Could a hospital invest in the infrastructure and equipment at an excepted off-campus location while the service is assigned to a new technology APC and be paid full OPPS new technology APC rates, only to have CMS assign the new technology to an APC that is part of a clinical family that would be "new" when compared to a baseline? Or does this mean that, by definition, all new technology services are not considered an expansion under the clinical families including when they are assigned to other APCs?

The PRT notes that emergency services and critical care are included in the clinical families. Pursuant to EMTALA obligations, every PBD location (whether on- or off-campus) must respond to an emergency. So, if an individual is an EMTALA patient at an excepted off-campus PBD that performed surgery services, and the on-site surgeons respond to the patient's emergency and render critical care, would it constitute an "expanded service" at that PBD location that is subject to reduced payment? This is patently unfair, as a major requirement for PBDs is meeting EMTALA obligations. Hospital emergency services should never be considered "expanded" services. Furthermore, emergency services are not likely due to an acquisition of freestanding physician practices. Finally, it is not logical that APC 5045 for trauma response with critical care be in a clinical family as this is, by definition, a hospital-only service; offices cannot provide trauma activation services.

The PRT is also concerned that approximately 1,976 of the 4,614 HCPCS codes contained in the clinical family APCs have an "NA" in the non-facility NA indicator field of the MPFS resource based relative value schedule (RBRVUs). This means the service is rarely (if ever) performed in an office or non-facility setting because either physicians lack the capacity or it is not safe to do so. Why would it be considered an "expansion" of services if a hospital performs these services when ordered by treating physicians and when the patient population needs these services? These services are not expected to be performed in physician offices, so when hospitals expand their capability at excepted, off-campus locations, it is in response to patient need, not to the purchase of physician practices that had been performing the service. All HCPCS codes and APCs with HCPCS codes that have a non-facility NA indicator should *never* be considered to be an expansion of services!

In summary, the PRT notes that Section 603 excepted PBDs (i.e., the locations and personnel and equipment) that were billing under the provider's CCN prior to 11/2/15 should be excepted, period. Since the provider-based entity is a department of the main provider, according to CMS' own definitions, it is intended to furnish the same services as the main provider. Therefore, any concept of expanded services does not and should not apply. Clinical needs and evidence-based medicine will evolve, and CMS should not monitor or limit services at legitimately excepted off-campus provider-based locations with any method.

If CMS proceeds with this policy, the result of CMS' "expanded services" and Section 603 policies will be to not only eliminate the expansion of non-excepted off-campus outpatient hospital PBDs, but also to erode those that are excepted and that existed prior to the baseline period. The future of off-campus hospital services is very unclear. If hospitals close excepted off-campus locations and no longer have an option to organize new ones due to the SoSS MPFS payment methodology, the result will be a significant barrier to outpatient care for this vulnerable population.

- The PRT urges CMS to recognize that that Section 603 excepted PBDs (i.e., the locations and personnel and equipment furnishing health care services of the same type as those furnished by the main provider) that were billing under the provider's CCN prior to 11/2/15 should be excepted, period.
- If CMS persists in this ill-advised policy, the PRT strongly objects to the use of the-PN modifier and asks that a unique and separate modifier be created.
- If CMS proceeds with this ill-advised policy, specific details must be provided regarding the determination of whether services remain a baseline service, or become an expanded service by virtue of usual/annual CPT and APC changes. How does CMS plan to update this policy annually?
- Is it CMS' intent that after a period of time there will be *no* excepted off-campus PBDs that are payable under OPPS?
- How will CMS address new technology services that are not included in the current proposal, but at some point will be assigned to other APCs? Will the assignment to a non-new technology APC create an expansion under the clinical families? Should CMS proceed with this ill-advised policy, there must be a permanent exception for emergency services provided as required by EMTALA. That is, hospital emergency services should never be considered "expanded" services regardless of the department location where they are rendered. Should CMS proceed with this ill-advised policy, there must be a permanent exception that all HCPCS codes and APCs with HCPCS codes that have a non-facility NA indicator shall not be considered to be an expansion of services!

CMS' Calculation of the PFS Relativity Adjuster

The PRT was interested in the discussion of CMS' calculation of the PFS Relativity Adjustor in the MPFS 2019 Proposed Rule. CMS outlined a change in its methodology this year: it identified the CPT services billed with modifier -PN and modeled MPFS payment for each service, each drug at ASP +6%, and each lab at the CLFS amount, and then compared the results to the OPPS payment rates, including no payment for packaged drugs, labs, and ancillary services. This new

methodology resulted in a PFS relativity adjustor of 40% of the otherwise applicable OPPS payment rates.

The PRT is curious whether any CPT services that were billed with modifier -PN have a non-facility NA indicator in the MPFS. We note that there are numerous CPT services in the clinical families (approximately 1,976) for which the MPFS has no practice expense value for the facility component. Across all HCPCS codes, there are approximately 2,400 CPT codes that have no facility practice expense component (i.e., the total non-facility RVUs equal the total facility RVUs) in the MPFS. This means that there is no facility practice expense in the MPFS for these services because they are always performed in either an outpatient hospital department or an ASC. (Some examples of services for which the MPFS has no facility payment include wound care treatments to remove and/or treat pressure sores, fracture repair surgeries, biopsies, and many endoscopy procedures.)

Therefore, the MPFS has no practice expense resources included in the practice expense relative values associated with these surgical procedure CPT codes. Does CMS value these at zero in the MPFS when developing the relativity adjustor calculation? We note that doing so would inappropriately suppress or reduce the value.

The PRT believes it is absolutely inappropriate to ever apply the SoSS MPFS payment rate of 40% to services with the non-facility NA indicator. This application is inappropriate because there is no non-facility practice expense built into the MPFS payment rate that is comparable to the OPPS payment rate for the outpatient hospital facility expense. There is no "relativity" relationship between the MPFS payment rate and the OPPS payment rate because the MPFS payment rate does not include any practice expense cost for performing the service. The OPPS rate is the only rate that CMS develops to pay for the resources required to perform the service in an outpatient setting. Even the ASC rate is developed off the OPPS rates!

- The PRT requests that services with a non-facility NA indicator be excluded from the relativity adjustor calculation and recommends that CMS determine another payment rate to apply to the facility costs of these services.

OPPS No Longer Results in Higher Payment for all Services

The PRT is concerned that the CMS, MedPAC, GAO and OIG analyses concerning "site neutrality" were performed prior to the significant expansion of packaging policies under OPPS beginning in CY 2014. While the PRT lacks the resources to do a full-scale claims analysis with assumptions, we have priced out a common outpatient hospital encounter, and the MPFS actually results in *higher* payment under CMS' proposal than the current OPPS payment. This is the case even including the physician professional component.

We believe that CMS should conduct modeling of payment for off-campus PBDs using claims with modifier –PO to determine whether there is still significant additional payment under OPPS. This analysis would inform Congress and CMS as they progress with implementation policies.

- The PRT recommends that CMS conduct modeling of payment for off-campus PBDs using claims with modifier –PO to determine whether there is still significant additional payment under OPPS and use this information to inform Congress and guide CMS's consideration of changes in implementation policies related to Section 603.

Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

The PRT, as expressed in our comments to the 2018 OPPS Proposed Rule, still fundamentally and emphatically disagrees with CMS' CY 2018 final policy to reimburse for separately payable drugs obtained by Covered Entities via 340B purchasing at ASP *minus* 22.5 percent. We believe the finalized policy action is of questionable legality and draws into question the boundaries of CMS statutory authority, as evidenced by the legal action initiated by the American Hospital Association (AHA).

As a general matter, the implementation of the -JG and -TB modifier process has been extremely burdensome for providers. For many, the policy has resulted in a substantial decrease in Medicare OPPS payments, to which they would be entitled in the absence of this misguided policy. Additionally, this policy instituted in CY 2018 inappropriately redistributes funds (via neutrality adjustment) that are intended specifically for 340B providers to the entire pool of OPPS providers.

As an overarching comment, our disagreement is well-documented, and we believe the policy should be reversed. CMS, however, is moving forward with the advancement of this policy to *additional* locations of nonexcepted providers operated by Covered Entities.

The PRT seeks clarification about how CMS can seriously characterize this proposal as a site-neutral policy, when CMS already applies OPPS packaging policies to nonexcepted locations (i.e. drugs under the $125 [2019 proposed] drug packaging threshold are not paid separately to nonexcepted locations, even though they are processed "under the applicable payment system" [which is the site-specific MPFS]).

We are not surprised to see this proposal. In the CY 2018 Final Rule, CMS stated:

> *As we discussed in the CY 2017 OPPS/ASC interim final with comment period (81 FR 79718) and reiterated in the CY 2018 MPFS final rule, payment for Part B drugs that would be separately payable under the OPPS (assigned status indicator ''K'') but are not payable under the OPPS because they are furnished by nonexcepted off-campus outpatient PBDs will be paid in accordance with section 1847A of the Act (generally, ASP+6 percent), consistent with Part B drug payment policy in the physician office. We did not propose to adjust payment for 340B acquired drugs in nonexcepted off-campus PBDs in CY 2018 but may consider adopting such a policy in CY 2019 notice-and-comment rulemaking*.

For CY 2019, CMS essentially ignores the position it took less than a year ago and states:

> *Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a*

percentage (40 percent) of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis. Therefore, we believe we have flexibility to pay for separately-payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

We disagree. Nonexcepted Off-Campus services, by definition, are *not* OPPS services. CMS should not arbitrarily and randomly change the definition of "applicable payment system" merely to suit its inappropriate pursuit of site-neutrality and its insinuation that providers are inappropriately redirecting drug administration services to nonexcepted locations. There is no substantive reason why CMS should "presume" there is currently *any* shift of services occurring based on the concern or assertion that there is an "incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs." It is egregious for CMS to imply this is happening in the absence of irrefutable evidence.

- The PRT wholeheartedly and emphatically disagrees with CMS' proposal to identify the PFS as the ''applicable payment system'' for 340B-acquired drugs and biologicals and to pay under the PFS instead of under section 1847A/1842(o) of the Act an amount equal to ASP minus 22.5 percent for drugs and biologicals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs.

Along with the above comments, the PRT reiterates our concerns and opposition submitted in 2017 concerning reimbursement for separately payable drugs obtained by Covered Entities via 340B purchasing at ASP *minus* 22.5 percent (ASP-22%). We recommend that CMS reverse this payment methodology.

CMS rationalized this proposal because "reports" indicate there has been no change to the charity care on hospital cost reports after implementation of the 340B program, and CMS believes that hospitals are not reinvesting the dollars saved by discounted drug purchasing into their communities. The PRT believes these statements are false and we strongly urge CMS to reverse this payment methodology. The PRT continues to encourage CMS' working with the Health Resources and Services Administration (HRSA) to evaluate how providers are redirecting 340B savings.

The PRT also rejects the idea that reimbursing for 340B drugs at ASP-22% will assist the underserved. Our own experience is that hospitals—including PRT member facilities—are *absolutely* both providing and expanding services to under-served and/or under-insured patients in our communities.

We also reiterate the provider operational considerations. CMS assumes *all* 340B hospitals purchase *all* drugs under the discounted program. Hospitals that participate in the 340B discount program continue to experience drug pricing variability. Many hospitals use a "virtual inventory system" for tracking 340B drugs. Hospitals must track, document, and achieve a certain number

of "credits" in the system before they are eligible to receive discount pricing. Discount availability is fluid and can change by individual drugs, different manufacturers, and time periods. Hence, hospital's replenishment for stock of a specific drug at 340B pricing depends on that pricing being available; if the pricing is unavailable, the hospital pays "regular" prices for the replenishment.

In addition, the drug supply system utilized for purchasing medications is completely separate from, and may not communicate with, the pharmacy's drug dispensing system and patient billing system. The knowledge of whether a specific drug was replenished under 340B or at regular pricing is not necessarily known when the drug is provided to the patient.

Another concern is that the OPPS rate-setting process *already* accounts for 340B savings as the hospitals' cost reports already reflect the 340B acquisition based on expenses reported in the pharmacy cost center. The OPPS rate-setting process already reflects a blend of discounting/lower expenses with respect to 340B drug acquisition, in the annual application of CCRs to pharmacy charges. It is inappropriate for CMS to seek additional reductions without considering the program's existing impact on OPPS rates.

The PRT appreciates CMS' desire to address the needs of under-served and low-income patients. The redistribution of funds in the OPPS does not, however, accomplish that goal and is outside the purview of CMS with this payment system. We continue to disagree with CMS reallocating funds that are intended for covered entities, across the OPPS payment system through a budget neutrality mechanism. We again note that reductions in payments and the redistribution of savings across the OPPS conflicts with Congressional and HRSA's intent regarding 340B hospitals' use of cost savings to expand care for underserved patients.

X. 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 Outpatient Quality Reporting (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 also appreciate the limitation of measures to one program and agree this will result in cost-savings for both providers and the agency.

Accounting for Social Risk Factors

The PRT is pleased that CMS has acknowledged the impact a patient's socio-demographic status (SDS) and social risk factors have on providers' ability to successfully comply with OQR Quality measures. We support CMS continuing to explore how best to account for social risk factors in the OQR program, including the effect of lack of income, education, social support, and community resources. These patients often require more intensive social services to achieve improved outcomes. We recognize that there are limited data on social risk factors and we are pleased to know that the National Quality Forum (NQF) has extended its trial to determine the impact of these factors on patient's health care outcomes.

Beneficiaries who have social risk factors may be at higher risk for noncompliance that can significantly and negatively impact their outcomes. For this reason, we recommend that CMS consider factoring the SDS into the measure calculation method, for those measures where patient behavior (i.e., compliance with medical advice) impacts his or her outcomes.

The Proposed Rule suggests using "dual-eligibility" as the factor for risk adjustment. The PRT believes this is only a temporary solution. We recommend that CMS take steps to ensure that *individual* measures account for SDS in *measure-level* risk adjustment. CMS should consider the full range of differences in patient backgrounds that may impact outcomes. These include age, income (i.e., being at or near poverty level), educational attainment, belonging to a racial or ethnic minority group, and living with disability. All can impact a patient's ability to comply. CMS should avoid payment penalties that mask health disparities.

- The PRT recommends that CMS consider factoring in the socio-demographic status in the measure calculation method when patient compliance impacts their outcomes.

Consideration Factors for Removing Measures

The PRT strongly supports the proposal to add "Factor 8 – The costs associated with a measure outweigh the benefit of its continued use in the program," in order to determine whether to remove measures from the Hospital Quality program. The PRT has made comments on prior Proposed Rules asserting the very same concern expressed by CMS.

- The PRT supports adoption of "Factor 8" when evaluating measures for removal from the Hospital OQR Program measure set.

Proposed Removal of Quality Measures

2020 Payment Determination

The PRT supports the removal of OP-27: Influenza Vaccination Coverage Among Health care Personnel. We have indicated, in prior comments, the same reasons for doing so that are CMS describe in this Proposed Rule. This measure is duplicative and the rate of employee compliance is high, partially as a result of requirements set forth by health care employers.

2021 Payment Determination

In this Proposed Rule, CMS states that it considered removal of a large group of measures for the 2020 payment determination (specifically, OP5, OP9, OP11, OP12, OP14, OP17, OP29, OP30, and OP31). The agency, instead, is proposing to delay their removal until the 2021 payment determination 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 the removal of these measures for the 2020 payment determination. We have noted issues with many of these measures – issues that we are pleased CMS explicitly identified in this Proposed Rule. We do not understand why providers should continue to have to report measures

that have been identified as repetitive, topped out, inappropriate for the hospital outpatient setting, and/or no longer aligned with current clinical guidance. While intense resources and system programming are required to ADD or REVISE a measure for reporting, there is limited burden to STOP reporting a measure.

- The PRT recommends that CMS remove the following measures for the 2020 payment determination and not delay until 2021 payment determination:
  - OP5 – Median time to ECG
  - OP9 – Mammogram follow up rates
  - OP11 – Thorax Computed Tomography (CT) – Use of contrast material
  - OP12 – The ability of providers with HIT to receive lab data electronically directly into their qualified/certified EHR system as discrete searchable data
  - OP14- Simultaneous use of Brain CT and Sinus CT
  - OP17 – Tracking Clinical Results between visits
  - OP29 – Endoscopy/Polyp Surveillance: Appropriate follow up interval for normal colonoscopy in average risk patient
  - OP30- Endoscopy/Polyp Surveillance: Appropriate follow up interval for patients with history of adenomatous polyps – avoidance of inappropriate use
  - OP31 – Cataracts – Improvement in patient's visual function within 90 days following cataract surgery

Proposed Hospital OQR Program Measure Set for CY2020 and CY2021

> OP-32: Facility 7 Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy: All causes, unplanned hospital visits (admissions, observation stays and ER visits) within 7 days of an OP Colonoscopy

The PRT has on-going concerns about the continuous claims-based measure: OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy: All causes, unplanned hospital visits (admissions, observation stays and ER visits) within 7 days of an OP Colonoscopy.

We recognize that CMS seeks to *"reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care."* While we support that goal, we note that, for any colonoscopy performed outside of the hospital's outpatient department, hospitals have *no* control at all over preparation, the procedure itself, or follow-up care. Adding this quality measure would force hospitals to ask each and every patient who presents to the Emergency Department (ED) whether he or she had a colonoscopy in the last week. Such an inquiry is bound to be confusing, annoying, and irrelevant to the vast majority of ED patients.

We are additionally concerned by CMS' proposal to exclude (a) patients with concomitant high-risk upper gastrointestinal (GI) endoscopy, (b) patients with a history of Inflammatory Bowel Disease (IBD) or diverticulitis in the year preceding colonoscopy, and (c) patients who lack continuous enrollment in Medicare Fee for Service (FFS) Part A and B in the one month after procedure. As above, we are unclear how facilities are to assess this patient history. We also note that there is no code for this. We seek clarification from CMS about how facilities will know,

having asked the patient if he or she has had a recent colonoscopy, whether there was also a high-risk upper GI endoscopy? The logistical nightmare and risks to patient satisfaction are both significant.

The PRT does *not* support the continued use of this measure of hospital outpatient department quality. We believe it is unfair to penalize *hospitals* for negative outcomes and other inadequate results from procedures that occur elsewhere.

- The PRT recommends that CMS remove OP-32 for the 2020 payment determination.
- If CMS proceeds with the measure, the PRT recommends that the agency reconsider the measure's design and only include it for cases when the initial colonoscopy was performed at the same facility in which the unplanned hospital visit occurred within seven days of the outpatient colonoscopy.

OP-33: External Beam Radiotherapy (EBRT) for Bone Metastasis

While we support all efforts to improve the quality of care, the PRT requests that CMS continue to be sensitive to the administrative burden that "web-based" (formerly "chart-abstracted") quality measures impose.

The PRT understands that CMS is interested in oncology care measures, since cancer is a prevalent condition that is often treated in the outpatient department setting. We doubt, however, that this specific measure serves the broad purpose of analyzing the quality of care provided to oncology patients in the outpatient setting.

We remind CMS that an abundance of readily available data about this issue is already captured through Tumor Registry services. We encourage CMS to consider using this source for needed data, rather than implementing another manually abstracted measure.

Further, the PRT believes that measures should apply to a unique and easily defined patient population. This proposed measure includes vague terminology and exclusions that are difficult for facilities to identify. We believe that the subjectivity of the measure descriptors creates challenges to the integrity of the data CMS receives on this measure. For example, the descriptor "painful bone metastasis" is used to identify the patient population to which this measure applies. Although we recognize that clinically speaking, metastatic bone cancer is obviously "painful," we note that there is no code in the ICD-10-CM code set that differentiates this key term, "painful."

The PRT is also concerned by the list of circumstances in which a patient is excluded from the measure. Exclusions apply if a patient:

(a) Has had previous radiation to the same site;
(b) Has femoral axis cortical involvement greater than three cm in length;
(c) Has undergone a surgical stabilization procedure; or
(d) Has spinal cord compression, cauda equine compression, or radicular pain.

These exceptions are difficult to identify in a hospital outpatient department record. Extensive record research spanning multiple encounters may be required to identify these characteristics, and the documentation may ultimately reside in the physician's office record.

In addition, the measure details listed in the NQF Specifications provide no further guidance on identifying exceptions. There are no ICD-10-CM codes to readily identify conditions described by exclusions (b) and (c), nor for "radicular pain" described in exclusion (d).

- The PRT recommends that CMS remove OP-33 for the 2020 payment determination
- The PRT recommends that CMS be sensitive to the administrative burden that "web-based" (formerly "chart-abstracted") quality measures impose on providers. In addition, (if this measure remains in the OP Quality Program), CMS should consider limiting this data collection to radiation oncology sites.

OP-35: Admissions and Emergency Department Visits for patients receiving outpatient chemotherapy

The PRT recognizes that CMS seeks to reduce adverse patient outcomes associated with chemotherapy treatment in the hospital outpatient setting. We have continued concerns with the details of this measure, however, and of the efficacy of the data received.

CMS notes that the "side effects" included in the measure are "predictable and manageable" and are potentially preventable through appropriately managed outpatient care and increased communication with patients. These side effects are: anemia, dehydration, emesis, fever, nausea, neutropenia, pain, pneumonia, and sepsis. CMS suggests that admission within 30 days of chemotherapy for these conditions necessarily results from chemotherapy's side effects, rather than as a natural progression of the patient's neoplastic disease.

The PRT notes that some of these conditions may be due to the patient's cancer itself, rather than a result of chemotherapy. Because of the often-debilitated state of cancer patients (whether they are receiving chemotherapy or not), these individuals are more susceptible to disease processes that may be inherent to their cancer diagnosis, or may occur because their immune system is compromised due to the effects of their cancer or their debility. It will often be virtually impossible for a physician to determine if the condition is specifically due to chemotherapy effects (as the measure suggests) versus the natural progression of the underlying disease process. ICD-10-CM codes are rarely granular enough to specifically link the symptom or condition to the chemotherapy. The PRT seeks clarification from CMS about ways that providers can indicate whether the condition is or is not a side effect of the chemotherapy.

Consider the scenario in which a patient who received chemotherapy services in a hospital outpatient department later experiences a fall in their home, and presents to the ED with back pain. The ED diagnosis (i.e., back pain) qualifies this patient for measure OP-35 and reflects poorly on the facilities' care of cancer patients, despite the fact that the condition is totally unrelated to the patient's cancer care.

It is also difficult to comprehend how conditions such as pneumonia and sepsis can be considered a controllable and preventable "side effect" of chemotherapy in this population, which typically has suppressed immunity.

The PRT requests more transparency on the risk-adjustment methodology for this measure. The details of the measure provide only vague references to demographics, cancer types, clinical comorbidities, and treatment exposures that impact the risk adjustment. We believe that the patient's stage of cancer and co-diagnoses significantly impact the timing and severity of the symptoms, as well as the timing of his or her treatment.

We cannot stress enough the impact of the patient's SDS on their care and outcome. The PRT asks that CMS strongly consider factoring SDS into the measure calculation method.

Although the measure is well-defined, the PRT continues to be concerned about the burden it places on hospitals that have little control of the treatment plan and post-procedure management for patients who receive chemotherapy in the outpatient department. The measure should be attributed *only* to circumstances in which the subsequent inpatient admission or ED visit occurs at the same facility in which the chemotherapy was administered. A hospital that receives a patient for care in the ED or inpatient hospital unit has absolutely no control over whether or not a treatment plan to support the management of a patient's condition was adequately administered in *another* hospital's outpatient department. For this reason, the PRT does *not* support the use of this measure of hospital outpatient department quality. We believe it is unfair to penalize *hospitals* for negative outcomes and other inadequate results from a service that may have occurred elsewhere — especially since the literature highlights the proposed conditions as *potentially preventable* in this population.

- The PRT recommends that CMS remove OP-35 for the 2020 payment determination.
- If CMS does not remove this measure, the PRT recommends that CMS develop a method of clearly associating the "potentially preventable" conditions to the chemotherapy, factoring in SDS, and providing more transparency on the risk-adjustment models.
- The PRT recommends that the agency redesign this measure to include cases in which the provision of outpatient hospital-based chemotherapy service occurred at the same facility in which the unplanned hospital inpatient admission or ED visit occurred within 30 days of the hospital outpatient chemotherapy.

OP-36: Hospital Visits after Hospital Outpatient Surgery

The PRT agrees with CMS on the importance of reducing adverse patient outcomes associated with surgery. We support CMS' definition of same-day surgery as those listed on Medicare's list of covered ASC procedures. This subset of procedures is well-aligned with the measure's target due to the fact that these surgeries do not typically require an overnight stay, are reviewed annually and updated by Medicare, and allows opportunity for a public comment.

The PRT has the same concerns regarding SDS with this measure as we have for OP-35, discussed earlier in this comment letter.

We also have concerns regarding risk-adjustment variables. The convoluted approach of adjusting for surgical procedure complexity using RVUs and the introduction of a complicated anatomical body system classification system make the risk-adjustment methodology unclear and difficult to understand.

While the PRT agrees that-risk adjustment is appropriate, we are concerned about using this method. In our experience, the documentation of co-morbid conditions on same-day surgery is very limited, due to the nature of the service. It is problematic to depend upon extensive documentation in a same-day surgery record to determine risk. Surgeons who bring a patient in for a specific ambulatory-type procedure typically limit documentation to conditions that are relevant to the specific body system related to the surgical procedure.

- The PRT recommends that CMS remove OP-32 for the 2020 payment determination.
- If CMS does not remove this measure, the PRT recommends that CMS delay the enforcement of this measure until the issues above are addressed, SDS can be factored in, and more transparency on the risk adjustment models can be provided.

Delay OAS CAHPS Survey Measures (OP 37a-e)

The PRT appreciates the continued delay of the OAS CAHPS Survey Measures. We remain concerned about the operational burden and repetitive nature of this extensive and complex outpatient survey. We urge CMS to allow only voluntary reporting through the upcoming fiscal year.

- The PRT recommends that CMS allow voluntary reporting for OP 37a-e for the upcoming fiscal year.

Public Display of Quality Measures

The PRT is pleased that CMS has acknowledged there are issues with the consumer's understanding of publicly displayed data. The PRT has often voiced this concern. We hope that the elimination of duplicative measures in multiple quality measure programs will help alleviate the confusion of beneficiaries who seek to use the data to make informed health care choices. We note that the difficulty in interpreting the displayed data makes the data virtually useless to the consumer. Adding to the concern is that the data are already two or three years old by the time they are made public.

Topics for Future Consideration

The PRT appreciates the opportunity to present topics for consideration for future outpatient quality measures. CMS notes in the Proposed Rule that the agency is moving toward the use of clinical outcome measures and away from use of process measures and aligning quality measures across the Medicare program. We strongly support this approach.

Electronic Submission of Data

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

The PRT supports the concept of using data that have been collected from EHRs, but we continue to oppose CMS having *direct access* to a facility's EHR for data abstraction. We believe that specific data submission from the EHR could be developed in order to provide necessary information electronically without increasing hospital burden. We would support access within our facility system firewalls to data in the EHR only when it specifically addresses the quality measure.

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

We also note that a requirement to submit data electronically may be premature since we have little confidence that health care providers are prepared to do this with great accuracy. Within the short-term, EHRs' prevalence and capacity are expected to significantly improve; data integrity will enable electronic submission of quality measures data to CMS.

- The PRT urges CMS not to use a direct portal to have open access to all data within a patient's EHR.
- The PRT encourages CMS to promote the development of systems for hospitals to submit only specific data elements in an electronic format.

XI. Requests for Information (RFI): Promoting Interoperability and Electronic Health Care Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare-Participating and Medicaid-Participating Providers and Suppliers

The PRT agrees that interoperability is an important goal for hospitals and providers alike. We support the goal of improving patient care through enhanced communication via the exchange of usable health care information. With the adoption of electronic health records (EHRs), health care providers have been focusing on implementing systems that enable them to fulfill their patient care and business needs.

The PRT agrees, in concept, with promoting measures that require the exchange of health information between providers and patients, and with incentivizing providers to make it easier for patients to obtain their medical records electronically. The PRT, however, does not agree with CMS' proposal to change the conditions of participation (COP) and require organizations to promote electronic communication and send the discharge electronically if the patient is being transferred. We do not believe that utilizing the CoPs, Conditions for Coverage (CfCs), or

Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to further advance electronic exchange of information will achieve CMS's goal to promote interoperability.

We believe that CMS' proposal puts the cart before the horse: industry-wide, the infrastructure for this activity does not exist. Hence, the industry should continue to focus on promoting data standards (i.e., terminology standards) and information content standards (i.e., reference information models and case definition templates, among others). Until greater alignment with these standards exists, the PRT cannot support a requirement that hospitals transfer information electronically to another facility when a patient is transferred or discharged. This proposal, if finalized, would penalize providers if the receiving institution cannot receive the information.

The PRT recommends promoting a standard data set and EHR functionality that allows users, hospitals, and patients to pull information from secure portals (e.g. patient portals). We believe this approach will enhance the transfer of usable health information to those who need it, and is preferable to automatically and unnecessarily pushing protected health data.

- The PRT does not support the proposal to change the conditions of participation (COP) and require organizations to promote electronic communication and send the discharge electronically if the patient is being transferred.

XII. Requirements for Hospitals to Make Public a List of Their Standard Charges via the Internet

The PRT appreciates that CMS discussed pricing transparency and sought provider feedback in this year's Inpatient Proposed Rule (IPPS), including on the definition of "standard charges." The PRT submitted comments on this proposal and responded to CMS' questions concerning price transparency. We are disappointed that CMS chose not to address our comments and adopt our recommendations, in the IPPS Final Rule. While the PRT continues to support data transparency, we do not believe this proposal would provide beneficiaries with *any* useful information or assistance. We note that the requirement to report "MS DRG" is a legislative requirement and seek CMS' guidance on how to translate this requirement to the OPPS setting.

We also seek CMS' clarification on the process to meet the requirement to "make available via the Internet in a machine readable format;" this terminology is very unclear. Without specific guidance, the agency will inevitably see huge variations in the information and data elements posted by providers on their websites. For example, does the agency intend for providers to post what is in their chargemasters? We note that providers could comply with this requirement by posting average charges and prices, without providing the associated CPT code that provides useful information to beneficiaries.

Finally, we urge CMS to clarify whether this requirement supersedes state requirements about information publication. **Appendix B** contains our full IPPS comments. Since the issue applies to the contents of the OPPS Proposed Rule, we did not feel it necessary to re-write what we have already submitted and we encourage CMS to review it carefully as it does not appear to have done so as part of the IPPS rule-making cycle, but perhaps it was because the time to review was too short.

In summary, we recommended that:

- CMS look to the individual insurance plans for education and information regarding an individual member's out-of- pocket costs, comparisons across sites of care, and in- and out-of-network providers and costs.
- CMS continue to require hospitals to publicize the methodology for patients seeking price estimates and financial counseling but not require hospitals to post their charges online.
- CMS work with stakeholders such as the Healthcare Financial Management Association (HFMA) and the State Hospital Associations regarding best practices that are currently in place.

XIII. Chimeric Antigen Receptor T–Cell (CAR-T) Therapy

Chimeric Antigen Receptor T–Cell (CAR-T) Therapy requires drawing blood from each patient and separating out the T-cells; then genetically engineering the cells to produce surface receptors, called "chimeric antigen receptors" (CARs) to fight cancer cells. The U.S. Food and Drug Administration (FDA) stated when it approved the first CAR-T products, that it represented a new frontier in medical innovation, with the ability to reprogram a patient's own cells to attack a deadly cancer.

Currently, no CPT codes exist to report the following services associated with CAR-T:

- Collection of autologous cells
- Preparation of cells to/from the manufacturer
- Receipt of cells from the manufacturer and preparation for infusion
- Administration of cells

Coding guidelines direct providers to: "*Select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided. If no such specific code exists, then report the service using the approximate unlisted procedure or service code."* The American Medical Association (AMA) has approved four new Category III CPT codes for use starting January 1, 2019, and CMS has assigned these a status indicator "B."

The PRT does not believe that CAR-T products should have a status indicator "B." Rather, we suggest that CMS should follow the HOPP Panel's recommendation and change the status for the new Category III CPT codes to "S" for a separately payable procedure. Since these are new codes representing these new services, we believe it would be appropriate to cross-walk these codes to existing transplant APCs, as shown in the table below. This change will enable hospitals to bill and be paid appropriately for the services provides in each step of the CAR-T process. The changes will also ensure that life-saving CAR-T services and associated hospital charges are identifiable on claims for CMS' future rate-setting purposes.

CPT Code	Description	Recommended Status Indicator	Recommended APC

0537T	CAR-T THERAPY HRVG BLD DRV T LMPHCYT PR DAY	S	5242
0538T	CAR-T THERAPY PREPJ BLD DRV T LMPHCYT F/TRNS	S	5241
0539T	CAR-T THERAPY RECEIPT & PREP CAR-T CELLS F/ADMN	S	5241
0540T	CAR-T THERAPY AUTOLOGOUS CELL ADMINISTRATION	S	5242

Moreover, the PRT recognizes that in order for CMS to assign payable status indicators to these services, the descriptions of CAR-T product Q-codes, Q2040 and Q2041 must be changed such that all references to clinical services in those codes is removed. We recognize this may be outside of the purview of the outpatient policy staff; however we urge this team to have a conversation with the HCPCS coding group and more broadly in the agency so that product drug codes remain just that and do not include patient care services that hospitals provide to their registered patients. In short, the Q2040 and Q2041 must be revised to reflect just the CAR-T cells, which will then easily enable the outpatient policy team to assign payment status indicators to the first three codes in the table above. The fourth code in the table above, 0540T must be assigned a status indicator of "S" since this service is not embedded in the CAR-T product Q-codes and will appropriately allow providers who infuse patients in the outpatient setting a mechanism to report the service.

- The PRT urges CMS to follow the HOPP Panel's recommendation and change the status indicators for the new Category III CPT codes for CAR-T to "S" and to work with the HCPCS Coding Group within CMS to adopt the recommendations provided by numerous presenters at the May 2018 HCPCS meeting asking for all patient care services to be removed from the definition of existing CAR-T product Q-codes.

XIV. Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Model

In general, the PRT supports any effort to curtail the unsustainable epidemic of high drug costs/prices—any cost reductions will directly benefit patients, providers, and the Medicare program. The PRT does not have any specific comment or feedback on the design of a potential model, other than the suggestion that perhaps hospitals should be excluded. The operational and logistical demands of providing physician-ordered drugs and biologicals to patients in real-time in outpatient departments would make functioning in a "vendor scheme" burdensome.

We wish to express several high-level concerns that we hope CMS will consider.

First and foremost, drug costs are an issue because manufacturers and distributors have made it one. Hospitals must purchase drugs in a marketplace, and, even with GPO and other discounts, do not exert any control over the list cost/list price of drugs. **Any potential alternative payment model must not be balanced, funded, and/or financed with any type of payment cut to hospitals.** (The only exception would be any inherent reductions related to not taking custody of drugs and/or no longer bearing the purchase expense, which would result in no longer including the item on the providers claim for payment.)

Second, the PRT requests that CMS be mindful of the fact that, operationally, nothing should change in the hospital setting. Our pharmacies should remain stocked and readily available to

dispense drugs, biologicals, and other pharmaceuticals immediately upon receipt of a dispensing order, both for inpatients and outpatients.

Finally, any "model vendors" should be required to bear any and all costs for administering and operationalizing the program, maintaining financial custody of products, ensuring that hospital pharmacies are appropriately and perpetually stocked, and that billing/claim submission occurs under their scope.

The PRT hopes that CMS will take these high-level concerns into consideration in the development and design of a potential model; we look forward to providing more substantive feedback once a proposal is set forth.

XV. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

Definition of ASC Covered Surgical Procedures, specifically related to the inclusion of Cardiac Catheterization procedures on the ASC Procedure List

CMS' offers an updated definition of "surgery" to include "surgery-like procedures" in order to include services described by HCPCS codes outside the surgical CPT code range as procedures that may be performed in an ASC. These procedures are currently paid under OPPS but are not on the list of ASC-covered surgical procedures. CMS' review determined whether changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting.

For CY 2019, CMS proposes to add 12 cardiac catheterization procedures to the list of ASC-covered surgical procedures (referenced in Table 40 in the OPPS Proposed Rule) and reviewed these procedures based on 42 CFR 416.166(c), which lists general exclusions from the list of ASC-covered surgical procedures based on factors relating to safety. CMS determined that there is no expected significant safety risk if these procedures are performed in ASCs; and there is no expected need for required active medical monitoring and care of the patient at midnight after these procedures.

The PRT is extremely concerned with CMS' proposal to change the definition of "surgery" to include "surgery-like" procedures in ASCs. This change would add procedures that are currently assigned codes outside of the CPT surgical range. In CY 2018, CMS noted that it did not make this change in the definition because there are many "surgery-like" procedures that may impose a significant safety risk to Medicare beneficiaries when performed in an ASC.

The PRT raises CMS' previously stated concern as a valid reason not to include the proposed procedures in the list of procedures performed in an ASC beginning in CY 2019. Many times, a diagnostic cardiac catheterization procedure reveals blockages in the coronary arteries that are best treated with an immediate intervention. Because the interventional procedure (e.g., stent, atherectomy, angioplasty) is not on the ASC list, the beneficiary *must* be transferred to a hospital for the intervention. This could require emergency transport or at the very least, the procedure is ended, the beneficiary is recovered and then referred to the hospital for the interventional procedure.

This concept goes against CMS' previously stated concerns about procedures being delayed in order to circumvent the packaging of services. There will be no other option in this scenario, as the interventional procedures are not, and should not be, performed in an ASC. In addition, cost to the Medicare program will increase if ambulance transport from the ASC to the hospital is required. At the very least, CMS should evaluate the frequency of diagnostic cardiac catheterization procedures that become interventional procedures. This will be apparent based on the claims data when both procedures are reported on the same claim. CMS should also share this data analysis with stakeholders and providers.

- The PRT asks CMS not to move forward with this proposal.
- Prior to CMS moving forward with the proposal to add cardiac catheterizations to the ASC approved list, the PRT strongly recommends that claims data be reviewed to assess how often a cardiac catheterization procedure occurs with an interventional procedure.

Appendix A. PRT Members

Attachment A: Provider Roundtable Members

Jennifer L. Artigue, RHIT, CCS
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Health Information Management (HIM)
Franciscan Missionaries of Our Lady Health System
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Kathy L. Dorale, RHIA, CCS, CCS-P
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Carole D. Hokeah, RN, MS, CCS, CPC
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Vanderbilt University Medical Center
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** Non-voting past PRT member*

Updated August 2018

Appendix B. PRT Comments from the 2018 IPPS Proposed Rule

Concerning Out-of-Network Co-Insurance

The PRT acknowledges that patients do at times receive bills for higher out-of-network co-insurance and that these may be from various physician groups (e.g.: anesthesiologists, radiologists, pathologists, emergency department physicians) who are independent medical groups and legally separate from hospitals. Hospitals solely negotiate for the entities within their legal structure and do not have the ability to negotiate on behalf of separate legal entities nor to ensure these healthcare providers accept the same insurance plans as the hospital accepts. Rather, we believe it is incumbent upon the insurance companies to inform and educate their customers on what is in-network and out-of-network under their particular plans. In fact, a provision of the Affordable Care Act specifies the requirements of insurance companies to disclose liabilities by participating and non-participating providers. We note that CMS published an example that is available at: https://www.cms.gov/CCIIO/Resources/Files/Downloads/sbc-sample.pdf.

Furthermore, Medicare Part A and Part B beneficiaries are not impacted by networks, so should CMS desire additional disclosure this must be addressed directly with the Part C plans and not through requirements of hospitals. CMS should explore the transaction set standards of the Administrative Simplification Act as a means to standardize what insurers should be required to provide for price transparency.

Posting "Standard Prices"

The PRT knows how important state rights are to this Administration. The issue of price transparency is one that individual states have and continue to address. Most states already require some method of price transparency. The National Conference of State Legislatures has provided a web page that addresses pricing transparency and provides a summary of enacted cost transparency legislation provided by state. Please see the link below: http://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx#Legislation

It appears that currently 29 states have provided some information for beneficiaries regarding pricing transparency including recent legislation passed in New Jersey. Since insurance design is governed by state law, it is logical that price transparency also be determined by state law. As evidenced by many other of its proposed 2019 policies, CMS is very interested in decreasing administrative burden stemming from Medicare policies and the PRT believes that price transparency is another area to relegate to the individual states.

The PRT agrees with the CMS statement "*We are concerned that chargemaster data are not helpful to patients for determining what they are likely to pay for a particular service or hospital stay*." This is one reason we are perplexed by the CMS proposal to require hospitals to make available a list of their current standard charges via the

internet in a machine-readable format. While there is no definition of "standard charges", we assume that a reasonable interpretation is posting the chargemaster charges.

Since the chargemaster or a list of standard charges from the chargemaster does not provide the beneficiaries with the information they are requesting or needing, the availability of this list online will only create more confusion and frustration on the beneficiaries' part. As CMS knows, the beneficiary liability for covered Part A and Part B services is strictly defined by CMS and participating hospitals must adhere to what CMS determines under its respective payment systems to be the beneficiary portion.

Alternatively, for Part C and other commercial insurances, each insurer is in the best position to provide the beneficiary with the most accurate information they need based on what is included in their individual plan, the discounts negotiated with in-network providers in the beneficiary's market and the year-to-date out-of-pocket payments already made by the beneficiary.

Defining standard charges

Concerning CMS' proposal to create a definition of "standard charges", the PRT notes that there is already a CMS definition of charges which is found in the Provider Reimbursement Manual, Part 1, Section 2202.4 and is quoted below:
"Charges refer to the rates established by the provider for services rendered. Charges should be related consistently to the costs of the services and uniformly applied to all patients, whether inpatients or outpatients. All patients' charges used in the development of apportionment ratios should be recorded at the gross value (i.e., charges before the application of allowances and discounts deductions)."

Hospital charges are tied to CMS' requirement for hospital cost reporting. Hospital charges must follow the requirements of the definition of charges and cost reporting principles. Because hospital charges are set based on the individual hospital's underlying costs, they vary significantly. Requiring hospitals to post these charges that have no bearing to what patients owe may result in external pressures due to media attention to change charges that would undermine CMS' rate setting process through the cost report.

In addition, hospital charges are becoming increasingly irrelevant to payments due to the increase in bundled (episodic) payments for outpatient procedures and MS-DRG payments for inpatient stays. The list of charges from the chargemaster will not assist the beneficiary in understanding what amount they are responsible for paying. Defining standard charges to be some representation of average or median co-insurance and deductibles would also be meaningless to individual beneficiaries because it would not apply to their circumstances. Finally, this information would not assist them in choosing a provider, even one that may be less costly for the beneficiary out-of-pocket. The information becomes useful and actionable by beneficiaries only with individualized patient financial counseling, tools and information provided by insurers.

Many hospitals already have tools in place that provide the prospective patient with an estimate of their hospital related costs. They also have financial counselors available to

assist patients with their estimates, bill, insurance questions and financial assistance. Until this proposal, CMS considered hospitals as meeting their obligation to post charges by the alternative of posting a telephone number for patients to call with questions about pricing of services. Furthermore, tax exempt hospitals must also meet the IRS Section 501(r) requirements concerning financial assistance and making patients aware of financial assistance and financial counseling.

Some suggestions the PRT offers for improvements in pricing transparency include:

- Holding 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. As previously stated, insurers are in the best position to assist their members with this information, as each policy contract has coverage and clauses that are unique. They have the most current information on where the member stands with respect to their deductibles and out-of-pocket maximums as well as which services are covered and which providers near the beneficiary are in- and/or out-of-network.
- Continuing to require hospitals to publicize how and whom patients seek price estimates and financial counseling.
- Work with stakeholders such as the Healthcare Financial Management Association (HFMA) to investigate and publish best practices currently in place at various hospitals around the country for financial counseling.

We strongly believe publishing hospital charges in a machine-readable format available on the internet will not meet the needs of the patients nor will it address the challenges CMS has outlined in the proposed rule. More important, this mandate will further confuse and frustrate patients as they navigate the healthcare system to determine their out of pocket costs. CMS should leave any further legislation or mandates to individual states while continuing to encourage hospitals to improve financial counseling; however, insurers should be held accountable through Administrative Simplification Act transaction requirements to provide patients with the information in which they are interested.

Additionally, the PRT offers responses to the specific questions posed by CMS in the Proposed Rule:

CMS QUESTION: *Should "standard charges" be defined to mean: average or median rates for the items on the chargemaster; average or median rates for groups of services commonly billed together (such as an MS-DRG), as determined by the hospital based on its billing patterns; or the average discount off the chargemaster amount across all payers, either for each item on the chargemaster or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of average contracted rate and the chargemaster? Or is the best measure of a hospital's standard charges its chargemaster?*
The CMS definition of charges can be found in the Provider Reimbursement Manual as cited below:

"Charges refer to the rates established by the provider for services rendered. Charges should be related consistently to the costs of the services and uniformly applied to all patients, whether inpatients or outpatients. All patients' charges used in the development of apportionment ratios should be recorded at the gross value (i.e., charges before the application of allowances and discounts deductions)." <Provider Reimbursement Manual Part 1, Section 2202.4, Charges>

Most hospital charges are set based on the individual Hospital's cost-to-charge ratio. There are many components to this that vary across hospitals. Hospital A's cost-to-charge ratio may be higher in their Cardiology department because they provide both Cath Lab services and non-invasive services in the same department. Hospital B's structure consists of separate Cath Lab and Cardiology departments, with a different cost-to-charge ratio for each based on the services provided. Therefore, if a patient is comparing hospital charges for the same service between Hospital A and Hospital B, there is likely to be a difference and one that can be significant. Comparing charges is much more complex than just offering a "price comparison."

Unfortunately, hospital charges are not as relevant as the public thinks they are. With the increase in bundled (episodic) payments for outpatient procedures and MS DRG payments for inpatient stays, the list of charges from the chargemaster are not going to assist the beneficiary in understanding what amount they are responsible for paying.

Many hospitals already have tools in place that provide the prospective patient with an estimate of their hospital related costs. They also have financial counselors available to assist patients with their estimates, bills and insurance questions.

CMS QUESTION: *What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interfaces with these data?*

Patients want to understand what their liability will be for the procedure or inpatient stay. This is driven by the individual patient's coverage through their payer and is unique to each patient at any specific time during the year. As has already been mentioned, there are tools being developed and refined to assist in this endeavor. Insurers are the best equipped to assist patients with this information based on each patient's individual plan.

CMS QUESTION: *Should health care providers be required to inform patients how much their out-of- pocket costs for services will be before those patients are furnished that service? What changes would be needed to support greater transparency around patient obligations? Should health care providers play any role in helping to inform patients of what their out-of-pocket obligations will be?*

Providers must obtain the information from the insurer and be confident that the information is accurate and up-to-date at the time it was obtained. Because the insurers

may receive additional claims prior to the Provider service, this amount most often changes. So the information is often outdated when it is provided to the patient. Insurers are the ones best equipped to handle what a person's out of pocket costs will be for the services in question. They will have the most current information and the details of the plan and their negotiated allowables with the Provider and other Providers both in- and out-of-network.

CMS QUESTION: *Should we require health care providers to provide patients with information on what Medicare pays for a particular service performed by a health care provider? If CMS were to finalize a requirement that this information be made available to beneficiaries by health care providers, what changes would need to be made by health care providers? What corresponding regulatory changes would be necessary?*

While each provider know what Medicare will pay it for a service provided to a fee-for-service Part A or Part B beneficiary, it may not have this information for a Medicare Part C plan. For other insurances, healthcare providers do not have the ability to provide patients with this information. They do not have individual plan information, the level of deductibles for each patient, or the coverage guidelines. Hospitals also do not have access to how physicians are going to bill the patients and what insurances they accept. Patients need to be educated on the fact they will be receiving a bill from the hospital for their hospital services and a bill from each physician who sees them at the hospital. Under the current system of physician bills and hospital bills, there is not a way to provide the patient with their total costs. For an inpatient stay, the hospital will be paid one fee (based on the MS-DRG assigned to the case which cannot be established until discharge since there is always the chance there will be complications), and the patient will receive bills from every physician who treats the patient while in the hospital, including consultants whom their primary physician will call in to assist with the case. Many times, a consultant is called in during the admission to address a specific condition; but this is not the time to be talking with a patient or patient's family about how much the provider is going to bill for the service.

CMS QUESTION: *What is the most appropriate mechanism for CMS to enforce price transparency requirements? Should CMS require hospitals to attest to meeting requirements in the provider agreement or elsewhere? How should CMS assess hospital compliance? Should CMS publicize complaints regarding access to price information or review hospital compliance and post results? What is the most effective way for CMS to publicize information regarding hospitals that fail to comply? Should CMS impose civil money penalties on hospitals that fail to make standard charges publicly available as required by section 2718(e) and (b) of the Public Health Service Act? Should CMS use a framework similar to the Federal civil penalties under 45 CFR 158.601, et.seq. that applies to issuers that fail to report information and pay rebates related to medical loss ratios, as required by sections 2718(a) and (b) of the Public Health Service Act, or would a different framework be more appropriate?*

CMS should review what the various state agencies and hospitals are currently doing to comply with pricing transparency. The information on what some of the states are

doing has been already provided in a link to the National Conference of State Legislatures. Perhaps eliciting input from the State Hospital Associations would be helpful in understanding the magnitude of the issue and how hospitals are currently dealing with these questions on a state-by-state basis. Gaining an understanding of the best practices already in place would be a first step in developing a sustainable solution to this issue.

For the most part Hospitals are attempting to assist their patients in understanding their bills and assisting them with questions on out-of-pocket costs. Hospitals are very in tune to excellent customer service. They understand if a patient is confused and frustrated with the billing process, even if they received exemplary clinical care, they fell short in providing that excellent customer experience. Hospitals are constrained by the information that is available to them. Penalties should certainly not be applied nor should they be under the purview of CMS.

CMS QUESTION: *How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do providers face in providing information about out-of- pocket costs to patients with Medigap? What changes would be needed to support providers sharing out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best suited to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care? What State-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?*

Hospitals do not have reliable information regarding out-of-pocket costs for patients with Medigap coverage. There are multiple plans that offer Medigap coverage and each plan is different depending upon the premium paid. The higher the premium for the insurance should theoretically provide more coverage. Once again, the insurers are the best prepared to provide patients with the information regarding their out-of-pocket costs for services.