Provider Roundtable

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

Ascension Health (AL, AZ, AK, CT, DC, FL, ID, IL, IN KS, LA, MD, MI, MO, NY, OK, PA, TN, TX, WA, WI)

Carolinas HealthCare System (NC, SC)

Community Hospital Anderson (IN)

Erlanger Medical Center (TN)

Forrest General (MS)

Franciscan Missionaries of Our Lady Health System (LA)

Harris Health System (TX)

Hartford Hospital (CT)

Holy Name Medical Center (NJ)

Kaiser Permanente, Southern California Permanente Medical Group (CA)

Ohio Valley Health Services and Education Corporation (OH, WV)

Robert Wood Johnson University Hospital (NJ)

University of Pittsburgh Medical Center (PA)

August 31, 2015

Mr. Andy Slavitt, MBA
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201
Attention: CMS-1633-P

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System [CMS-1633-P]

Dear Mr. Slavitt,

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the 2016 Outpatient Prospective Payment System (OPPS) Proposed Rule, as published in the *Federal Register*.

The Provider Roundtable (PRT) includes representatives from 14 different health systems, serving patients in 33 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 225-765-8847 or via email at: *Jen21306@ololrmc.com*.

Sincerely,

Jennifer L. Artigue, RHIT, CCS
PRT Chair and
Corporate Director, Health Information Management
Franciscan Missionaries of Our Lady Health System
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Baton Rouge, LA 70808

2% Conversion Factor Reduction

CMS has determined that it over-estimated packaging of laboratory services in the 2014 OPPS Final Rule, and as a result has "over-paid" by $1 billion for lab services that continue to be paid separately under the CLFS. In response, CMS proposes to apply a 2.0 percent reduction to the conversion factor for CY 2016 to redress purported inflation in the current APC weights.

The PRT opposes this reduction. As noted in the Lab Packaging section below, in CY 2014, providers were required to adopt two *entirely different* mechanisms for billing separately payable laboratory tests. The agency itself has noted that the resulting 2014 claims data were inconsistent and contradictory. Specifically, CMS received lab-only claims with no "L1" modifier as well as an unexpectedly large volume of laboratory tests that were identified as being separately payable. We believe that the requirement to implement two very different mechanisms to identify separately payable diagnostic laboratory tests within a six-month time span resulted in a significant amount of provider confusion and inaccurate claims data.

The PRT recognizes that CMS has a fiduciary responsibility to the Medicare Trust Fund, but we believe the agency has not provided sufficient information regarding the methodology and assumptions used in the process that initially packaged the labs. We note that, in its comment letter to the 2014 OPPS Proposed Rule (dated September 13, 2013, in response to CMS-1601-CN), the American Hospital Association (AHA) states that its contractor (The Moran Company), was unable to replicate the methodology in order to validate CMS' calculations -- even after the publication of corrected data from CMS.

CMS maintains that the $1 billion in question represents 2 percent of total overall OPPS 2014 spending. The PRT seeks clarification regarding what will happen if any errors are perpetuated in CY 2015, CY 2016, and beyond. CMS has not clearly indicated that it believes the agency has successfully resolved the problem, or whether it might recur in the future.

The PRT does not have confidence in the original packaging calculations or in the current analysis. We firmly believe that CMS lacks accurate data with which to make a final determination about either its initial laboratory packaging estimates or the appropriateness of the proposed conversion factor reduction.

> **The PRT requests that CMS publish explicitly detailed information about the original process used to determine the amount of laboratory packing in 2014, so the provider community can analyze the methodology and assess the outcomes.**
>
> **The PRT urges CMS to postpone any conversion factor reductions until more data have been collected and analyzed to confirm that this is an appropriate action.**

Packaging of Services

Clinical Diagnostic Laboratory Tests

Starting in CY 2014, CMS began packaging most laboratory tests when they occur on the same date of service as another APC payable procedure; the agency made this change because it considers these laboratory tests to be related to a "primary" procedure. Recognizing that there are

instances in which laboratory tests are the only services performed on a single date of service, CMS initially instructed providers to bill lab-only encounters on bill type 14X, beginning on January 1, 2014. At the same time, CMS permitted hospitals to carve out "unrelated" laboratory tests by also billing these tests on a 14X bill type. ("Unrelated" laboratory tests are defined as tests that are ordered by a different physician for a different diagnosis.)

Shortly after hospitals implemented this process, and as a result of concerns expressed by the National Uniform Billing Committee (NUBC), CMS created modifier L1 and instructed hospitals to disregard previous billing instructions regarding bill type 14X; instead, facilities were instructed to append the L1 modifier to identify separately payable clinical laboratory tests on bill type 13X.

Both of these processes for identifying separately payable laboratory tests have proven to be inherently problematic and administratively burdensome to hospital providers. This was particularly evident in CY 2014, when providers were asked to implement two very different billing mechanisms for laboratory tests within a very short period of time.

The PRT believes that these instructions likely resulted in the submission of inaccurate claims data regarding the volume of separately reimbursable laboratory tests. Our belief is evidenced by CMS' statement that the agency found few claims with laboratory tests on different dates of service with the L1 modifier, but also received lab-only claims without the L1 modifier. This inconsistency in provider claims data unquestionably indicates that there are flaws in the 2014 claims data that CMS is using for CY 2016 rate-setting.

Despite the clearly problematic claims data, CMS has proceeded with a CY 2016 OPPS proposal to package laboratory tests at the claim level, rather than continuing to package by date of service. In addition, to alleviate some of the administrative burden, CMS also proposes to use status indicator Q4 to conditionally package laboratory tests when they appear on a claim with status indicators J1, J2, S, T, V, Q1, Q2, and Q3.

> **The PRT fully supports the adoption of conditional packaging status indicator Q4 for laboratory tests that remain packaged by date of service, but not by claim.**

The use of a conditional packaged status indicator will allow the OCE to automatically generate separate payment through the Clinical Laboratory Fee Schedule (CLFS) when labs are the only services provided on a particular date of service. This will reduce the administrative burden and confusion that providers currently face when CMS uses the unconditionally packaged status indicator (i.e., status indicator N) to administer what is essentially a conditional packaging policy for laboratory tests.

CMS also intends to continue its policy to separately pay for molecular diagnostic tests and proposes to pay for preventative laboratory tests through the CLFS; these separately payable laboratory tests are assigned to status indicator A.

> **The PRT fully supports the assignment of status indicator A to molecular diagnostic laboratory tests and preventative laboratory tests.**

The PRT notes that other payers have denied payment for lab-only claims even when the L1 modifier is reported solely on the basis of the "N" status indicator assigned to packaged labs.

Therefore, a change from status indicator N to Q4 will indicate that there is legitimate, separate CLFS payment when clinical diagnostic laboratory tests are the only services provided and billed on a 13X claim.

The PRT requests that CMS reconsider certain elements of its laboratory packaging proposals as outlined below:

1. **The PRT asks CMS to delay its proposal to expand packaging of clinical laboratory tests from date of service to claim-level packaging**. **We request that CMS continue its current clinical lab packaging by date of service.**

The implementation of Comprehensive APCs as identified by status indicator J1 and the newly proposed status indicator J2 results in larger bundles of services that include additional laboratory packaging that span more than a single date of service. We believe that laboratory services provided on a different date of service from primary services -- which are not identified by J1 and the proposed J2 -- are less likely to be integral, ancillary, supportive, dependent, or adjunctive.

We are also concerned about the administrative burden caused by requiring providers to append the L1 modifier to identify unrelated services on a claim. In fact, PRT members report that their organizations generally *do not* append the L1 modifier to unrelated laboratory tests billed on the same claim as other services, solely due to the burden associated with this manual process. As the 2014 claims data and our own collective experiences have shown, the administrative burden of appending the L1 modifier to laboratory tests results in provider confusion and potentially inaccurate claims data.

Therefore, we believe it is prudent for CMS to analyze the impact of its proposed Q4 status indicator and J1 and J2 expanded packaging prior to implementing the policy change of packaging laboratory tests at the claim level.

2. **The PRT asks CMS to reconsider the "primary" services into which laboratory tests are packaged by status indicator Q4.**

The PRT strongly believes that the creation of a conditionally packaged status indicator for laboratory tests is the most efficient and least burdensome mechanism to package laboratory tests. However, we question CMS' decision to package laboratory tests into services designated as Q1, Q2, and Q3.

The packaging of laboratory tests is premised on the notion that laboratory tests are often integral, ancillary, supportive, dependent, or adjunctive to a *primary* service. Yet, other than services identified by status indicator J1 and the proposed status indicator J2, CMS has not clearly defined services it believes to be "primary services." Rather, services with status indicator Q1, Q2 and Q3 are themselves, ancillary, supportive, dependent, and adjunctive. The PRT submits that it is illogical to further package clinical laboratory services into these services, which are, by definition, *non-primary* services.

We believe the "top down" packaging of laboratory tests, as represented by comprehensive APCs (C-APCs), when done with careful deliberation and thoughtfulness, is a more accurate and appropriate method for packaging ancillary services. This contrasts with the "bottom up" packaging of ancillary services, which lacks the same consideration and analysis.

The services identified by the conditionally packaged status indicators Q1, Q2 and Q3 are ancillary services which — when they are not the sole services on a claim — are packaged into a primary service, which is generally represented by status indicators S, T and/or V. CMS' proposal to package laboratory tests into the ancillary services represented by status indicators Q1, Q2, and Q3, essentially packages ancillary services into ancillary services. This will result in inappropriate payment and inaccurate data for future rate setting. In fact, many of the Q4 assigned laboratory tests have 2015 CLFS payment rates that exceed the Q1, Q2, and Q3 ancillaries into which they could be packaged.

The PRT believes that packaging labs into other ancillary packaged services is inherently problematic and will result in future rate setting irregularities stemming from ancillary service reimbursement evolving to a point where it is no longer representative of the service's individual cost. As CMS recognizes in the Proposed Rule, hospitals can, and do, provide these types of services alone, without another "primary" service.

The table below illustrates that the packaging of laboratory tests into ancillary services represented by status indicators Q1, Q2, and Q3 represent approximately nine percent (9%) of claims submitted in CY 2014. We believe this volume of lab-into-ancillary-packaging is significant enough to result in future rate-setting irregularities of ancillary services, as well as insufficient payment to providers for clinical laboratory tests.

2014 Claims with Conditionally Packaged Lab Tests	Number of Claims	Percentage of Claims with Labs
Lab Only Claims	9,311,474	29.37%
C-APCs with Labs	767,818	2.42%
Observation Claims with Labs	13,244,677	41.78%
Lab Claims with a S, T, or V Service	5,592,311	17.64%
Q3 Lab Claims with no S, T, or V Service	1,611,863	5.08%
Q1 and Q2 Lab Claims with no S, T, or V Service	36,352	0.11%
Q1 Lab Claims with no S, T, or V Service	1,067,768	3.37%
Q2 Lab Claims with no S, T or V	68,605	0.22%

Multiple laboratory tests are often ordered together with non-lab ancillary services to assist physicians in diagnostic and medical decision-making. It is not clear if the "bottom up" packaging of clinical laboratory services reflects this pattern of laboratory testing.

Consider the following common scenario: a patient is seen by an independent primary care physician office, and the physician orders a chest X-ray, a complete blood count with WBC differential, an influenza test by EIA, a blood culture, and a sputum culture. The patient reports to the outpatient hospital department for tests, including the blood draw and sputum collection. The microbiology lab identifies the bacterial pathogen and conducts sensitivity testing to guide the patient's treatment.

In this case, there is no true "primary" service as there is no S, T, or V service billed. Rather, the physician evaluates the collective results of the ancillary services to make the diagnosis of bacterial pneumonia. The payment for the diagnostic laboratory tests, if provided independently, would be $84.20 (based on the 2015 CLFS). As a result of the packaging initiatives, however, the entire battery of medically necessary diagnostic laboratory tests is packaged into the chest X-ray, and generates payment of only $61.57. The PRT believes this is inadequate reimbursement for services provided.

As previously noted, future rate-setting for commonly ordered ancillary services into which diagnostic laboratory tests will be packaged is likely to be skewed as a result of this ancillary-into-ancillary packaging schema. The PRT is concerned this will ultimately result in the corruption of future payments that would no longer be realistically tied to the provider's costs for providing these services. We illustrate the impact of the proposal in the chart below:

CPT	Description	Proposed 2016 Status Indicator	2015 CLFS Payment	Proposed 2016 OPPS Payment
71030	Chest x-ray 4/>views	Q1		$61.57
85025	Complete cbc w/auto diff wbc	Q4	$10.58	
36415	Routine venipuncture	N	$3.00	
87400	Influenza a/b ag eia each	Q4	$16.32	
87070	Culture other specimen aerobic	Q4	11.72	
87205	Smear gram stain	Q4	$5.81	
87040	Blood culture for bacteria	Q4	$14.05	
87077	Culture aerobic identify	Q4	$11.00	
87186	Microbe susceptible mic	Q4	$11.77	
Total			**$84.25**	**$61.57**

3. The PRT asks CMS to allow submission of multiple claims per date of service in order to identify unrelated laboratory tests.

CMS will continue to permit the use of modifier L1 to identify unrelated lab services when provided on the same date of service as other separately payable APC services. The PRT notes that many providers find the submission of multiple claims on a single date of service to be less burdensome than using modifier L1.

For example, a patient who is on Coumadin therapy is monitored with bimonthly prothrombin time testing. It is not unusual for these patients to schedule unrelated procedures (i.e., bone density testing, mammography, screening colonoscopy, etc.) on the same date of service. Many providers create separate registrations for the laboratory test and unrelated non-lab services as a result of operational and system reporting requirements, such as directing the test results to different ordering providers through the EMR.

In these situations, providers must move the laboratory charges to the 13X claim with the unrelated OPPS charges, per CMS' instructions in the Medicare Claims Processing Manual (Chapter 16, Section 40.3). This requires a manual review for the appropriateness of appending the L1 modifier to the unrelated laboratory test in order to trigger separate payment. Doing so requires the billing office to hold the claim, conduct a manual review to decide whether the laboratory test is unrelated to the OPPS service and, if so, indicate this by appending the L1

modifier. For most providers, this is outside the billing office staff's scope of work and expertise, which results in additional staff resources to independently review each claim with laboratory services in order to determine whether the modifier is appropriate. Hence, this operational burden causes many providers (including those represented on the PRT) to *not* append the L1 modifier to laboratory tests billed with non-lab services.

To mitigate operational burden and to offer providers some flexibility in how they prepare claims for submission to CMS, the PRT asks CMS to permit the submission of two separate claims as an alternative mechanism to identify unrelated laboratory tests. The claim with unrelated lab-only services would be paid through the CLFS using the proposed Q4 status indicator. Providers could choose the most appropriate and least burdensome mechanism (i.e., submit separate claims or use the L1 modifier) to identify unrelated laboratory tests, based upon their individual internal processes. CMS would be able to monitor the appropriateness of the separate claims by checking that the ordering provider differs on the lab-only claim and the same-day OPPS claim.

Packaged Pathology Services

The Current Procedural Terminology (CPT) defines the "specimen" as the unit of service for pathology service codes 88300 – 88309. CPT states that: "a specimen is defined as tissue or tissues that is (are) submitted for individual and separate attention, requiring individual examination and pathologic diagnosis." When pathology services are provided outside of a C-APC, the specimen is, in every practical sense, the primary service.

Consider the following example: an independent dermatologist removes three separately identifiable skin lesions from a patient and submits them to the local hospital for pathological evaluation. This results in the following services:

Service	**CPT**	**Proposed 2016 Status Indicator**	**Proposed 2016 Payment Rate**	**Final Payment Generated**
Skin lesion, upper back	88305	Q1	$48.63	$48.63
Special stain	88313	Q1	$48.63	-
Immunohistochemistry Stain	88342	Q2	$209.49	$209.49
Skin lesion, left shoulder	88305	Q1	$48.63	-
Immunohistochemistry stain	88342	Q2	$209.49	-
Immunohistochemistry stain, each additional	88341	N	-	-
Skin lesion, back of neck	88305	Q1	$48.63	-
Special stain	88313	Q1	$48.63	
Immunohistochemistry stain	88342	Q2	$209.49	-
Total			**$871.62**	**$258.12**

Because of the conditional packaging of these services, the hospital is paid only for the highest-paying Q1 and Q2 codes; reimbursement is essentially limited to a single specimen even though three distinct specimens were submitted for evaluation, and three medically necessary services were performed. Even if all pathology services that are identified by CPT codes 88300 – 88309 were changed to status indicator Q2, as proposed by CMS, for CPT codes 88307 and 88309, the reimbursement would be identical, because payment is limited to the single highest-paying Q1 and Q2 codes. The following chart illustrates this problem.

Service	CPT	Status Indicator if 88300-88309 were Q2	2016 Proposed Payment Rate	Final OPPS Payment Generated
Skin lesion, upper back	88305	**Q2**	$48.63	-
Special stain	88313	Q1	$48.63	$48.63
Immunohistochemistry Stain	88342	Q2	$209.49	$209.49
Skin lesion, left shoulder	88305	**Q2**	$48.63	-
Immunohistochemistry stain	88342	Q2	$209.49	-
Immunohistochemistry stain, each additional	88341	N	-	-
Skin lesion, back of neck	88305	**Q2**	$48.63	-
Special stain	88313	Q1	$48.63	
Immunohistochemistry stain	88342	Q2	$209.49	-
Total			**$871.62**	**$258.12**

This is not an isolated example. It is not unusual for hospital laboratories to receive multiple specimens from outside sources for pathological examination. The PRT can provide additional examples, upon request.

The PRT requests CMS change the status indicator of pathology procedures 88300 – 88309 to status indicator S.

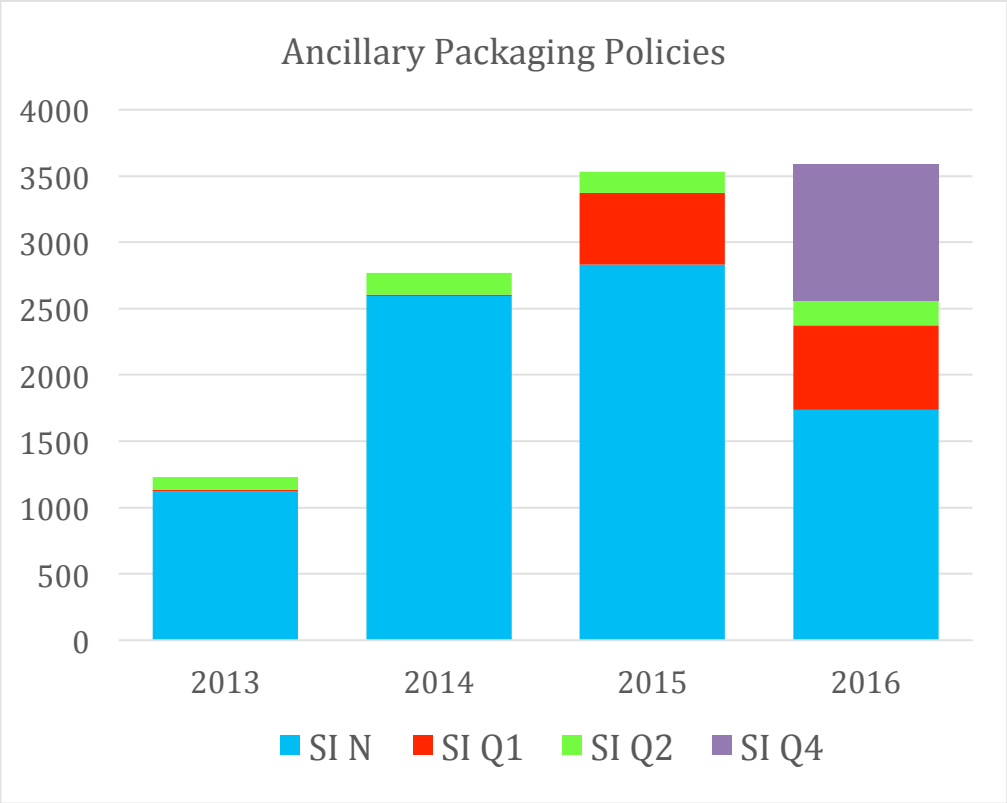
This would permit the appropriate payment of individual pathology specimens when they are performed outside of a C-APC, while still packaging lower cost related special stains and services into the pathology specimen. When pathology services are performed in conjunction with a C-APC, these services would be appropriately packaged into the primary J1 procedure. We believe this is a more logical and appropriate mechanism to pay for the primary pathology services that are represented by CPT codes 88300 – 88309. Our recommendation is illustrated in the table below.

Service	CPT	Status Indicator if 88300-88309 were S	Proposed 2016 Payment Rate	Final Payment Generated
Skin lesion, upper back	88305	**S**	$48.63	$48.63
Special stain	88313	Q1	$48.63	-
Immunohistochemistry Stain	88342	Q2	$209.49	$209.49
Skin lesion, left shoulder	88305	**S**	$48.63	$48.63
Immunohistochemistry stain	88342	Q2	$209.49	-
Immunohistochemistry stain, each additional	88341	N	-	-
Skin lesion, back of neck	88305	**S**	$48.63	$48.63
Special stain	88313	Q1	$48.63	
Immunohistochemistry stain	88342	Q2	$209.49	-
Total			**$871.62**	**$355.38**

Other Ancillary Packaging Considerations

The PRT is also generally concerned with the potential consequences of the rapid increase in OPPS packaging — and particularly with packaging initiatives that involve the "bottom up" packaging of ancillary services.

We recognize that CMS transitioned most services with a geometric mean cost of less than or equal to $100 to a conditionally packaged status indicator, primarily status indicator Q1. We believe, however, that the arbitrary packaging of "ancillary" services by geometric mean cost — without consideration of the services into which they will be packaged — is likely to result in unintended negative consequences. We believe this type of packaging has both current and future financial implications for Medicare providers and beneficiaries. We ask CMS to consider the following data:



The number of conditionally and unconditionally packaged ancillary services, represented by status indicators N, Q1, Q2 and the newly proposed Q4, have more than tripled since calendar year 2013. The PRT is concerned with the rapidity at which CMS has adopted these "bottom up" packaging proposals, for which the impact has yet to be fully determined.

The PRT concerns related to the packaging of ancillary services are outlined below.

1. Medically Unlikely Edits (MUEs) on Packaged Ancillary Services

PRT members often encounter administrative and operational difficulties associated with medically unlikely edits (MUE) that intersect with CMS' packaging initiatives. It is a relatively common circumstance for some MUE to be triggered during the billing process.

For example, HCPCS code C1725 (catheter, transluminal angioplasty, non-laser) has a published MUE limit of 9 units. The status indicator for C1725 is "N" and there are clinical circumstances that may necessitate the use of additional catheters. In this instance, the claim should reflect the actual number of catheters as documented in the patient's medical record, but in doing so the provider ends up receiving an edit that has to be resolved which is time-consuming and which the provider has little incentive to resolve.

Another example are HCPCS codes that have unpublished MUE limits, such as Q9967 (Low osmolar contrast material, 300-399mg/ml/per ml). The medical record reflects the amount of contrast utilized during the service/procedure. In these cases, providers are required to file a redetermination in order to resolve the MUE denial. In both examples, the claim reimbursement is unchanged since the services are packaged yet providers expend much time and energy resolving edits.

Currently, providers face the administrative burden of reconfiguring a claim or appealing a denial as a result of an MUE when the service is packaged, even though the correct reporting of the "edited" services on the claim does not change the claim's reimbursement. The PRT is concerned that providers may choose to simply remove the service from the claim in order to avoid the MUE edit and that such a practice will result in inaccurate/incomplete claims to CMS.

In order to address this concern and promote the submission of correct claims data, the PRT offers the following specific recommendations to CMS:

- Review the utility of MUE limits for all packaged services (status indicator "N") and exclude these unconditionally packaged codes from MUEs;
- If CMS determines that MUE limits are necessary for packaged services, the allowable units should be published to assist providers in knowing when an outlier is present and validate their claims prior to submission;
- Create a modifier to be appended to an unconditionally packaged code which allows providers to attest that the number of units has been validated and is supported in the individual record documentation
- CMS should allow the additional units to be billed with the appropriate HCPCS code and the new modifier on a separate claim line.
- The modifier usage and additional units reported can be validated against the documentation through the current audit process (e.g., MAC reviews, ADR requests).

2. Payment for Multiple Q1 Codes on a Claim without a Primary Service

Currently, the OCE pays for only the highest-paying Q1 status indicator code when multiple Q1 codes are billed on a claim without a status indicator S, T or V service. Prior to 2014, this payment policy was not an issue, as there were relatively few Q1 codes in use (12 in 2013 and 11 in 2014). Since 2014, however, the number of Q1 codes has increased exponentially to 542 in 2015 and 636 in 2016 (as proposed).

Given this rapid increase, it no longer makes sense to pay for only the highest-paying Q1 code when billed on a claim without an S, T, or V service. Most ancillary services have now been assigned a Q1 status indicator, and since it is quite common to have more than one Q1 service on

a claim without a corresponding primary service, we believe CMS should provide additional separate payment.

The following table shows the number of service dates reported in CY 2014 with one or more Q1 codes on claims that did not contain a "primary" service represented by status indicators J1, S, T, or V. As the table illustrates, more than twenty-six percent (26%) of these dates contained two (2) or more Q1 codes, with more than ten percent (10%) of service dates containing four (4) or more Q1 codes.

Number of Q1 Codes on a Date of Service without Status Indicator J1, S, T, or V	**Number of Dates of Service**	**Percentage of Total Dates of Service**
Dates of Service with one Q1 Code	789,837	73.97%
Dates of Service with two Q1 codes	92,233	8.64%
Dates of Service with three Q1 codes	76,985	7.21%
Dates of Services with four or more Q1 codes	108,713	10.18%

While the PRT understands — and is generally supportive of — OPPS packaging, the significant increase in the number of Q1 codes demands that CMS very closely review and reconsider its reimbursement policy when multiple Q1 codes appear on claims without a primary service.

> **The PRT respectfully asks CMS to consider implementing a policy to pay a discounted payment rate for the second and subsequent Q1 service(s) reported on a claim without a status indicator S, T, or V.**

This would be similar methodology to the multi-procedure discounting policy currently in place for the payment of claims containing multiple status indicator T codes. The PRT believes this policy would support appropriate reimbursement of ancillary services that are performed outside of a primary service, and lessen the compounding influence of ancillary-into-ancillary packaging in future rate setting.

Conclusion

In summary, the PRT supports the use of status indicator A to identify separately payable molecular diagnostic and preventative laboratory services. We strongly support the use of status indicator Q4 to identify conditionally packaged laboratory tests.

We ask CMS to limit laboratory packaging to those services more likely to be primary services (i.e., S, T, and V) and defer claim level packaging of laboratory services until more reliable data is available for analysis.

The PRT believes that status indicator S is the most appropriate status indicator for primary pathology services represented by CPT codes 88300 - 88309. In addition, to ensure adequate payment, CMS should implement a mechanism to reimburse multiple Q1 codes on a claim without a primary service.

Finally, the PRT cautions the agency against implementing multiple reconfigurations and packaging policies in a single rule making cycle in order to avoid confounding data which impacts future rate-setting.

Consolidation /Reconfiguration of 9 APCs

For the CY 2016 Proposed Rule, CMS has conducted a comprehensive review of the structure of the APCs and proposes a continuation of the restructuring and reorganization of existing APCs into homogeneous families. The goal of the reorganization is improved clinical homogeneity, improved resource homogeneity; reduced resource overlap in long-standing APCs; and greater simplicity and improved understandability of the OPPS APC structure.

The PRT is concerned with the significant reconfiguration of APCs, particularly when CMS is *also* proposing expanded packaging and a significant expansion of C-APCs. It is extremely difficult to analyze the impact and the inter-relationship of the different policies to determine potential impacts to these policies.

Specifically, the PRT disagrees with CMS proposing to reconfigure and consolidate APCs while *simultaneously* proposing to change the status indicators of many of the codes being reconfigured. If CMS wants to reconfigure the APCs, then it should proceed with that change only, and not also propose a status indicator change. Implementing both changes simultaneously will result in confusion and is likely to generate flawed data for future rate-setting.

The PRT members reviewed the information provided in the OPPS Proposed Rule, but were unable to identify the methodology CMS used to assign the clinical groups. We began our analysis by reviewing the new APC groupings by CPT groupings based on the CPT manual, geometric mean, and relative weight by CPT or HCPCS code. Yet, the PRT was unable to identify the process for CMS' proposed consolidation and reconfiguration.

Clinicians do not appear to have been included in the discussions about clinical homogeneity for the CY 2016restructuring proposal. For example, as noted at the August HOP Panel meeting, the Nuclear Medicine and PET restructuring does not take body systems into consideration, just costs. This is not necessarily appropriate, as stated in the testimony of the stakeholders, who are experts in the field and provide these services daily. The PRT notes that all prospective payment systems are based on guiding principles, including the principle that groupings (i.e. APCs) are based on services that are homogeneous in their resource use and clinical characteristics.

> **The PRT requests that CMS reconsider the consolidation and reconfiguration proposal. Providers find it extremely concerning to have these changes layered on top of the significant number of other packaging changes that are occurring.**

If CMS proceeds with this reconfiguration, we submit that CMS should develop guiding principles to help ensure a system that retains clinical and resource homogeneity, such as:

- If a specific cost center and revenue code are defined for the service, then at a minimum APCs should reflect and maintain these separately. Examples include: PET, diagnostic nuclear medicine, therapeutic nuclear medicine, CT, MRI, radiation therapy, chemotherapy, non-chemotherapy drug administration, etc.

- To help guide clinical homogeneity, CPTs should be grouped by the sections of the CPT Manual, such as E/M, surgical by body type and type of procedure. As an example, skin debridements are not in the same CPT section as skin excisions. We believe debridements are not the same clinically, and should not be grouped into the same APCs as surgical

excisions. Another example is to keep all the radiation source application codes in the same APC or series of APCs.

If CMS insists on proceeding with the consolidation / reconfiguration, the PRT offers our comments on each of the nine APCs, below.

1. Airway Endoscopy Procedures

CMS proposes to restructure upper and lower endoscopy procedures by consolidating the number of APCs in order to improve clinical and resource homogeneity. The proposal is to move CPT 31515 (Laryngoscopy for aspiration, APC 0073) to APC 5152. Similar procedures involving aspirations, CPT codes 31629 and 31645 are assigned to APC 5154.

The PRT recommends that CMS should instead assign CPT code 31515 to APC 5154.

2. Diagnostic Tests

Current diagnostic tests and related services groupings are divided according to organ system or physiologic test type. These groupings are based on clinical categories that do not reflect significant differences in the delivery of these services in the hospital outpatient department. CMS is proposing to restructure these groupings for a prospective payment system using payment groupings and not code-specific payment rates.

We believe that CPT codes 95909 and 95910, which are proposed to be assigned to APC 5722, should instead be reassigned to APC 5723. CPT 95910 has similar resources within the same service line as CPT 95961. CPT 95961 is based on time, specifically the initial hour. The time required to perform CPT 95909 and 95910 is comparable if not exactly the same as 95961, which makes them resource comparable. CPT 95909 and 95910 were new for CY 2013 so CMS may lack sufficient data to reflect accurate cost data.

Therefore, the PRT recommends reassigning CPT codes 95909 and 95910 to APC 5723.

3. Incision and Drainage and Excision/Biopsy

CMS identified 115 CPT codes that could be reorganized into four clinically homogenous and resource related C-APCs for incision and drainage and excision/biopsy procedures.

- CPT 57022, which describes incision and drainage of a vaginal hematoma in an obstetrical or postpartum patient, is currently assigned to APC 0007. CMS proposes to move this procedure to APC 5071. The PRT agrees that the procedure could be considered clinically homogeneous with other I&D procedures; we submit, however, that the procedure is more clinically consistent with those procedures proposed for inclusion in APC 5074. CPT 57023 describes incision and drainage of a vaginal hematoma in a non-obstetrical patient. This procedure has the same clinical characteristics as CPT 57022 except for the etiology of the hematoma.

  The PRT recommends moving this procedure to APC 5074.

- CPT 62269, which describes a percutaneous needle biopsy of the spinal cord, is currently assigned to APC 0005. The PRT believes that this procedure is more clinically and resource homogenous with the services proposed for assignment to APC 5073. The APC family for 5073 includes other biopsies performed percutaneously and with/without fluoroscopy guidance.

  The PRT recommends moving CPT 62269 to APC 5073.

- CPT 21725, which is currently assigned to APC 0006, is proposed for reassignment to APC 5071. The PRT believes this CPT should be assigned to APC 5071, since this procedure is similar to CPT 21720, which is already assigned to APC 5071. Both codes describe the same procedure, a division of the sternocleidomastoid for torticollis, with 21720 used to report an open procedure *without* cast application and 21725 reported for those procedures performed *with* a cast application.

  The PRT recommends moving CPT 20725 to APC 5121.

- CPT codes 10080 and 10081 both include incision and drainage of a cyst that involves an incision overlying the pocket. The procedures differ in technique slightly, in that CPT 10081 requires an additional slit to form a continuous surface from the exterior surface to the interior surface of the cyst or abscess so it can drain freely. The PRT submits that the resources are similar and both CPTs are clinically the same. In the Proposed Rule, CMS assigns CPT 10080 to APC 5071, and CPT 10081 to APC 5072. The PRT believes that both procedures are clinically homogenous to those procedures proposed for APC 5072.

  The PRT recommends moving CPT 10080 to APC 5072, and supports CMS' proposal to move CPT 10081 to APC 5072.

- CPT 35226 is currently assigned to APC 0020. CMS proposes to reassign this procedure to APC 5072. The procedure is used to report the repair of a blood vessel, direct lower extremity. This code represents an open repair of the leg vessels and is not used to report percutaneous vascular procedures. A similar procedure performed on the upper extremity is described by CPT code 35206. CPT code 35206 is currently assigned to APC 0093 and CMS proposes to reassign the procedure to APC 5182.

  The PRT recommends that both CPT 35226 and CPT 35206, which are clinically consistent, be assigned to APC 5182.

4. GI

CMS proposes to realign the current GI APC groupings from upper and lower endoscopy procedures to categories that better reflect the consistent set of clinical categories throughout the entire spectrum of GI-related procedures.

As part of this realignment, CMS proposes to reassign ablation procedures performed with a laparoscopic approach from APC 0174 to APC 5362. Other ablation procedures with different approaches are predominately reassigned from APC 0423 to APC 5352.

The PRT recommends that similar ablation procedures, CPT codes 0336T, 47370, 47371, and 50542 be included in the ablation alignment within APC 5352.

5. Imaging Services

CPTs 77761, 77762, and 77763 reflect the number of radiation source applications and are currently assigned to APC 312. CPT 77761 represents one to four sources; CPT 77762 represents 10 sources; and CPT 77763 represents more than 10 sources.

CMS proposes to reassign CPT codes 77761 and 77763 to APC 5623, and to reassign CPT 77762 to APC 5622. The resources utilized by CPT 77762 are greater than those required for CPT 77761.

The PRT recommends that CMS reassign CPT 77762 to the same grouping as CPT 77761 and 77763, which is APC 5723.

The reassignment request would better ensure that the costs and clinical characteristics of procedures are aligned within the same APC assignment.

CMS proposed to assign CPT 78811 (PET imaging, limited) to APC 5592; CPT 78812 (PET imaging, skull to mid-thigh), and 78813 (PET imaging, full body) to APC 5593. CMS also proposes to assign PET CT studies CPT 78814 (PET CT, limited), CPT 78815 (PET CT, skull to mid-thigh), and CPT 76615 (PET CT, whole body) to APC 5593.

The PRT recommends that CMS reassign CPT 78811 (PET imaging, limited) to APC 5593, to reflect similar clinical homogeneity and geometric mean cost similar to CPT 78814 (PET CT limited study).

The PRT also recommends the following which is consistent with what we requested the Hospital Advisory Panel (HOP) and also consistent with the Society of Nuclear Medicine:

- Maintain the distinct APC for all PET procedures (CPTs 78811 - 78816 78459, 78608, 78491, 78492, currently APC 0308);
- Maintain the distinct APC for therapeutic nuclear medicine procedures (CPTs 79005-79999, currently APC 0407);
- Maintain individual APCs for diagnostic nuclear medicine tests (CPTs 78013-78807).

6. Orthopedic Procedures

CMS identified 1082 CPT codes that could be reorganized into nine clinically homogenous and resource related C-APCs for orthopedic-related procedures.

- CPT 10021, FNA without imaging, is proposed to be assigned to APC 5052. We believe that it is more closely related, both clinically and in terms of resource use, to the incision and drainage and excision/biopsy procedures in APC 5072. FNA with imaging, CPT 10022, is proposed for inclusion in the Level 2 Excision/Biopsy/Incision and Drainage family.

The PRT recommends assigning CPT 10021 to APC 5072.

- CPT 23397 is reported for procedures involving multiple muscle transfers, any type, shoulder or upper arm. This CPT is currently assigned to APC 0051. CMS proposes to reassign the multiple procedures code to APC 5122 while assigning the single procedure to APC 5123. These procedures are clinically similar with similar resource utilization and both should be assigned to APC 5123.

  The PRT recommends assigning CPT 23397 to APC 5123.

7. Debridement and Skin Procedures

There are 259 CPT codes that CMS identified for reorganization into five clinically homogenous and resource-related C-APCs for skin-related procedures.

We agree with the CMS' proposed assignment of the debridement and skin procedures into the proposed restructured/renumbered CY 2016 APC.

8. Urology

CMS is proposing to reassign ablation procedure CPT code 50542 to APC 5362 (Level II Laparoscopy procedures).

The PRT identified a large variation in the geometric mean cost from approximately $4,698 — $10,520 for the procedures assigned to APC 5362. The specific geometric mean cost for CPT 50542 is $9,959. We believe the high cost of this APC warrants placement in a separate APC.

Therefore, the PRT recommends that CMS create a new APC 536X - Level III Laparoscopy - and assign the higher-weighted procedures based on their geometric mean to this APC to address the cost variation.

9. Vascular Procedures

CMS is proposing to reassign APC 103 to APC 5181. While the titles of both APCs are similar, the PRT submits that there are some procedures within APC 103 that are more comparable clinically and with respect to resources to procedures assigned to APC 5188.

- APC 103 (Miscellaneous Vascular Procedures) currently contains only four heart procedures in this APC grouping: CPT 33215 (Repositioning of a pacing lead), CPT 33226 (Repositioning of a ventricular lead), CPT 93503 (Insertion/Placement of a flow directed catheter), and CPT 93505 (Biopsy of heart lining). CMS is proposing to reassign APC 103 to APC 5181, Level 1 vascular procedures.

  The PRT recommends that CMS reassign the CPT codes in APC 103 (a vascular APC) into APC 5188 (other heart procedures).

- APC 279 (Level 2 Angiography and Venography) currently has CPT 36222, CPT 36223, and CPT 36225 assigned to this group. CMS proposes to reassign these CPT codes to

APC 5526 (Level 6 X-Ray and Related Services). The PRT believes that these CPT codes should be reassigned to APC 5183 (Level 3 Angiography and Venography), which would place CPT 36222, 36223, and 36225 in alignment with similar procedures and similar clinical characteristics. APC 5183 contains CPT 36224 (Selective Catheterization of an internal carotid artery) and CPT 36226 (Selective Catheterization of a vertebral artery).

The PRT recommends reassigning CPT codes 36222, 36223, and 36225 to APC 5183.

Summary of PRT-Requested APC Reconfiguration Changes

CPT	Proposed APC	Recommended APC
31515	5152	5154
95909	5722	5723
95910	5722	5723
57022	5071	5074
62269	5071	5073
21725	5071	5121
10081	5071	5072
35226	5072	5182
35206	5072	5182
0336T	5362	5352
47370	5362	5352
47371	5362	5352
50542	5362	5352
77762	5622	5723
78811	5592	5593
10021	5052	5072
23397	5122	5123
33215	5181	5188
33226	5181	5188
93503	5181	5188
93505	5181	5188
36222	5526	5183
36223	5526	5183
36225	5526	5183
50542	5362	Create a Level 3 Laparoscopy APC

Comprehensive APCs with a New Modifier for Data Collection

Proposal for the Addition of Nine Comprehensive APCs

The PRT understands that CMS is proposing to expand its list of Comprehensive APCs (C-APC) from the current 25 to 34 by adding nine new C-APCs for CY 2016, under the payment policy methodology that was made effective in CY 2015. The PRT appreciates that CMS is proceeding in a more thoughtful manner, but we have concerns about CMS proceeding so quickly with additional C-APCs.

CMS finalized and implemented the C-APC concept in the 2014 OPPS/ASC Final Rule. Although the policy was finalized in 2014, its effective date was delayed until January 1, 2015, to allow additional time for analysis, public comment, and systems preparation. In the 2014 OPPS comment period, the PRT urged CMS to delay implementation of C-APCs in order to provide the public more time to review, understand, and comment on the data and the methodology utilized to develop the C-APCs. We appreciate that CMS listened and delayed implementation for one year; in the end, C-APCs were implemented with modifications and clarifications that were made in response to public comments.

We understand that a prospective payment system does not reimburse for itemized services and that CMS proposes to increase the number of C-APCs as part of its long-term plan to pay for episodes of care in the outpatient setting. We respectfully disagree, however, with CMS' proposal for creating nine additional comprehensive APCs for CY 2016. We believe this extension of the policy is based on insufficient data, inadequate time for analysis of the C-APC impact (both from CMS and provider/stakeholder perspectives and providers have uncertainty on how this will impact their organizations and cash flow). In addition, the expansion of the C-APCs will complicate implementation of ICD-10.

The PRT opposes the creation of nine additional C-APCs for CY 2016.

Our specific objections are detailed below:

- As noted, the C-APCs policy was not implemented until CY 2015. Hence, there has been very little time to analyze the resulting data and fully understand how packaging (including the labs) will affect overall hospital reimbursement in the long run. CMS has an established practice of using claims data from two years prior to the Rule year to guide and model proposed changes. Implementing the proposal to create nine additional C-APCs without first conducting data analysis on the existing 25 conflicts with CMS' usual analysis methodology, since the claims data related to C-APCs are from CY 2015, rather than the CY 2014 claims data upon which the current OPPS Proposed Rule is based. This change means that the expansion of a significant reimbursement policy decision under the OPPS would be made using minimal claims data of less than one year, which has yet to be made available to the provider community. This hampers stakeholders' ability to analyze, model, and provide thoughtful and "real scenario" comments to CMS.

  It appears that CMS' focus is on rapidly creating C-APCs in order to transition OPPS to more closely mirror the Inpatient Prospective Payment System (IPPS), without acknowledging the very real differences in outpatient utilization patterns, which are inherently less connected. While we understand, and generally support, the identification of larger bundles of services, the PRT suggests that CMS evaluate the current C-APC claims to assess whether everything is packaged appropriately prior to proceeding with additional C-APCs. This is beneficial to CMS, providers, and stakeholders; most important, it is also beneficial to the program's beneficiaries.

  Methodical and validated changes will ensure that beneficiary services are appropriately maintained and based on the true cost of services. We note that multiple services provided on the same claim *should not automatically* package into other services on the claim. All services reported on a claim cannot be assumed to always be related to a single, primary type-service reported on that claim. In order to have meaningful data and

reimbursement methodology, CMS should package the appropriate costs into the appropriate service, and not just select a set of codes to always be the primary service on a claim.

- The Proposed Rule does not address or explain how CMS factors and/or accounts for denials that are appealed and overturned when calculating the reimbursement rates. This speaks to the accuracy or inaccuracy of the data included in setting the rate for the C-APC.

- The number of CPT codes that are affected by the proposal increases from 219 to 791 codes, which is an almost three hundred percent (300%) increase. This significant increase along with the other proposed changes has made it virtually impossible for providers to assess the proposal's net impact on our facilities. Hospitals will be challenged to model these changes, especially given the limited resources facilities have in this area.

- ICD-10 will be implemented in October 2015, and hospitals anticipate experiencing disruptions in workflow and productivity (with resulting cash flow issues for providers). The challenges of implementing both ICD-10 and increased bundled payments will make it *extremely* difficult for providers to track and trend all of the reimbursement issues and address these changes in an effective manner.

  The PRT requests that CMS release the information regarding what services are being considered for the following calendar year to the HOPS panel at the winter meeting in order to allow stakeholders insight about future proposals.

  We also request that CMS release the data that are being used (while recognizing that these data are preliminary); this would provide stakeholders adequate time to analyze the available data and offer alternatives and/or additional information to the Panel and CMS at the summer meeting.

The PRT attended the HOP Panel meeting and noted that there were a number of requests from the Panel regarding what alternative data the presenters had available and what other alternatives the presenters/commenters wished to offer. The consistent response from presenters was that they had not had sufficient time to run the data. There is very little time from release of the Rule to the deadline for submitting Panel presentations to CMS for review. Even the 60-day window from display of the Rule to the comment period closure is a very tight time frame for providers and stakeholders to analyze the data and provide meaningful commentary and alternatives.

This is especially critical for hospital providers, who have to read the entire Proposed Rule because *everything* in it pertains to us. We have to digest the proposal's operational impacts as well as attempt to process and analyze the data. The PRT members, who work on the front-lines of OPPS implementation, lack the resources to hire consultants to model the Proposed Rule for us.

The early release of a preliminary data set and additional details in the proposed rule about the proposed changes — along with a public version of OCE software that would allow providers to model the impact of CMS' proposed rules — would enable us to analyze new proposals and also provide more specific information to members of the HOP Panel and CMS. Providers understand

that the OPPS is a prospective payment system and not a fee-for-service methodology; we simply want to validate that it is based on a valid, reproducible methodology, so all providers can model and understand the potential impact of new proposals to their facilities.

> **We respectfully request that CMS provide the preliminary data and allow additional time for data analysis, which will result in more meaningful discussion of alternatives at the summer meeting.**

Observation Comprehensive APC

For CY 2016, as part of the proposed C-APCs expansion, CMS is proposing to pay for all qualifying extended assessment and management encounters through a newly created Comprehensive Observation Services C-APC. Services in this APC will be assigned to the proposed new status indicator J2. The J2 status indicator would be used to designate specific combinations of services that — when performed in combination with each other and reported on a hospital Medicare Part B outpatient claim — allow for all other OPPS-payable services and items reported on the claim (excluding preventive services and certain Part B inpatient services) to be deemed "adjunctive services" representing components of a comprehensive service. A single prospective payment would be made for the comprehensive service based on the costs of all services reported on a claim.

The PRT offers a number of suggestion refinements for CMS' consideration prior to the agency finalizing or introducing an Observation C-APC. These are detailed below along with a final summary of our recommendations.

Separate Payment for J2 C-APC

The PRT appreciates that this new payment methodology would result in beneficiaries having only a single co-pay for the comprehensive service. The PRT submits, however, that CMS must allow for separate payment of the J2 service if it occurs on the day prior to a status S, T, or J1 procedure, since the procedures can occur as the result of the active treatment and monitoring provided to the beneficiary as part of their observation services. Because the observation services provided prior to the procedure would meet the current criteria for separately payable observation services, the PRT recommends that CMS create this as a complexity adjustment to the J1 C-APC. The PRT believes CMS must refine its Observation C-APC logic and release it again for comment at the 2016 Winter HOP Panel meeting.

Complexity Adjustment Factor

The PRT requests that CMS release the data related to the calculation of the Observation C-APC, so that providers and stakeholders can specifically see the inclusion of additional services (e.g., Observation with drug administration services, Observation with drug administration services and imaging services, etc.). This will allow providers and stakeholders to see the cost curve based on reported services and reimbursement when Observation is in play.

The PRT believes that the additional services were factored into the equation, but the data have not been released to enable providers to replicate the methodology and validate this assumption. The PRT data shows that drug administration services and advanced imaging services increase the patient acuity and the cost of the overall observation services — and thus could be considered

and/or used to develop either a complexity adjustment factor or APC splits.

As noted above, we believe that CMS should consider using a complexity adjustment factor to account for situations in which patients who receive the C-APC observation service also receive drug administration and/or advanced imaging services versus those who do not. Additionally, analyzing whether the time receiving observation services impacts providers' overall costs in a manner that warrants the creation of additional C-APCs to account for complexity and resource differences is important.

We believe CMS must conduct analyses such as these to determine whether complexity adjustment factors and/or additional C-APCs are needed prior to implementing the proposed observation C-APC.

Carve Out Observation Hours

Additionally, providers are currently required to "carve out," from separately reportable observation hours, the time spent on services that also require active monitoring. The requirement for this manual and administratively burdensome effort can be found at *Medicare Claims Processing* (PUB. 100-04), Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS), 290.2.2 - Outpatient Observation Services, Reporting Observation Hours.

Given the creation of a C-APC, the PRT requests that CMS no longer require providers to incur the administrative burden of identifying observation "carve outs," which, we believe is no longer necessary and must be eliminated. Doing so will significantly reduce provider burden, resulting from the need to manually remove time associated with separately payable procedures that have an inherent period of "monitoring."

As stated above, an important consideration for a complexity adjustment is the number of hours for which the Observation service is provided. A minimum of eight hours is required before the current Composite or the newly proposed Comprehensive APCs are triggered. Based on the new regulation requiring notification and explanation to the beneficiaries that they are actually an outpatient receiving outpatient services (not an inpatient of the hospital even though they may be in a hospital room), along with the financial impact for the beneficiary, the PRT believes that the hours that the patient receives observation could be used to adjust for complexity and/or could be a reason to have two observation C-APCs instead of a single C-APC.

Removing the "carve out" will also prevent the situation in which different beneficiaries with similar times spent in observation incur different cost-sharing obligations because one observation stay resulted in less than eight hours of observation as a result of the provision of actively monitored services. We note that the fundamental principles of CCRs applied to charges will ensure that there is not a duplication of payment should the hours begin to be reported as observation hours.

Similarly, in order to avoid beneficiary confusion about what type of visit level can trigger an Observation C-APC or not, we believe CMS should allow all Emergency Department (ED) Visit Levels in the trigger for the Observation C-APC. The PRT believes CMS should alleviate providers' current administrative burden that stems from having to "carve out," from the reported number of observation hours, time when other services that require active monitoring (which are currently reimbursed separately) are provided during the same period that the patient receives

observation services.

Addressing the above concerns will decrease the beneficiary copayment responsibility and allow for a single copayment. It would also make the status of patients receiving observation more consistent. This is even more important with the added requirement for face-to-face notice and counseling of patients in observation status that is required by the recently enacted NOTICE Act.

In summary, the PRT offers the following recommendations most of which are related to the types of refinements we would like to CMS make before implementing the OBS C-APC:

- CMS should provide separate payment for the OBS C-APC if the observation service is provided on the day before the J1 procedure AND reimburse for services with status indicators S, T, or J1 procedure provided on the day after the observation service.

- CMS should analyze using a complexity or acuity adjustment for Observation C-APCs.

- CMS should study the appropriateness of creating multiple Observation C-APCs based on considerations related to the number of hours of observation hours/services received, the inclusion/exclusion of drug administration services, the inclusion/exclusion of advance imaging services, and inclusion/exclusion of other services that may impact providers' overall costs.

- CMS should alleviate the administration burden of "carving out", from the reported observation hours, the number of hours associated with active monitoring, which are currently reimbursed separately.

- Once additional refinements are made, CMS should release the OBS C-APC logic again for comment and ideally provide a preview of it at the 2016 Winter HOP Panel meeting. This will allow stakeholders to provide more meaningful comments to CMS at that time as well as during the OPPS CY 2017 Proposed Rule-making cycle.

Proposed Data Collection for Non-primary Services in C-APCs

The PRT understands that CMS proposes to establish a HCPCS modifier to be reported with every code that is adjunctive to a comprehensive service but is billed on a different claim. According to information in the Proposed Rule, this stems from CMS' desire to identify related, integral, and adjunctive services that are furnished prior to an associated primary J1 C-APC procedure. CMS' goal is to ensure that future rate-setting for C-APCs includes all related services and that the payment rate is as accurate as possible.

Specifically, CMS proposes that hospitals would report this modifier for services that are adjunctive to a primary procedure HCPCS code with status indicator J1 but are billed on a different claim than the primary J1 service. CMS believes that providers perform services that are integral, ancillary, supportive, dependent, and adjunctive to a comprehensive service prior to delivery of that service. This may include testing leads for a pacemaker insertion or planning for radiation treatment. With expansion of C-APCs, CMS seeks to implement a mechanism for identifying those adjunctive services that are furnished prior to the associated primary service, in order to create reimbursement for an episode-of-care C-APC.

While we understand what CMS wants to achieve, the PRT *does not* support CMS' proposal for CY 2016. The PRT respectfully, but adamantly, disagrees with CMS' proposal, because it would be extremely burdensome for facilities to operationalize. There is virtually *no way* for a hospital, which processes thousands of outpatient claims per day, to add modifiers to specific patient claims for services that could span several different claims.

CMS stated that this modifier would be used for services that are adjunctive to the primary procedure, but it has not presented defined criteria to determine *what* is considered adjunctive to the primary service. The exception is SRS planning, where facilities may be able to more easily identify adjunctive services since CMS lists specific CPT codes in the Proposed Rule. We note that, even for SRS, although specific CPT codes indicate "planning," it will still be problematic to add a modifier to the adjunctive services, since these services will be billed on several different claims at different times.

Providers will have to dedicate staff (which they do not have and which will increase costs to the system) to manually review claims and add the modifier to services after the primary J1 procedure is provided. These services are typically generated at the department level utilizing the Charge Master, and charge entry is done by department staff at the time the service is rendered. Second, the modifier should not be added until the related (J1) procedure is provided in order to preserve the integrity of the data. If the modifier is added to the claim in expectation of the provision of the service, CMS will receive flawed data for those times when the primary procedure is not completed.

The PRT is concerned as the phrase "primary services" has been loosely utilized. It is already being used in reference to C-APCs to refer to the primary (J1) service on a claim, and in the current proposal being used as a reference for the data collection proposal. The terminology needs to be specifically defined and validated, in order to not be left open for interpretation. This was illustrated at the HOP Panel meeting, when one of the panel members assumed a 30-day window for related claims for data collection, but CMS staff clarified that there was no established or related time frame for the data collection.

CMS should better define an episode of care. OPPS is moving to episode of care payment but there is no clear understanding or definition of what this really means. Bundled payment is in process and defined. But, CMS is determining an episode of care across the spectrum. It is unfair to put added administration burden on hospitals to provide additional data. The global period for OP services has previously been defined as single DOS or a claim. CMS has a different methodology for C-APC in order to accomplish a truly prospective payment system. The PRT believes that CMS is approaching the process in a piecemeal fashion that adds to hospital's administrative and operational burden, and increases cost to the system.

The PRT suggests that SRS be the test subject for an analysis of how to keep the claims associated. CMS should use its claims processing ability, programming logic, or common working file to locate the specific CPT codes related to Cobalt or LINAC services. CMS can then use data analytics to gather data on other C-APCs based on the J1 CPT code, and use the HOP Panel, stakeholders, and clinical focus groups to determine *which* services are related vs. unrelated to a C-APC. The best plan is to work through the C-APCs methodically, addressing a few each year, in order to ensure that services stay aligned and that operational burden is reduced

for both providers and CMS. (Another result is that this expands the Panel's scope of work.) We understand this will take a longer time period to accomplish, but supports the critically important goal of guaranteeing that prospective/episodic payments are based on accurate data and all stakeholders have been engaged in the process.

Other than for SRS, CMS has not provided a clear definition of what is considered "related." Even if exact criteria were defined by CMS and known by facilities, it would still be burdensome to operationalize. It is a common practice for facilities to "drop" clean claims to insurers within three or four days. At the time of billing, there may or may not be an actual anticipated date of service for the J1 C-APC procedure. At this time, the PRT has not been able to identify what sort of criteria the facility could use to identify related services that may have already been provided in order to hold the claim.

> **The PRT urges CMS not to adopt this proposal. The agency must better define an "episode of care" in order to provide clarification of what episode of care payment means.**
>
> **The PRT recommends that CMS use SRS as the test subject for analyzing how CMS can keep claims associated, then methodically work through the C-APCs (in partnership with the HOP Panel and other stakeholders) to ensure that services are aligned and operational burdens are minimized.**

Number, Order, and Use of Modifiers

The PRT remains concerned by the ever-expanding number and types of modifiers being proposed and/or required by CMS for payment policy changes. For example, in CY 2016, hospitals will be required to begin using the "PO" modifier, which must be reported with every Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology (CPT) code for all outpatient hospital items and services furnished in an off-campus provider-based department of a hospital. These modifiers present administrative and operational challenges for providers, particularly when modifiers must be manually applied to claims.

We are also concerned by the lack of clear guidance regarding how many modifiers can be submitted on an individual claim line, and in what order, to mitigate the risk of the claim being rejected during claim processing by the MACs. Our members researched the question of how many modifiers can be submitted on a claim line and be successfully processed. We discovered that there is quite a variation in guidance and instruction on modifier use.

For example, the *UB-04 Claim Form Instructions*, released by the National Uniform Billing Committee (NUBC), which works in conjunction with the AHA, states that the UB-04 field for the HCPCS code "allows up to 9 characters. Only one CPT/HCPC code and **up to two modifiers are accepted.**" (Emphasis added.)

But, the *Uniform Billing Editor* instructions in Appendix 5 (Modifiers Used for Facility Reporting) states that: "The UB-04 **accommodates up to four modifiers** per line and electronic versions 5.0 and 6.0 flat files. If more than two modifiers need to be reported next to a CPT code, repeat the CPT procedure code with the additional modifier appended." (Emphasis added.)

And, the *Medicare Claims Processing Manual* chapter entitled, "Use and Acceptance of HCPCS codes and modifiers" (chapter 23, section 20.3) states: "Carriers/MACs and DME MACs are required to **accept at least 2-position numeric or alpha modifiers** and process both modifiers completely through the claims processing system (including any manual portion) as far as payment history. Intermediaries **must be able to accept at least five modifiers** and process them completely through the system. It is not acceptable merely to be able to accept multiple modifiers and then drop one before complete systems processing. Dropping of a modifier leads to incomplete and inaccurate pricing profiles." (Emphasis added.)

The PRT urges CMS to provide clear and explicit guidance and clarification on reporting modifiers based on how many will be processed per line item. It would be administratively burdensome for providers to have to report multiple line items for the same HCPCS code just to report the appropriate number of modifiers. Plus, there is the inherent risk that the claims processing system will either reject claims for reporting the same HCPCS code on multiple line items or process reimbursement on multiple line items with the same HCPCS code, when the intent of the reporting was *only* to report all appropriate modifiers. The agency must also ensure that the CMS claims processing logic "uses" or "sees" all reported modifiers on a claim line and that payment is calculated only *after* all of the modifiers have been accounted for in the correct order based on OPPS methodology. Until these questions have been clarified, the agency should not require providers to use additional modifiers as there is no guarantee that all modifiers will be captured correctly in the claims data.

> **We urge CMS to work with stakeholders regarding expansion of the number of modifiers providers can submit and that the MACs' system will process, as well as provide clear and explicit guidance regarding the order in which to correctly report modifiers, as the number the agency is requiring be reported continues to increase.**

SRS Treatment

CMS discusses differences in billing practices for Cobalt-60 based vs. LINAC-based treatments. Definite differences in Cobalt-60 and LINAC methodologies exist as the basis for the differing practices. For Cobalt-60, a brace/halo device is attached to the patient to position the head for treatment. All planning services must be done quickly on the same day because the patient is not sent home with the halo device. LINAC planning is done in advance because it is more complex and positioning is accomplished through a mask that is easily applied and removed. The patient does not have to be present throughout the planning process, which can be completed and finalized before the patient arrives for treatment.

Based on claims data, CMS proposes to change the payment structure for SRS treatment by identifying all services that are reported in support of HCPCS codes 77371 and 77372, both on the same claim and on claims one month prior to delivery of SRS services (including planning and preparation services). CMS proposes to remove these items from the C-APC geometric mean calculation for CY 2016 and CY 2017 while data are collected using the newly proposed modifier. Eventually CMS expects to create a new single encounter payment for this C-APC by packaging all planning and preparation services that occur prior to the primary J1 procedure and are associated with it.

The PRT does not believe that CMS' proposal will lead to a more accurate payment rate. We agree that SRS is an appropriate treatment modality to provide a bundled payment for the entire course of therapy, since it is a relatively standard plan of care. However, we believe that CMS must utilize a different approach to set the bundled payment rate. We also believe CMS must take into consideration patient severity — as some patient conditions will require more complex treatment planning, more complex devices, and changes during the course of therapy. In these instances, it would likely be inappropriate to only pay a single C-APC rate. We recognize that the OPPS is an averaging system, but this concept only works when payment rates are appropriately set. Therefore, the PRT asks CMS to respond to providers' concerns that the data are solid and appropriate, as noted above.

> **The PRT understands that CMS is migrating to an episode of care payment methodology, which we support, but we ask the agency to move cautiously to ensure that the payment rates it sets for these episodes are accurate.**

Two-Midnight Rule

The PRT appreciates CMS' acknowledgement of providers' concerns about potential exceptions to the two-midnight rule; we appreciate that the agency is proposing to allow physician judgment to be the deciding factor when making an admission decision. The PRT has concerns, however, that this proposal reverts to the pre-two midnight rule era, when admission status was to be determined based on physicians' medical judgment and medical necessity but, all too often, that judgment was second-guessed and over-ruled by the RACs. This resulted in significant appeal backlogs.

Initially, as a gauge for medical necessity, providers were to consider a 24-hour period as the benchmark for making inpatient hospital admission decisions (i.e., "order inpatient admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis"). Subsequently, the patient staying over two midnights became the standard for making these decisions.

These guidelines presume that all patient treatment will follow a predictable course, which is not the case. For example, a patient is seen in the Emergency Room (ER) at 11:59 pm and spends two midnights in the facility. This scenario would be considered as an Inpatient — and the hospital would be appropriately reimbursed under Part A. In contrast, a patient who arrives at 12:01 am and has a work up completed before the two-midnight time frame would be considered an Outpatient based purely on the time of arrival in the ER— even if both of these patients had the exact same diagnoses and treatment. This is clearly an example where physician judgment should be the deciding factor in the admission decision.

CMS states that it will: *"allow for payment under Part A on a case by case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights."* The documentation for two patients in the example provided above is likely to be very similar, since their diagnoses and treatment are the same. We are also concerned that CMS has not provided examples of situations in which a patient may require hospital care less than 24 hours and still qualify for Inpatient.

CMS does not outline specific medical review criteria for Inpatient hospital admissions that are not expected to span at least two midnights. Yet, CMS acknowledges that there are nationally recognized criteria for Inpatient admission determination. The PRT understands that these criteria are guidelines and that the physician's clinical judgment is always a driver. If hospitals choose to use criteria — whether nationally published or hospital-specific — those criteria should be considered to be in support of the admission decision, when the admission is audited. CMS should create a condition code allowing the facility to attest that their selected criteria were used and met. This would allow identification through data analytics. These could be targeted for audit, and if the audit shows that the facility is applying the criteria consistently and appropriately, then future audits could be decreased, decreasing the cost to the system and preventing the backlog of appeals.

If the criteria is not met, but the physician believes in his/her clinical judgment that the patient should be admitted as IP, then the facility would not apply the condition code to the claim. This allows the data to reflect the differences in the claims and also supports the long-term basic rule that the physician's clinical judgment is the driver for the admission status.

In fact, CMS has already set this precedent under the OPPS with use of Hospital Evaluation and Management (E/M) criteria (i.e., criteria for the level of resource allocation, consistently applied, rarely altered, etc.). The application for inpatient admission is very similar to the E/M situation: the hospital provider, in conjunction with the physician who has the final determination, would apply the criteria for Inpatient admission consistently across all patients. Otherwise, each admission decision truly is made on a "case-by-case" basis. When reviewed later during an audit, consideration must be given to the physician's reasoning in determining the patient's admission status; the attending physician is looking at the scenario as it unfolds and does not know the outcome until the workup is completed. Upon review of the record post-care, the picture is clearer as it is not being viewed from the same perspective.

Physician judgment at the time the patient presents should be reviewed *by a physician* in order to assess whether the admission status was truly appropriate. It is not within a nurse's or other reviewer's training or basis of education to be able to second-guess a physician's medical judgment. This should be a physician peer review.

CMS allows the use of Occurrence Code 72 to help define an episode of care, especially for patients who are Outpatient (e.g., in the Emergency Room) for one midnight and then Inpatient for one midnight. The PRT seeks clarification from CMS if the episode of care concept will still be considered as meeting two midnights? And, will the BFCC QIO review these scenarios?

The PRT also has several concerns and questions related to moving the primary "short-stay" reviews from the MACs to the BFCC QIOs. Specifically:

- We note that there are currently only two BFCC QIOs to review all admissions nationwide. Additional staff will be required to handle the additional increased work volume. The larger BFCC QIO (KEPRO) currently has 10 provider outreach specialists for its entire coverage area. This increased responsibility will tax the organization's resources and potentially reduce resources available for provider feedback and/or education. We seek clarification from CMS how the new staff will be prepared? The PRT is also concerned about the level of clinical experience for staff providing feedback. Many times, coders are the selected staff and, while knowledgeable, they are not

physicians. We believe there should be an escalation process to the physician level for physician review, since admission determinations are based, as they should be, on the physician's medical judgment.

- CMS just announced that the initial review will be 25 cases for smaller hospitals and 50 for larger hospitals. It is not clear, however, if those results will be correlated with the existing Probe and Educate results. The PRT appreciates that CMS will allow hospitals to appeal the initial results, but has concerns that the BFCC QIO will not have the resources to manage the appeals in a timely manner.

- We are concerned that KEPRO currently does not accept medical records via email, which causes operational issues for both the provider and KEPRO regarding submission of the medical record documentation. The options are either by disc or paper, which raises HIPAA concerns, as PHI is involved. In addition, paper records printed from EHRs are voluminous, cumbersome, and expensive to generate and reproduce.

- The QIOs will refer "high rates of improper billing" to the RACs. The PRT is concerned about the calculation of an "improper" billing rate. In cases where the BFCC QIO determines that the appropriate status does not match the order (based on its review), will the order be overturned? This will occur post-discharge, and the order was based on the physician's judgment at the time the patient was in the hospital. By regulation, as noted in CMS' *Claims Processing Manual* (Pub 100-04), CMS neither allows nor recognizes retroactive orders. Upon QIO review and disagreement with the treating/attending physician's judgment, will CMS make an exception and allow a change to the order? Otherwise, CMS should expect to see an increase in "Part B billing on a Part A claim."

- When a patient is placed in Inpatient status and, upon review by the UR committee and discussion/agreement by the attending physician, the status is determined to truly be Outpatient, Condition Code 44 is currently reported to reflect this situation and denote that all documentation is present to support the change. We expect this guideline to remain in place and ask CMS for confirmation?

- CMS has stated that the admission status is a "reimbursement issue." The PRT agrees that the proposed changes to the two-midnight rule appear to better incorporate physician judgment as the director of patient care. The change appears, however, to actually *reduce* the clarity of the two-midnight timeline and place the burden of a "reimbursement issue" on the physician's clinical documentation, when the point of the physician documentation is to support the level of care of the individual patient.

  The PRT recommends that CMS create a condition code allowing the facility to attest that nationally recognized criteria were used and met to determine Inpatient admission. This would allow identification through data analytics when the record is audited. If an audit shows that the facility is applying these criteria consistently and appropriately, future audits should be decreased.

Proposed Changes to the Inpatient-only List

CMS proposes to remove the following seven procedures from the Inpatient-only List for CY 2016:

1. 0312T: Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming;
2. 20936: Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from the same incision;
3. 20937: Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision);
4. 20938: Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricotical (through separate skin or fascial incision);
5. 22552: Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace;
6. 54411: Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including the irrigation and debridement of infected tissue; and
7. 54417: Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative sessions, including irrigation and debridement of infected tissue.

The PRT has asked CMS to eliminate the list of procedures paid only in the inpatient setting on more than one occasion in our comments on previous OPPS rules. We reiterate this request, since we believe that the inpatient-only list is unnecessary. The list also increases Medicare expenses by maintaining procedures in the inpatient setting long after technology and medical advances have made them safe to be performed in the outpatient setting. CMS has stated that the inpatient-only list is maintained as a safety mechanism to protect the older Medicare beneficiaries.

We note, however, that age alone should *not* be used to determine whether a procedure is appropriately provided in the inpatient and/or outpatient setting. Medicare beneficiaries may be, and often are, healthier and hardier than younger patients covered by other types of insurance. The appropriate surgical setting should be decided by the physician's assessment of the patient's clinical picture, in conjunction with the desires of the patient and his or her family.

If CMS insists on maintaining the Inpatient-only List, we agree with removing the first five procedures from the Inpatient-only list as these procedures can be performed safely in the outpatient setting.

We asked a trauma surgeon and a neurosurgeon on staff at one of the PRT member hospitals to comment on the list of procedures proposed for removal from the inpatient-only list. They agreed with the removal of all of the proposed codes except for CPT codes 54411 and 54417, citing safety as the reason the codes should not be removed from the list. These codes' descriptions indicate the presence of an "infected field." The trauma surgeon stated, "*I agree with your concerns about the last two [codes, 54411 and 54417] as those patients will require close monitoring, will need a period of IV antibiotics, [and will] likely [need] cultures [obtained] at*

the time of surgery that require a minimum of 48 hours to return with the sensitivity report to know the appropriate IV antibiotic(s), and, in that particular area, "organ loss" would be a devastating complication."

Based on the above the PRT does not support removal of CPT codes 54411 and 54417 from the inpatient-only list. We do not believe these codes meet CMS's criteria for removal from the inpatient-only list.

> **The PRT asks that CMS maintain 54411 and 54417 on the Inpatient-only List for patient safety reasons, but we support the removal of CPT codes 0312T, 20936, 20937, 20938, and 22552 from the Inpatient-only List.**

Lung Cancer Screening

For CY 2016, CMS is proposing to assign HCPCS code GXXX1 (Counseling visit to discuss need for lung cancer screening) to APC 0432 and GXXX2 (Low Dose CT scan for lung cancer screening) to APC 5570.

The PRT appreciates CMS assigning these codes to an APC, but we are deeply concerned about services that we have already provided but for which we have not received payment. We have provided these services in good faith since CMS released its coverage decision, and have been waiting for codes to use to bill these services.

The PRT requests that, in the CY 2016 OPPS Final Rule, CMS clearly explain how payment is to be received for these services. We also request the agency to address whether the two new HCPCS codes will be made effective retroactively to CY 2015, so facilities can receive payment for the services provided in CY 2015 (i.e., after the coverage decision was released).

If the services cannot be billed retroactively, we urge CMS to provide clear guidance about how facilities are to be reimbursed for these important and covered services provided in CY 2015.

Hospital Outpatient Quality Reporting Program Updates

The PRT appreciates that CMS' goal is to align various quality reporting programs' clinical quality measure requirements. Consistency among these measures will reduce the operational burden needed to comply with multiple sets of quality measures.

Despite supporting this overall goal, however, the PRT continues to have a broad concern that applies to many of these quality measures. Specifically, we note that follow-up for several of these procedures usually occurs *outside the hospital outpatient department*. Many patients are seen for follow-up in their physician's office. This means that hospitals have *no way* of assessing the patient's outcomes, as indicated by these quality measures. The PRT believes it is unfair use these measures to penalize *hospitals* for negative outcomes and inadequate results, when these facilities are not consistently responsible for conducting follow-up.

The PRT once again endorses the concept of further selection of measures for the Hospital OQR. We recommend that *all* quality measures selected should have an easily identifiable correlation with clinical outcomes and to the patient's experience of care.

Hospital OQR Program Quality Measures Adopted in Previous Rulemaking

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 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."* We support that goal, but note that, for any colonoscopy performed outside of the hospital outpatient department, hospitals have *no* control at all over preparation, the procedure itself, or for follow-up care. Adding this quality measure would force hospitals to ask each and every patient who presents to the Emergency Department (ED) whether they have 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 GI endoscopy, (b) patients with history of IBD or diverticulitis in the year preceding colonoscopy, and (c) patients who lack continuous enrollment in MC FFS Part A and B in the one month after procedure. As above, how are facilities to assess this patient history? We 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 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 procedure that occurred elsewhere.

> **The PRT recommends that CMS reconsider the design on this measure to include cases in which the initial colonoscopy was performed at the same facility in which the unplanned hospital visit occurred within seven days of the outpatient colonoscopy.**

Proposed Hospital OQR Program Quality Measures for Removal for CY 2017 Payment Determination and Subsequent Years

OP-15: Use of Brain CT in the Emergency Department for Atraumatic Headache

The PRT supports the removal of OP-15: Use of Brain CT in the Emergency Department for Atraumatic Headache.

> **The PRT agrees that this measure is not in accordance with current clinical practice and it does not accurately represent appropriateness of care.**

Proposed New Hospital OQR Program Quality Measures for CY 2018 and CY 2019 Payment Determination and Subsequent Years

OP-33: External Beam Radiotherapy (EBRT) for Bone Metastasis (NQF #1822)

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 will serve the broad purpose of analyzing the quality of care provided to oncology patients in the outpatient setting.

We remind CMS that there is an abundance of readily available data 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 patient population that is easily defined. This proposed measure includes vague terminology and exclusions that will be difficult for facilities to identify. We believe that the subjectivity of the measure descriptors will create challenges to the integrity of the data CMS will receive, if this measure is implemented.

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."

In addition, dosages of external beam radiation therapy (EBRT) are not always readily available in the hospital medical record documentation. EBRT provision is likely to occur in a setting other than the hospital outpatient department, and specific documentation of dosage would be included in the record where service was provided.

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 very 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 be sensitive to the administrative burden that "web-based" (formerly "chart-abstracted") quality measures impose on providers.

In addition, CMS should consider limiting some of this data collection to radiation oncology sites.

OP-34: Emergency Department Transfer Communication

The PRT concurs with CMS that continuity of patient care is greatly enhanced by the availability and communication of vital patient information.

This proposed measure consists of 7 subcomponents comprised of **27** data elements. Once again, the PRT asks CMS to consider the administrative burden of keeping records about which exact data elements are provided to receiving hospitals during a patient transfer. While the goal of most health care providers is to have data electronically created in an EMR, the reality is that many of us still function in a hybrid medical record environment.

Although documentation of the required data elements likely exists somewhere in the hybrid record, it is unclear how a facility will be able to easily validate that it complied with submission of *each* of the 27 individual elements on each individual transfer. The measure requirement is also unclear about whether or not this is an "all or none" measure.

Also concerning to the PRT is the method of determining the facility "score." The complex proposed methodology will require a burdensome manual process of calculation. CMS is very likely to receive inconsistent and inaccurate data as a result of this complicated self- calculation.

The PRT suggest that CMS review the design of this proposed measure. Questions remain about how the score is calculated when the data required are not all available in the medical record (i.e., when a patient is transferred quickly to receive a higher level of care).

If CMS' goal is to promote better transition of care, it is not clear that the measure is needed in the OPPS. The PRT reminds CMS that the Meaningful Use Stage 2 requirements very closely resemble this proposed measure.

We request that CMS review these requirements and strive to prevent duplication of effort from on the part of providers. We believe that the Meaningful Use requirements may more effectively capture these data.

Electronic Submission of Data

The PRT agrees that the evolution and infrastructure of EHR will increase 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 collected from electronic health records, 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 burdens. 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 of a direct portal for CMS to have open access to all data within a patient's electronic health record. We encourage the development of functionality for 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 and there is little confidence that health care providers are prepared to do so with great accuracy. Within the next four to five years, the prevalence of EMRs will be greatly expanded and the integrity of data will be such that electronic submission of quality measures data will be beneficial.

Conclusion

In conclusion, although the PRT supports the efforts to promote quality of care provided in hospital outpatient departments, we ask CMS to consider the volume of measures and what a recent Institute of Medicine Report aptly described as "measure madness."

We respectfully ask CMS to more broadly identify the goal of quality measures and work with providers to achieve that goal through establishing a limited number of measures that provide consistent and meaningful data.

Intensive-Device-Dependent Edits

Use of Device Code

The PRT recognizes that, for CY 2016, CMS is proposing that only procedures requiring the implantation of a device assigned to a device-intensive APC will require a device code on the UB04 claim.

We are concerned that only editing for one "device code" on a device-intensive APC grouping will limit the claims data available to CMS for analysis. We note that many implanted devices have multiple components to them. An example that illustrates this concept is an Implantable Cardiac Defibrillator (ICD), which consists of a pulse generator, two leads, and a possible third lead (biventricular pacing electrode) for coronary sinus (CS) pacing. This third lead is a very expensive item. If CMS does *not* require all components on a claim, it will skew the cost data for future claims analysis and rate-setting.

CMS maintains that the claims processing edits are such that any device code would satisfy the edit when it is reported on a claim with a procedure assigned to an APC listed in Table 38 of the CY 2016 OPPS Proposed Rule. The information in Publication 4, chapter 4, section 10.3 references that CMS uses only claims with "correct" device codes to set the median cost for device-dependent APCs. Since the dual device edits from CY 2014 have been discontinued, the PRT seeks clarification from CMS about how the agency can be certain that the "correct" device code(s) are still being reported.

The PRT believes that the removal of these multiple procedure to device code edits has the potential to cause device-to-procedure code mismatches in the 2015 claims data, which, ultimately, could result in incorrect APC reimbursement rates. These edits have enabled

providers to ensure that costs were reported accurately and billed correctly, especially in an environment of increased bundling. The Proposed Rule does not include any information describing why CMS removed the dual device edits in CY 2014.

The PRT is concerned that CMS does not maintain a specific list of devices that fall into the category of "device-intensive APCs." The assignment of a device to a procedure code that would be subject to the 40 percent threshold may vary among hospitals due to the items' purchase costs. The devices subject to the 40 percent threshold may be considered to be objective.

> **The PRT requests that CMS revert to the specific device edits that were in place in CY 2014 that pertain to the specific CPT codes that are included in the APCs from Table 38, to ensure accuracy of data that are reported by hospitals and captured by CMS.**

Reduction in Payment Due to Cancelled Procedures

For procedures involving implantable devices assigned to a "device-intensive APC" (defined as APCs with a device offset greater than 40 percent), CMS proposes to reduce the APC payment amount for discontinued device-intensive procedures (where anesthesia has not been administered or the procedure does not require anesthesia) by 100 percent of the device offset amount prior to applying the additional payment adjustments that apply when the procedure is discontinued.

The PRT understands the appropriate use of modifiers -52 and -73 and our members only apply them when it is medically indicated. We are curious about the inclusion of modifier -52 in this proposal, since the procedures indicated in Table 38 typically require some form of anesthesia along with an implantable device. We seek clarification from CMS about whether the claims data show modifier -52 with device-intensive procedures, since these instances could be improperly coded claims.

We note that the use of the modifier (-52 or -73) will *not* provide CMS with information about whether or not the device was opened. A more accurate method for indicating that this occurred (i.e., the device being opened) would be for hospitals to apply a token charge for the device in these instances. This would provide a better mechanism for gathering the information needed for CMS to decide whether these modifiers should reduce the overall APC payment by the full offset amount and the 50% reduction in payment.

We appreciate that CMS did not include modifier -74 in this proposal. It is likely that, in all instances where modifier -74 was applied, the hospital opened the sterile device, rendering it useless for another patient, and incurring the full cost of the device.

> **The PRT requests that CMS analyze the use of revenue code 278 for these specific procedures and report the number of occurrences seen in the claims data, where procedures were cancelled and the devices were reported with the associated charges.**
>
> **We also request that CMS provide information about how often this happens in the Final Rule.**

We note that, if the number is small, then the issue is not material, since the prospective payment systems — like the OPPS — operate on an averaging system. Instances where the device was already opened when the procedure is cancelled are likely to be balanced out by potentially higher costs resulting from such cancelled procedures. CMS should conduct an analysis to determine whether the 50% payment reduction it already applies to the APC procedure payment when modifiers -52 and -73 are reported is appropriate, or whether it is too high, given the extra costs providers face when a procedure is discontinued. Only by providing this information will CMS and other stakeholders be able to accurately assess these costs.

Hospital Cost Reporting: Refining Cost Centers and Revenue Code to Cost Center Crosswalk

The PRT wishes to comment on the OPPS revenue code to cost center crosswalk, and how it relates to CMS' request for comments concerning cost report changes and issues in the 2016 IPPS Proposed Rule.

PRT members are very aware of the importance of correct cost reporting and correct claims reporting, due to these activities' impact on the IPPS and OPPS rate-setting processes. We do not believe, however, that all hospitals share our in-depth level of understanding of the importance of cost and claims reporting. The PRT has previously commented to CMS that the agency's provision of more explicit examples of the ways that cost reports and claims data are matched, trimmed, summed, and averaged would help a larger number of hospitals appreciate the importance of accuracy in these activities.

The PRT is aware that CMS wants all hospitals to report correctly and consistently in order to prevent IPPS and OPPS weight miscalculations. This is challenging, however, since most hospitals cannot determine a return on investment for investing the additional resources needed to change their general ledger and accounting practices in order to ensure such accurate cost reporting.

The PRT has supported CMS' previous proposals to create the subscripted cost center for implantable devices and the new standard cost centers for MRI, CT, and cardiac catheterization services. The PRT agreed with RTI's conclusions regarding charge compression and had hoped that these cost report changes would help mitigate charge compression for these services in the rate-setting process.

In 2013, CMS noted that accuracy issues were occurring due to hospitals using the MRI cost center as a result of cost allocation methodologies. Because this practice has a significant impact for OPPS rate-setting (particularly for MRI APCs), CMS granted hospitals additional time to change their allocation methods. The PRT appreciated this flexibility. We recommend that, if CMS made additional proposed changes, the agency should include *detailed* instructions regarding options for direct cost assignment, overhead allocation, and matching revenue codes. Such instruction would foster provider accuracy in the use of the new cost report centers and increase their understanding how these data will be used in rate-setting. It would also emphasize the importance of hospitals expending resources to make the necessary general ledger and accounting changes.

We have also previously commented to CMS that we believe that Medicare Administrative Contractors' (MACs) audit staff should be *required* to engage in additional audit review steps to

ensure the accuracy of cost and revenue code reporting and appropriate cost and revenue reclassifications.

> **The PRT reiterates now that, with *any* cost report change, CMS should instruct the MACs' audit staff how to verify that hospitals are adhering to CMS guidance. The PRT remains concerned that, without a mechanism to hold hospitals more accountable for accurate cost reporting, CMS will receive mixed results from providers if the agency implements any cost report changes.**

CMS clearly describes the issues surrounding use of the updated cost reporting forms (i.e., a three-year lag before data are available) and the related challenges presented by the MedPar file extracts lacking the charge data exclusively for revenue code 0278 and the implantable device subscripted cost center. This discussion highlights what the PRT believes should be an important tenant of CMS' future cost reporting changes: the need to first examine the cost report detail, accuracy issues, and associated claims and charge issues for a representative hospital sample *before* proposing any changes. CMS should highlight discrepancy issues and provide examples of how the data will be used.

For example, it would be a significant benefit for hospitals if CMS provided examples of instances in which hospitals correctly assigned implantable device expense into a specific GL account, when the expense is associated with device charges reported with revenue code 0278. CMS should also provide clear examples of how hospitals should reflect this situation in the subscripted cost center, how the cost-to-charge ratio (CCR) is calculated, and how CMS applies the CCR to charges reported under revenue code 0278 on Inpatient claims (for MS-DRG rate-setting) and on Outpatient claims (for APC rate-setting).

While CMS provides detailed explanations to describe *some* of its rate-setting processes in preamble discussions, it would be significantly more helpful to providers if the agency showed actual calculations with even *one* representative claim. Such an example would illustrate the methodologies used, and improve understanding of how provider claims are treated and the need for accurate and complete cost reporting. It could also help hospitals understand issues related to mark-ups, charge compression, etc.

CMS devotes significant discussion in the 2016 IPPS Proposed Rule to the inconsistencies the agency noted in hospitals' use of subscripted non-standard cost centers. The agency describes how the cost report labels for the subscripted cost centers did not relate to the standard cost center to which it is subscripted and "rolls up." The PRT agrees with CMS that these issues can impact CMS' calculations for the 19 IPPS cost centers as well as the revenue code to cost center crosswalk for OPPS cost centers.

The PRT notes that MAC audit staff examine each cost report using CMS desk audit procedures, and then further scrutinize each cost report during the MAC audit. Yet, MAC auditors rarely, if ever, review the general ledger to cost report mappings. MACs, much like hospitals, focus their audits on cost-based/pass-through areas that impact final settlement.

As CMS knows from its quality reporting initiatives, what is incentivized improves. While the PRT is not suggesting a monetary incentive for improved cost reporting, we do believe that *MAC audit staff* should be incentivized to improve the scope of their audits and cost report accuracy

from their hospitals. One type of incentive would be to create a published ranking or scoring system of MACs with the highest number of hospitals that have accurate mapping.

> **The PRT recommends that the cost reporting software be updated/refined to add the standard cost center description to each subscripted line. Doing so will help hospitals "see" that the expense must relate to the standard cost center to which it rolls. If a hospital wishes to create a subscripted cost center under Cardiology, for example, then the subscribed cost center needs to read Cardiology-Cardiopulmonary and Cardiology-Cardiac Rehabilitation.**

Another suggestion is to specify the revenue codes that are matched to each standard cost center. Hospitals could then be required to check that at least one of the matched revenue codes is used in the Charge Master for the hospital departments assigned to the standard and subscripted cost centers. This resembles CMS' proposal to "lock in" assignments, but retains flexibility. The PRT cautions CMS that any "lock in" proposal must, before it is finalized, be preceded with significant communication and education to hospitals, and additional audit instructions for MACs.

Furthermore, the PRT does not believe any "lock-in" provision should apply to hospitals that are excluded from IPPS and have some level of cost-based reimbursement (such as CAHs). We also urge CMS to retain flexibility in the reporting that should be verified by the MAC auditors in order to give hospitals legitimate options to minimize administrative burden with regard to general ledger and cost reporting changes.

In addition, the PRT notes that our review of the OPPS revenue code to cost center crosswalk for revenue code 0819 shows that cost center 8600 for "other organ acquisition" is the primary and sole cost center mapped to this revenue code. But, in the 2016 IPPS Final Rule, CMS clarifies its instruction that providers should report their HCT donor-related costs using cost report lines 62 or 63 (since CMS maps revenue code 0819 to the blood and blood products cost center group of 6200 and 6300). Based on this instruction, it appears CMS uses a different methodology for estimating the HCT costs that are included in MS-DRG 014 vs. those that are included in outpatient transplant APC 0112.

We do not believe that CMS intentionally created such a methodological difference; we encourage the agency to streamline its revenue code to cost center crosswalk between the OPPS and IPPS for this revenue code, and for any others where a similar mismatch appears. Furthermore, the PRT believes the best method to correct this issue is to create a standard cost center for donor costs and to match SCT donor revenue billed with revenue code 0819. CMS should also apply the same blood CCR methodology under OPPS that it applies under IPPS.

Another cost center the PRT believes should be defined as a standard cost center is PET. Currently, PET is either a subscripted cost center or is reported under the diagnostic therapeutic cost center of 3450.

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status That Are Not Packaged

CMS proposes to maintain the payment for separately payable drugs and biologicals without pass-through status at the average sales price (ASP) plus 6 percent. The PRT appreciates CMS

maintaining the current payment level, but we continue to believe that this payment level is not sufficient to cover both our acquisition and pharmacy overhead costs.

Drug Packaging Threshold

For CY 2016, the PRT understands that CMS proposes to increase the drug-packaging threshold to $100. We continue to disagree with CMS' use of a drug-packaging threshold in the hospital setting since a similar threshold is not used in the physician's office setting. We understand the need for packaging, as well as the "efficiency incentives" that CMS hopes to create through larger and larger bundles of payment.

> **We note that if CMS is interested in creating payment parity across sites of service, then the agency should eliminate the drug-packaging threshold.**

Biosimilars

The PRT appreciates the CMS' proposal to reimburse for biosimilar drugs in the same fashion and method as other drugs.

Diagnostic Radiopharmaceuticals

The PRT once again reiterates that it does *not* support CMS' packaging decision for diagnostic radiopharmaceuticals, since we believe that radiopharmaceuticals fall into the category of drugs rather than supplies.

Under CMS' current drug payment policy, radiopharmaceuticals should be reimbursed separately if they are above the packaging threshold. We do not understand why CMS continues to view diagnostic radiopharmaceuticals as "supplies" rather than "drugs." Unlike radiopharmaceuticals, supplies are ordered in bulk and stored on a shelf waiting to be used. Unlike radiopharmaceuticals, supplies are often interchangeable.

It is the PRT's continued belief that diagnostic radiopharmaceuticals should be treated as drugs rather than as supplies and should not be packaged. As such, separate reimbursement should be provided for *all* diagnostic radiopharmaceuticals.

> **If the drug-packaging threshold remains in place, the PRT once again urges CMS to provide separate reimbursement for all diagnostic radiopharmaceuticals that exceed the 2016 proposed drug-packaging threshold, if it is finalized at $100.**

<u>Advance Care Planning Services</u>

The PRT commends CMS for recognizing the importance of Advance Care Planning (ACP) services. We support CMS providing reimbursement for ACP services effective January 1, 2016 for CPT codes 99497 and 99498 under the Medicare Physician Fee Schedule (MPFS), and updating the current status indicator "I" (invalid) to status indicator "A" (active).

ACP services are a collaborative effort between the Medicare beneficiary, their families, and care team providers. These services are essential to discussing care options with the physician and medical team before the patient becomes too ill to make decisions, for the completion of an advance directive, and to understand what to expect as the disease process progresses.

The quality of patient care will increase when patients and their care providers work through advance care planning issues to ensure that patients receive the care they want, and have time to prepare themselves and their loved ones for the progression of their disease. In addition, these services have the potential to decrease unnecessary resource use, as the patient's wishes about interventions will be identified, clarified, and carried out as directed.

Many different types of staff effectively provide ACP services to beneficiaries today, including physicians and non-physician practitioners such as NPs and PAs as well as other qualified health care professionals such as RNs, CNSs, and CSWs.

We note that ACP services are often provided through a team-based approach in the facility setting; the physician may start the conversation with the patient and family about end-of-life issues, but other qualified staff are usually involved. Starting this process early in the patient's treatment is important so the patient and their family have time to absorb and process the information.

ACP services provided under the direction and supervision of treating practitioners are within the scope of practice of RNs, CSWs, etc. For example, oncology nurses and CSWs often have palliative care certifications and other training that make them well-qualified to hold these discussions with patients. It is not unusual for an RN or CSW to have separate visits with patients and/or their family members to continue these conversations. In fact, patients are often more comfortable discussing ACP with their RN and/or CSW, who they see on an ongoing and frequent basis.

During the HOP Panel meeting on August 24, 2016, there was some discussion about who can provide ACP services in the hospital setting. The PRT members were confused why these questions arose, since the provision of these services does not differ from most other services. Following the HOP Panel meeting, PRT members conducted research on this in order to provide CMS with information about the evolution of the application of HCPCS/CPT codes for outpatient hospital services since the beginning of OPPS.

The paper-based manual reference at CMS Program Manuals - Hospital (PUB. 10) Chapter IV - Billing Procedures 442. HCFA Common Procedure Coding System (HCPCS) states: "CPT-4 codes are used by physicians to report physician services, and do not necessarily reflect the technical component of a service furnished by the hospital. Therefore, *ignore any wording in the CPT-4 codes that indicates that the service must be performed by a physician*. In cases where there are separate codes for the technical component, professional component, and/or complete procedure, use the code that represents the technical component. If there is no technical component code for the service, use the code that represents the complete procedure." [Emphasis added.]

Similarly, current language in the CMS' *IOM Manual 100-04* (Chapter 4, Section 20.2) clarifies and reflects the same intent as the original paper-based manual language:

> *The CPT codes generally are created to describe and report physician services, but are also used by other providers/suppliers to describe and report services that they provide. Therefore, the CPT code descriptors do not necessarily reflect the facility component of a service furnished by the hospital. Some CPT code descriptors include reference to a physician performing a service. For OPPS purposes, unless indicated otherwise, the usage of the term "physician" does not restrict the reporting of the code or application of related policies to physicians only, but applies to all practitioners, hospitals, providers, or suppliers eligible to bill the relevant CPT codes pursuant to applicable portions of the Social Security Act (SSA) of 1965, the Code of Federal Regulations (CFR), and Medicare rules. In cases where there are separate codes for the technical component, professional component, and/or complete procedure, hospitals should report the code that represents the technical component for their facility services. If there is no separate technical component code for the service, hospitals should report the code that represents the complete procedure. Tables describing the treatment of HCPCS codes for OPPS are published in the Federal Register annually.*

We believe the above language clearly instructs hospital staff to report the CPT codes that reflect the services and facility resources provided, including ACP services.

> **The PRT requests CMS recognize ACP services in the same manner that the agency recognizes all HCPCS/CPT reporting of services when performed by qualified health professionals and other practitioners acting under their scope of practice and hospital bylaws**.

We believe the information above guides the reporting of services in the facility setting. For example, this is the information we use when reporting services such as hydration (96360-96361) and therapeutic, prophylactic and diagnostic injections and infusions (96365-96379). The role of the physician or other qualified health care professionals related to hydration injection and infusion services predominately involves affirmation of the treatment plan, specific orders, and direct supervision of facility staff who provide these services.

We believe ACP services (99497-99498) can be provided in a similar manner.

> **Given that CMS is going to provide reimbursement for the exact same services as defined by CPT codes 99497 and 99498 under the MPFS, the PRT requests CMS also recognize and reimburse the services under OPPS beginning January 01, 2016 and assign these CPT codes to APC 5012 and 5011 respectively.**

Doing so will ensure consistency of covered services available and provided to all beneficiaries across sites of care. Providing payment for ACP under OPPS via specific CPT codes will enable CMS to collect data on these critically important services regardless of the site of service in which they are performed. CMS needs to be able to conduct costing and quality analysis on these services and assess whether and how ACP services impact the cost of care provided to beneficiaries.

Attachment A: 2015 Provider Roundtable Members

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