Provider Roundtable

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

Carolinas HealthCare System (NC, SC)

Community Hospital Anderson (IN)

Erlanger Medical Center (TN)

Fletcher Allen Health Care (VT)

Forrest General Hospital (MS)

Franciscan Missionaries of Our Lady Health System (LA)

Harris Health System (TX)

Hartford Hospital (CT)

Health First Inc. (FL)

Kaiser Permanente (CA)

Mercy Health System (AR, KS, LA, MS, MO, OK, TX)

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

Raritan Bay Medical Center (NJ)

Robert Wood Johnson University Hospital (NJ)

University Health System (TX)

University of Pittsburgh Medical Center (PA)

Virtua (NJ)

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

September 5, 2013

Re: 42 CFR Parts 405, 410, 412, et al. Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals; Proposed Rule

Dear Ms. Tavenner,

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the 2014 Outpatient Prospective Payment System (OPPS) Proposed Rule.

The Provider Roundtable (PRT) includes representatives from 18 different health systems from around the country. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services under 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 and recalibration 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,

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Corporate Director, Health Information Management
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Introduction

The PRT would like to acknowledge the latest release to 42 CFR Parts 405, 410, 412, et al. [CMS-1601-CN], RIN 0938-AR54 dated Thursday, September 5, 2013. The PRT is aware that this additional notice to the proposed OPPS rule that allows for an additional 10 days for comment, which we believe is insufficient. The PRT does not believe the additional information will change our overall perspective and, therefore, we are submitting our comments per the original comment deadline date of Friday, September 6.

Proposed OPPS Payment for Hospital Outpatient Visits (E/M)

The PRT understands that CMS proposes to create three alphanumeric Level II HCPCS codes to replace the existing five codes currently assigned to new patient clinic visits (CPT codes 99201-99205), established patient clinic visits (CPT codes 99211-99215), Type A ED visits (CPT codes 99281-99285) and Type B ED visits (HCPCS codes G0380-G0384). CMS proposes to replace each of these code groups with a Level II HCPCS Codes GXXXC (clinic codes), GXXXA (ED Type A), and GXXXB (ED Type B), respectively. We also understand and appreciate that CMS is now interested in eliminating the distinction between new and established patient clinic visits.

CMS states the following reasons for its rationale for this proposal:

- To move towards using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient manner;
- To remove incentives for hospitals to provide unnecessary services to achieve a higher level of visit payment under OPPS;
- To reduce hospitals' administrative burden;
- To use more claims for the rate-setting process; and
- To eliminate incentives for hospitals to "upcode" visits that do not clearly fall in to one category or another.

Since CY 2000, the agency has instructed hospitals to develop their own internal criteria for levels that accurately reflect the resources expended by the facility. In the *Federal Register*, CMS states:[1]

> *"We emphasize the importance of hospitals assessing from the outset the intensity of their clinic visits and reporting codes properly based on internal assessment of the charges for those codes, rather than failing to distinguish between low-and mid-level visits "because the payment is the same." The billing information that hospitals report during the first years of implementation of the hospital outpatient PPS will be vitally important to our revision of weights and other adjustments that affect payment in future years. We realize that while these HCPCS codes appropriately represent different levels of physician effort, they do not adequately describe non-physician resources. However, in the same way that each HCPCS code represents a different degree of physician effort, the same concept can be applied to each code in terms of*

[1] Federal Register http://www.gpo.gov/fdsys/pkg/FR-2000-04-07/pdf/00-8215.pdf

the differences in resource utilization. Therefore, each facility should develop a system for mapping the provided services or combination of services furnished to the different levels of effort represented by the codes. (The meaning of "new" and "established" pertain to whether or not the patient already has a hospital medical record number.)

We will hold each facility accountable for following its own system for assigning the different levels of HCPCS codes. As long as the services furnished are documented and medically necessary and the facility is following its own system, which reasonably relates the intensity of hospital resources to the different levels of HCPCS codes, we will assume that it is in compliance with these reporting requirements as they relate to the clinic/ emergency department visit code reported on the bill. Therefore, we would not expect to see a high degree of correlation between the code reported by the physician and that reported by the facility."

As CMS is aware, the PRT has consistently asked the agency to create national guidelines and has submitted comments over the years. We have also consistently asked CMS to eliminate the distinction between "new" and "established" patients due to the difficulty providers experience when attempting to apply these criteria. Despite the PRT's comments, and requests by other industry stakeholders (such as the AHA) for national guidelines, CMS has not moved forward.

The agency has consistently maintained — including in the 2013 OPPS Final Rule— that there is no need to develop national visit guidelines on the basis of hospital claims data or make changes to visit-level reporting. CMS stated that it, *"continue[s] to believe that, generally hospitals are billing in an appropriate and consistent manner that distinguishes among different levels of visits based on their required hospital resources."* This statement indicates that CMS has monitored facility reporting of CPT codes and believes that hospitals are billing codes in accordance with internal criteria and resources.

We do not understand the impetus behind CMS' proposal for CY 2014 given its own statement that hospitals are generally following coding regulations in this area. The effort also conflicts with CMS' statement in the CY 2014 OPPS proposed rule that its proposal would: *"eliminate any incentive for hospitals to upcode patients whose visits do not clearly fall into one category or another or provide medically unnecessary services to achieve a higher level of visit payment."* If CMS has specific concerns about particular facilities' upcoding, it has other avenues with which to address them, such as provider-specific audits.

The PRT appreciates CMS' concern regarding facilities' administrative burden to develop and maintain facility-specific E/M guidelines, but this concern is unwarranted. Providers did face a burden, years ago, when they were first asked to develop guidelines. Since then, providers have risen to the challenge presented by this requirement, and implemented it. Since CY 2000, providers have often incurred large expenses for the purchase of software systems to ensure compliant documentation and billing practices. Providers also conducted large-scale staff education efforts on the proper use and documentation of their facility guidelines, updated the system on an annual basis, and performed internal and/or outsourced audits to

validate compliant coding processes. Additionally, hospitals persuaded their non-Medicare payers to accept the same facility-specific criteria as CMS, and most have agreed to use these in their audits. At the present time, providers have been using their facility-specific guidelines for 13 years and do not find this burdensome.

The PRT supports CMS' proposal to (finally) eliminate the distinction between new and established clinic visits, and we urge CMS to finalize this change for CY 2014. We have significant concerns with CMS' proposal to create three alphanumeric Level II HCPCS codes to describe all levels of each type of clinic and ED visits.

One of the most critical points in CMS' 2000 directive (which has been repeated annually) is that the facilities' internal guidelines *"be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes."* The PRT believes that this statement clearly acknowledges that CMS is fully aware that resources expended by the facility differ significantly between visit levels. Therefore, it is unclear why CMS would now propose something that completely disregards the different types of services rendered to different types of patients.

Another issue we have with CMS' proposal is that most non-Medicare payers will continue to require the use of the current five-level CPT code structure. This will result in one coding system using the single HCPCS G code for Medicare beneficiaries, while non-CMS payers will continue to require providers to use the current CPT codes. This requirement will increase, rather than decrease, provider burden, as CMS suggests.

The PRT's specific recommendations for CMS are as follows:

CMS should <u>not</u> implement the single G code proposal. A single G code for clinic visits, a single G code for Type A ED, and a single G code for Type B ED visits will *never* reflect the acuity and resource differences among patients seen in these varying care settings. If CMS implements this proposal, certain clinic types will be rewarded while others will be penalized on a consistent basis. We urge CMS to recognize the negative financial impact for providers that truly have consistently higher visit levels due to the types of patients that they routinely treat. Implementing this proposal is likely to result in inappropriate payment rates, disruption of beneficiary access to services, and/or more fragmented delivery of care.

CMS should implement its proposal to eliminate the distinction between "new" and "established" patient visits.

Additionally, CMS should work with the American Medical Association (AMA) to develop facility-specific CPT codes for E/M clinic visits (with no distinction between new and established patients), Type A ED visits, and Type B ED visits. This will have several benefits, including to:

- Eliminate the long-standing confusion stemming from hospitals having to report physician-applicable CPT codes / nomenclature with hospital-developed guidelines.

- Simplify and ensure consistent reporting of hospital visits for all providers, while capturing clinical and resource differences.
- Allow CMS to collect accurate and complete outpatient clinic and ED visit data from hospitals, which is critical to create future APC payment rates.

Finally, CMS should seek input from industry stakeholders (specifically, hospital representatives) to develop descriptions for these new codes that allow for their consistent application by hospital outpatient clinics/facilities. We feel strongly that hospital representatives should be involved in this effort. The PRT has spent considerable time working on developing guidelines and is very happy to participate in such an effort. We are willing to serve as an advisory group to vet ideas and generate clear language for the code descriptors.

We recognize it will take some time for these codes to be developed and implemented. In the interim, if CMS feels strongly that it must shift from the existing use of CPT codes, then we would be willing to migrate to five levels of HCPCS G-codes for clinic visits (GVVV1 through GVVV5), five levels of HCPCS Type A ED visits (GAAA1 through GAAA5), and to maintain the existing Type B HCPCS G-codes, which will allow providers to continue using their existing guidelines. The PRT believes providers could accommodate this change if CMS felt it necessary to take this interim step.

Proposed Changes to Packaged Services

New Packaging Policies for CY 2014

The PRT understands that a prospective payment system is based on packaging of services and providing a bundled payment, and that CMS has noted in past rules that this is the direction in which the OPPS will be heading increasingly in the future. We also understand that, for CY 2014, CMS proposes to package the following:

- Clinical Diagnostic Laboratory Tests
- Skin Substitutes
- Ancillary services (Status Indicator "X")
- Diagnostic Tests on the Bypass List
- Supplies
- Procedures Described by Add-on Codes
- Device Removal Procedures
- Stress Agents

The PRT believes that the current packaging proposal will produce a compounded effect on facility payment and may produce unintended consequences with respect to how care may be delivered to patients in the future. Unfortunately, we have not had sufficient time — or adequate information related to the data from CMS — to fully analyze the impact of CMS' proposal. Despite this lack, however, we would like to share some of our initial thoughts on CMS' packaging proposal below.

The PRT agrees with the concept of packaging and supports it, but *only* when there are sufficient historical data that confirm the proposed packaging changes. For example, the PRT might be able to support the proposed packaging of stress agents and DME supply items, since claims data support the services with which these items can be packaged.

In addition, the PRT *conceptually* agrees that some of the items/services proposed for packaging under the OPPS may be reasonable for future consideration — once CMS provides additional information and providers have had adequate time to analyze this proposal's impact. The items that we believe *may* be reasonable for packaging include clinical diagnostic laboratory tests, ancillary services, diagnostic tests on the bypass list, and device-removal procedures.

Historical claims data are, and always have been, the foundation for determining OPPS payment and packaging policies. We feel *strongly* that CMS should not use CY 2012 data as a basis for packaging clinical laboratory tests, as these data are inherently flawed. For CY 2012, the claims data do not include *any* indication about what labs might be related or unrelated to any procedure(s) that are reported on the same claim. CMS notes that billing instructions could be amended to allow for the capture of information about tests that are unrelated, but we note that *must* be on a "go-forward" basis and not based on the current historical claims data.

We agree *conceptually* that clinical lab tests could be packaged but believe that they must be conditionally (rather than unconditionally) packaged, and only *if* there is further analysis of claims data and consideration about specific procedures to which these tests should be packaged. None of this, however, is possible for CY 2014.

CMS proposed several other categories for packaging, which the PRT emphatically disagrees; we strongly recommend that these items should *never* be packaged. We offer additional details to support our views, below.

Drug, Biologicals, and Radiopharmaceuticals that Function as Supplies When Used in Diagnostic Tests or Procedures

Clarification Regarding Supplies that are Packaged in the OPPS

In Transmittal R1702CP, CMS states: *"when medical and surgical supplies (other than prosthetic and orthotic devices as described in the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, §120 and §130, and take-home surgical dressings) described by HCPCS codes with status indicators other than "H" or "N," are provided incident to a physician's service by a hospital outpatient department, the HCPCS codes for these items should not be reported because these items represent supplies."*

Hospitals are aware of this regulation and while, they may assign a charge for the item, they do *not* assign the HCPCS code for the supply when it is used during the course of a procedure or service. By not assigning HCPCS codes, the supply costs are packaged and no separate DMEPOS fee schedule payment is made.

In addition — and quite separate from supplies issued during the course of a hospital outpatient encounter — hospital outpatient departments also issue specific take-home dressings under the prosthetic DMEPOS benefit to allow a continuum of care post-discharge. These items are carved out of the OPPS and included in separate coverage and payment provided by DMEPOS. There has been an exception, which enables hospitals to bill the MAC on the 837i (i.e., UB04 by 13x bill type) and be paid under DMEPOS solely for the take-home surgical dressing benefit.

The PRT would like to point out that several of the items on Addendum P (listed in Attachment B of our comment letter) are classified as either a prosthetic/orthotic (PO) or surgical dressing (SD). When medical and surgical supplies (other than prosthetic and orthotic devices as described in the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, §120 and §130, and take-home surgical dressings) described by HCPCS codes with status indicators other than "H" or "N," are provided incident to a physician's service by a hospital outpatient department, the HCPCS codes for these items should not be reported because these items represent supplies.

Claims containing charges for medical and surgical supplies used in providing hospital outpatient services are submitted to the Medicare contractor providing OPPS payment for the services in which they are used. The hospital should include charges associated with these medical and surgical supplies on claims so their costs are incorporated in rate-setting, and payment for the supplies is packaged into payment for the associated procedures under the OPPS, in accordance with 42 CFR 419.2(b)(4).

The PRT recommends that CMS not package the items we have listed in Attachment B to our comment letter, as they represent a non-OPPS benefit to the patient.

Drug and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure

Skin Substitutes

The PRT understands that CMS' goal in packaging is to promote more efficient resource use by hospital providers, but we disagree that packaging skin substitutes into the related surgical procedure supports this goal. To achieve the best clinical outcome for wound healing and possible limb salvaging, the most appropriate skin substitute must be used for the specific, unique wound. This decision should be based on clinical efficacy, and not on cost.

FDA-approved indications and the mechanism for healing a wound determine the most appropriate skin substitute. While the code definitions for the procedures are based on the size of the wound and wound location, the skin substitute used is *specific* to the individual patient condition. The selection of the skin substitute depends on the size, depth and width of the wound, the location of the wound, the viability of the wound bed and any complications and co-morbidities. Different wounds respond differently to different skin substitutes.

Not using the appropriate skin substitute can hamper the process of wound healing. This can increase the risk of an infection, which could increase the size and depth of the wound, and cause the wound infection to spread to the bones/tendons — which could ultimately lead to a systemic infection and might lead to amputation. All of these outcomes increase future expenditures by expanding the number of hospital visits, readmissions, and more complex surgical procedures.

In addition, the PRT refutes CMS' statement that skin substitutes are similar to surgical dressings in order to support packaging. The major difference between skin substitutes and a surgical dressing is that the former act as autologous skin grafts by adhering to the wound bed, and provide the physiological (i.e., growth factors, cells and extracellular matrix) and mechanical functions of the skin. The cost of most skin substitutes is much higher than surgical dressings and, as CMS itself states, the cost for skin substitutes *"varies considerably."*[2]

The PRT is extremely concerned that the proposed packaged reimbursement for the application procedure and the skin substitute does not cover the cost incurred for purchasing skin substitutes. We reviewed one PRT member's cost with respect to reimbursement data, and observe that the cost of the skin substitutes alone exceed CMS' proposed increase in the bundled payment for the application (CPT codes 15271 through 15278) plus the skin substitute product. The table below clearly illustrates how the increase in payment for CY 2014 does not even come close to covering the cost of the skin substitute in the majority of cases.

CHARGE DESCRIPTION	Skin Sub Cost	CPT Chgd	2014 APC Pmt Increase	Gain/(Loss) per case
APLIGRAF - PER 44SQ CM (Q4101)	$ 1,704.00	15271	$ 623.23	$ (1,080.77)
used in 27% of cases		15273	$ 983.87	$ (720.13)
		15275	$ 623.23	$ (1,080.77)
DERMAGRAFT PER 37.5 SQ CM (Q4106)	$ 1,590.00	15271	$ 623.23	$ (966.77)
used in 26% of cases		15275	$ 623.23	$ (966.77)
THERASKIN PER 39SQ CM (Q4121)	$ 845.00	15271	$ 623.23	$ (221.77)
used in 38% of cases		15273	$ 983.87	$ 138.87
		15275	$ 623.23	$ (221.77)
OASIS WOUND MATRIX 10 SQ CM (Q4102)	$ 92.13	15271	$ 623.23	$ 531.10
used in 9% of cases		15275	$ 623.23	$ 531.10

[2] *Federal Register* Vol. 78, No. 139 July 19, 2013, p. 43573.

As further advances are made in the care of wounds, skin substitutes will continue to evolve. As that occurs, costs are likely to increase with continued need for additional treatments, potential for infection, readmissions, and amputations.

The PRT is very concerned that patient care will be compromised by hospitals feeling pressured to use skin substitutes based primarily on cost rather than clinical effectiveness. We fear that important aspects of the system — such as clinical effectiveness and quality measures — will be compromised if facilities are forced to prioritize the economics of skin substitutes used for wound care treatment. We also note that CMS already has local coverage decisions that specify the appropriate use of skin substitutes to support medical necessity and prevent the overuse of these costly products.

The PRT agrees with CMS' statement concerning the continued use of pass-through status for the available new skin substitutes that meet the pass-through criteria. In addition, the PRT recommends that skin substitutes not be packaged due to the great variability in the cost.

Based on this adverse possibility, the PRT strongly disagrees with CMS' proposal to include skin substitutes in the packaging methodology.

Procedures Described by Add-on Codes

For CY 2014, CMS proposes to unconditionally package all procedures described by add-on codes in an effort to provide more accurate OPPS payment for these procedures. As previously noted, the PRT supports CMS' overall goal of establishing further prospective payments through bundled services; however, we are *extremely* concerned that the data used to calculate the proposed payments for add-on codes is insufficient. CMS itself acknowledges that calculating geometric mean costs for add-on codes is problematic.

CMS also indicates that the procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary surgical procedure. At the same time, CMS continues to indicate that add-on codes were developed to capture additional costs associated with increased complexity and resource intensity. The PRT is concerned that packaging these codes negates the primary intent for creating add-on codes.

If the frequency of add-on codes for each primary procedure were consistent, then packaging these codes would be more feasible. In many cases, however, add-on codes take more time and are more costly than the primary code. One example of this scenario concerns CPT codes 97597 and 97598. The primary code (97597) is defined as selective debridement "first 20 sq cm," and the add-on code (97598) is defined as "ea additional 20 sq cm." If the debridement involves a total of 100 square centimeters or more, the add-on code is *significantly* more costly due to the number of units reported to reflect the service. Another example is the chemotherapy infusion codes. The primary code (CPT 96413) is defined as "first hour of infusion" and the add-on code (CPT 96415) is defined as "ea additional hour." The add-on chemotherapy infusion code could easily reflect six or more hours.

Therefore, based on the above factors, the inability to evaluate the data related to the impact of the proposed packaging of add-on codes, and our concerns that the payment rate will not accurately capture the true cost, the PRT emphatically disagrees with CMS' proposal to package add-on codes.

Comment Solicitation on Increased Packaging for Imaging Services

The PRT is pleased to offer comment, per CMS' request, regarding the contemplated proposal for CY 2015 to conditionally package all imaging services with any associated surgical procedures. We understand that when these imaging services are provided as an independent service, CMS would continue to either pay for them separately according to a standard clinical APC or a composite APC but when provided with a surgical procedure, they would be packaged.

The PRT is very concerned about implementing packaging proposals without adequate data and the opportunity to analyze these data; our concerns apply to both CY 2014 and CY 2015. We recognize that CMS is interested in moving the OPPS toward a more bundled payment system in the future, and as long as this is done in a methodical, well-thought-out and phased-in manner, it could be acceptable. However, the PRT cautions that in light of the data integrity issues and the multiple proposed packaging categories we are unable to model the impact on our individual institutions.

Conclusion

In summary, the PRT recommends CMS *not* finalize the proposal to package services for CY 2014, given the need for more data analysis and study.

The PRT acknowledges that two of the proposed categories (stress agents and supplies other than skin substitutes) could be packaged now, but we are *only* comfortable with this *conceptually,* as we have not been able to conduct any data-driven analyses on this or the agency's other packaging proposals.

Several categories could *potentially* be packaged at a later time; these include clinical lab services, ancillary services, diagnostic tests and device-removal procedures. Yet, the current lack of available data and modeling prevents us from being able to conduct adequate analysis and appropriately evaluate these proposals' impacts.

Two categories (skin substitutes and add-on codes) should *never* be packaged, for the reasons enumerated above.

<u>Proposed Establishment of Comprehensive APCs</u>

For CY 2014, CMS is proposing to make a *single payment* when there is a primary procedure on the claim and to make no separate payment for any other services on the claim. Under this proposal, a new status indicator would be assigned to the 136 HCPCS codes that fall into the

29 APCs listed in the Table 5 in the proposed rule.

The PRT understands that, under CMS' proposal, all services that are provided on the same claim as the procedure designated with a status indicator J1 will be packaged. This includes the following services:

- Diagnostic procedures and tests;
- Laboratory tests;
- Therapy services;
- Treatments and procedures that assist in the delivery of the primary procedure;
- Visits and evaluations performed in association with the procedure;
- Un-coded services and supplies used during the service; and
- DME, prosthetic, and orthotic items when provided as part of the OP service.

CMS' proposal suggests that the methodology it used assumed *all* procedures that were present on CY 2012 claims were packaged. We suspect that all procedures present on the claim were packaged with no regard to whether they were truly "related" to the main procedure (now designated with status indicator J1) or not. The PRT does not understand how the agency can make this assumption in developing accurate payment rates.

CMS' current billing regulations mandate that all services performed on the same date of service be included on a single claim. Hence, CY 2012 outpatient claims would provide *no way* for the agency to differentiate services that were "related" to the primary procedure vs. those ordered by other physicians that may be unrelated to the primary procedure. This would include reference labs (14X bill type) and specimens drawn at the hospital (13X bill type). Therefore, for CY 2012, CMS likely received claims in which the primary service and unrelated lab services ordered by other practitioners were both present.

For this reason, the PRT believes CMS took all of the billed procedures present and packaged them to the primary procedure now designated by status indicator J1 *regardless of whether or not they were related*. If that is the case, then CMS' current calculations are based on the assumption that we believe are inappropriate, since the agency had no way of knowing or assessing what proportion of services on a claim were related vs. unrelated. Thus, CMS really cannot apply its proposed logic for creating the comprehensive APCs. It must be able to determine what services on a claim are related and what are unrelated to the J1 designated primary procedure codes before creating the comprehensive APCs.

If, however, CMS were to issue billing instructions for CY 2014 that allow providers to designate the unrelated services, then the agency would be able to resurrect this proposal for CY 2016, using CY 2014 claims data. On the face of it, this proposal has some merit, but until CMS can accurately assess what services on a claim are related in support of the primary procedure for packaging purposes, and which ones are not, the PRT can neither make any meaningful comments about this proposal's value, nor support it.

For these reasons, the PRT respectfully recommends that CMS *not* implement the proposed 29 APCs for CY 2104. We encourage the agency to focus instead on providing

instructions that allow providers to report related and unrelated services on the same claim in order to provide the agency with accurate data, and then bring this proposal back for comment in the future.

Room and Board

One final item we'd like to address with respect to CMS' discussion about this proposal has to do with CMS' discussion about room and board related revenue codes in the CY 2014 OPPS proposed rule. CMS states:

> *As an example, room and board revenue center charges are not included in OPPS rate-setting calculations because room and board is typically not separately charged for outpatient services. In the case of these 29 device-dependent procedures, the patient typically stays overnight to recover from the procedure. Thus, for these 29 comprehensive services, the cost of the room, nutrition (board) and nursing care that is required to sustain the patient while the comprehensive device-dependent service is delivered will be associated with the service even if the hospital reports the costs in room and board revenue codes that are not usually used to report outpatient procedure costs…*
>
> *We believe that the cost of the bed and room occupied by the patient, the cost of nursing services, and the cost of any necessary fluid and nutrition (board) are considered covered costs when incurred during the provision of an OPD service, that is, during the provision of the comprehensive service. Because we are able to assign all costs on the claim to the comprehensive service, we believe we have an opportunity to better capture costs by including these costs in our calculations even when they appear in certain revenue centers not usually used to report OPPS costs. Specifically, we are including costs reported with room, board, and nursing revenue codes 012X, 013x, 015X, 0160, 0169, 0200 through 0204, 0206 through 0209, 0210 through 0212, 0214, 0219, 0230 through 0234, 0239, 0240 through 0243, and 0249, as we believe these revenue centers are sometimes associated with the costs of room, nutrition, and nursing care provided during these comprehensive services.*

The PRT seeks clarification about what CMS means by "Room and Board" (R&B). We note that, currently, hospitals are not allowed to report revenue codes such as 014X on an outpatient claim because these are inpatient revenue codes. The proposed rule, as noted above includes revenue codes 012x, 013x etc., but fails to recognize other revenue codes deemed inpatient such as 014x, which we believe should also be included in CMS' list. Hospitals were not allowed to report these revenue codes on CY 2012 claims, the year of claims data that CMS is using to set CY 2014 payment rates. If providers did not report these revenue codes on their claims (because they are not allowed to), then we cannot understand the basis for CMS' assumption that R&B costs are built into the costs that are included in the newly proposed status indicator J1 procedure codes.

In other words, it is impossible for CMS to have included R&B charges reported in revenue

code 14X or others as noted above, in the Comprehensive APCs rate-setting, since these revenue codes are not present on the CY 2012 outpatient claims. Therefore, we are perplexed by the agency's proposal and seek clarification about whether the entire discussion in the proposed rule is focused on the future and how rate-setting will be done at a later time, or if it also relates to how CMS has conducted the rate-setting for CY 2014. These are two different things and must not be confused.

The PRT supports proposals that enable providers to report R&B costs in the future under the OPPS.

To that end, we encourage CMS to issue instructions that allow providers to report R&B revenue codes such as 14x in their outpatient claims. This change would facilitate more accurate reporting and billing, and result in better underlying data for CMS to use in future rate-setting. If CMS creates this mechanism by changing the agency's billing regulations, we would be pleased to report these costs. Under this process, CMS would collect facilities' data for two years and then model the data in order to set the rates. If it adopts this process, however, we encourage the agency not to cherry-pick the revenue codes for use, and to include, in the future, revenue code 110 or 11x in the proposal.

Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

The PRT supports the proposal to allow *any* visit that is furnished by a hospital in conjunction with observation hours of substantial duration (e.g., greater than 8 hours) to qualify for payment through the Extended Assessment and Management (EAM) Composite APCs. The PRT believes that this concept can be implemented within the structure of current composite APCs 8002 and 8003, as illustrated in the table below.

This proposal more accurately captures hospital resource use for patients who are placed in observation, which is independent of the level visit that precipitates the patient's placement in this setting. In other words, patients with lower-level clinic visits and Emergency Department (ED) visits who are subsequently placed in observation still utilize substantial hospital resources. These resources include nursing care, ancillary services, assessments, medications, care coordination, education, and discharge planning.

Current Structure			
APC 8002 - Level I Extended Assessment and Management			
	99205/99215	Level 5 Clinic Visit	
	G0379	Direct Referral	
APC 8003 - Level II Extended Assessment and Management			
	99284	Level 4 Type A ED Visit	
	99285/G0384	Level 5 Type A/Type B ED Visit	
	99291	Critical Care	

Proposed Structure			
APC 8002 - Level I Extended Assessment and Management			
	GVVV1	Level 1 Clinic Visit	*(Currently 99201/99211)*
	GVVV2	Level 2 Clinic Visit	*(Currently 99202/99212)*
	GVVV3	Level 3 Clinic Visit	*(Currently 99203/99213)*
	GVVV4	Level 4 Clinic Visit	*(Currently 99204/99214)*
	GVVV5	Level 5 Clinic Visit	*(Currently 99205/99215)*
	G0379	Direct Referral	
	GAAA1/G0380	Level 1 Type A/Type B ED Visit	*(Currently 99281/G0380)*
	GAAA2/G0381	Level 2 Type A/Type B ED Visit	*(Currently 99282/G0381)*
APC 8003 - Level II Extended Assessment and Management			
	GAAA3/G0382	Level 3 Type A/Type B ED Visit	*(Currently 99283/G0382)*
	GAAA4/G0383	Level 4 Type A/Type B ED Visit	*(Currently 99284/G0383)*
	GAAA5/G0384	Level 5 Type A/Type B ED Visit	*(Currently 99285/G0384)*
	99291	Critical Care	

The PRT recommends that an EAM composite be paid whether or not the claim contains a procedure with a T Status Indicator (SI). Observation payment should not be negated merely due to the presence of an SI-T procedure. It should be noted that the reimbursement for SI-T procedures varies widely, from a low of $10.41 to a high of $14,871.18 (see 2014 NPRM addendum B). Reimbursing for the procedure alone can lead to disparate reimbursement levels that may not compensate for the resources used.

It would be erroneous for CMS to assume that all observation services that are billed on the same claim with a SI-T procedure are an inherent or related part of the procedure. Many patients placed in observation arrive in the hospital via the ED with an undiagnosed complaint. SI-T procedures may be performed to assist in diagnosis or as part of the patient's treatment. These procedures are separate and distinct from the observation care that is being provided. In fact, the time required to monitor the patient related to a procedure must currently be carved out of the observation time for billing.

Given these factors, the PRT believes it is inappropriate for CMS to deny payment for the observation composite if it is billed with an SI-T procedure. The PRT urges CMS to delete the EAM composite requirement for payment that *"No procedure with a T status indicator can be reported on the same day or day before observation care is provided."*

As in previous comments submitted by the PRT, we continue to assert that patients in "observation" receive what is essentially the same care as patients who are formally admitted as hospital inpatients. The physician's orders for clinical services are determined based on the patient's clinical needs — not on the patient's status.

Although the 2014 Inpatient Prospective Payment final rule attempts to better define "observation status," the PRT encourages CMS to continue to explore more objective criteria to distinguish inpatient from observation (i.e., patient's severity of illness and the intensity of services provided). We continue to question the validity of determining patient status based upon the number of nights spent in a hospital, and protest the increased risk of denial of inpatient stays given the lack of objective criteria.

Hospital Outpatient Quality Reporting Program Updates

The PRT appreciates that CMS' goal is to align hospital Outpatient Quality Measures (OQM) program with the IQR and ASCQR programs as well as with the HHS and CMS Strategic Plans. Such consistency will reduce the operational burden needed to comply with multiple sets of quality measures. We also appreciate CMS's recognition of the need for *"measure sets to evolve so that they include a focused set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider category."*

We have a broad concern that applies to many of these measures, however. We note that follow-up for several of these procedures can, and usually does, occur *outside* the hospital outpatient department. Many patients are seen for follow-up in their physician's office. For this reason, hospitals have no way of assessing the patient's outcomes as indicated by these quality measures. So, the PRT believes that it would be unfair to penalize *hospitals* for negative outcomes and other inadequate results using these measures, when we are not consistently responsible for follow-up.

Our comments on the specific components of the HQRP updates follow.

Removal or Suspension of Quality Measures From the Hospital OQR Program

The PRT appreciates and supports CMS's proposal to remove both OP-19 and OP-24.

Influenza Vaccination Coverage Among Healthcare Personnel

While the PRT understands that influenza has devastating costs to the Medicare population — in both personal terms and health care costs — we remain concerned about this measure for several reasons.

First, CMS notes that the Centers for Disease Control and Prevention (CDC) already collect these data. It is an unnecessary duplication of effort for CMS to include this measure, given that another government entity already collects these data. We find it interesting that CMS seeks to add this measure at the same time that it is proposing to remove OP-19 in order to *"reduce duplicative requirements among programs."* If this measure is finalized, as with OP-19, providers would be required to submit these data to both the Hospital QQR Program and the CDC.

Second, we are concerned by the apparently now annual shortage of influenza vaccines, which continues to be an issue for providers. If CMS insists on linking provider payments to the achievement of this quality measure, it *must* create a provision for the inevitable situations when hospitals are unable to obtain the vaccine. Third, we are concerned with CMS' definition of health care personnel (HCP) to include employees who are not directly involved in patient care, such as clerical and billing personnel. In today's health care environment, many clerical and billing personnel are located in offices outside the hospital facility and rarely visit the facility. We do not understand why these employees should be included in the vaccination requirement.

For these reasons, the PRT does not support the proposal and asks CMS not to implement it.

Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures

The PRT agrees that loss of vision following cataract surgery is rare and that the number of cataract cases is increasing due to the country's aging population. The PRT also agrees that "advances in technology and surgical skills" have improved over the last 30 years. Precisely because there have been such advances, however, the PRT does *not* support the use of this measure of hospital outpatient department quality. Rather, it is a measure of the quality of the *surgeon's* skill.

The PRT supports the use of this measure as a physician quality indicator (PQRS#191) and strongly opposes its use as a hospital quality measure.

Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients AND Endoscopy/Poly Surveillance for Patients with a History of Adenomatous Polyps

The PRT agrees that a large number of colonoscopies are being performed, but we believe it is a result of the age of the Medicare beneficiary population, rather than a result of over-utilization. This indicator is a measure of quality of the physician and not the facility where the procedure is performed. Surgeries and endoscopies are scheduled and controlled by the *surgeon* and his or her office staff.

Since these data are already collected through PQRS #320, the PRT objects to this as a hospital indicator.

Cataracts – Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

The PRT strongly objects to this quality measure because the hospital facility does not always see the patient at 90 days post-surgery. As noted above, this is an area where follow-up is likely to occur in another setting than the hospital outpatient department. As such, we do not

believe that it is an appropriate quality measure for our facilities. It is unclear how the hospital would have access to the data needed to know if the patient's visual acuity has or has not improved at 90 days. The PRT also believes that this is a measurement of the *surgeon's* skills that does not reflect the quality of care the hospital may provide.

Because it is already a physician indicator (PQRS 192), it should not be used to measure hospital quality.

Partial Hospitalization Programs (PHPs) that are part of HOPDs

CMS is soliciting comments on the following potential quality measure topics for PHPs in HOPDs: Poly-therapy with antipsychotic medications; Post discharge of continuity of care; Alcohol and drug use: Tobacco use assessment; and Follow-up after hospitalization for mental illness. These topics would align measurement of PHPs in HOPDs with that of the IPFQR Program.

CMS also seeks input on possible additional requirements for the written plan of treatment to best direct PHP resources to appropriate discharges and follow-up services. These may include expedited discharge for patients who are no longer at-risk for inpatient psychiatric hospitalizations, and specific actions to assist patients at discharge (i.e., written instructions describing their medications, having the next appointment with the appropriate Medicare Part B participating practitioner, confirming they have a residence, care coordination information, etc.). In addition, CMS also seeks feedback on quality measures that could be used for a PHP, including the content of the measures and whether the measures should be similar to or the same as those used under the IPF Quality Reporting Program.

The PRT makes the following recommendations on the proposed quality indicators and discharge requirements for PHP.

- **CMS should require PHP programs to identify a specific appointment within 14 days of discharge from the PHP; this discharge continuing care information must be provided directly to the follow-up provider.**

- **CMS should establish Quality Service Criteria for use in judging performance, including criteria relating to at least the following aspects of care:**
  - Access: The number of program days of scheduled operation from the time of a request for services to the first scheduled day of service.
  - Treatment intensity: The percentage of scheduled attendance consistent with a minimum attendance average of 4 days per calendar week over an episode of care.
  - Discharge planning: The percentage of patients with a scheduled follow-up appointment within 14 days after the date of discharge (as needed).
  - Continuity of care: The percentage of post-discharge continuity of care plans provided to next level of care providers upon discharge.

Follow-Up After Hospitalization for Mental Illness

As noted above, this is an area where follow-up is likely to occur in another setting than the hospital outpatient department.

As such, we do not believe that it is an appropriate quality measure for our facilities and do not support the addition of this measure.

Conclusion

As the PRT has stated previously, we understand and support the need to report quality indicators for Medicare outpatient beneficiaries. We believe that the quality indicators CMS requires must be very specific, and must relate to the patient's *current* outpatient visit. Outpatients are typically in our hospitals for 24 hours or less. In that time, staff provide medical assessments, diagnostic studies, treatments, and evaluations to determine whether admission is warranted.

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

We also ask, once again, for CMS to provide information about how reporting a specific measure will affect the measurement of hospital quality, and how facilities can ensure that the data are captured efficiently. Only in this way will providers understand how the proposed standards will specifically measure *quality*, and how reporting the measures will affect the hospital's ability to capture the data element efficiently.

Proposed Calculation of Single Procedure APC Criteria-Based Costs: Device-Dependent APCs and Nuclear Medicine Procedure-to-Radiolabeled Product Edits

Device-to-Procedure and Procedure-to-Device Edits; Nuclear Medicine Procedure-to-Radiolabeled Product Edits

The PRT understands that CMS believes it is no longer necessary to implement procedure-to-device edits and device-to-procedure edits for any APC or the Nuclear Medicine procedure-to-radiolabeled product edits. The agency is proposing to discontinue procedure-to-device edits, device-to procedure edits, and the Nuclear Medicine procedure-to-radiolabeled product edits. The PRT recommends that CMS not remove or discontinue these edits; we believe they should stay in place.

CMS originally implemented the edits in response to hospitals' concerns that devices and other products were not being reported consistently (these included devices associated with device-related procedure APCs and radiolabeled products associated with nuclear medicine procedures). We understand that CMS was concerned that, if hospitals failed to report devices or radiolabeled products, the agency would lack the necessary cost data for these items to

package into the procedure APC. The PRT appreciated and supported CMS' introduction of these edits, which enabled the agency to obtain complete claims and cost information for use in future years' rate-setting.

In the CY 2014 proposed rule, CMS indicates that the use of these edits is burdensome to hospitals and no longer needed, due to hospitals' current experience in coding and reporting these claims fully.

The PRT respectfully disagrees with CMS. Far from being burdensome for our hospitals, these edits actually *help* facilities ensure that highly expensive devices and radiolabeled products are billed correctly with their associated procedure. Hospitals rely on these edits to assure accurate charging of supplies based on the device-to-edit procedure performed. Hence, keeping these edits is critical to maintaining the integrity of the data, particularly since CMS has proposed the use of more comprehensive APCs.

We are concerned by the proposal to remove these edits for the same reason the agency itself expressed when it originally implemented them: there is a very real risk that that hospitals will fail to report devices and radiolabeled products consistently unless these edits remain in place. Incomplete and/or incorrect data compromise future cost data CMS has to use in the rate setting process.

Therefore, the PRT *strongly recommends* that CMS continue to utilize these device and nuclear medicine radiolabeled edits.

Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

The PRT agrees with CMS' proposal to revise the current FB/FC modifier use. We agree that the use of the FD value aligns the impact on reimbursement between inpatient and outpatient claims to reflect the amount of credit received from the manufacturer.

Further, we would like to propose that hospitals only report the FD value code when the value of a credit memo received due to recall or warranty exceeds 50% of the offset value of the APC code or CPT code (ASC) which require reporting.

In last year's comments, CMS stated that they required providers to report the FB or FC modifier on CPT codes that included the cost of multiple devices even if the value of the replaced device was less than 50% of the offset value of all devices. This created undue reductions in reimbursement.

For example, the CPT code 33249 includes the reimbursement for both the ICD generator and a lead. This CPT code has a device offset value of 88.84% of the CPT value. The lead represents approximately 5% of the offset value and the ICD generator represents about 95% of the offset value. In some cases, hospitals receive a device credit of $400-$600 (the cost of the lead); yet, were forced to report the FB modifier on code 33249. The national payment

rate for code 33249 is $30,680. The FB modifier reduced the payment by 88.84%, to $3,424, while hospitals continued to bear the cost of the ICD generator.

The benefits of using the offset value as a benchmark to determine the reporting of FD modifier includes the use of a consistent denominator to calculate whether reporting is required, and the reduction in hospital administration burden when an insignificant (cost less than 50% of the offset value) device is provided by a manufacturer free of charge.

To illustrate our proposal, the current process is as follows: Credit memo value received is compared to the cost of the newly implanted device cost. If this value is greater than 50%, then the FB/FC modifier is reported if the value received is greater than 100%/50%, respectively. The reimbursement is then reduced based on the offset table. The future process is as follows: Credit memo value received is compared to the offset value published by CMS. If this value is greater than 50%, the FD value code is reported with the value of the credit memo. The reimbursement is then reduced based on the value of the credit memo.

The PRT agrees that the use of the FD value aligns the impact on reimbursement between inpatient and outpatient claims to reflect the amount of credit received from the manufacturer.

Requirements for Payment of Outpatient Therapeutic ("Incident to") Hospital or CAH Services

CMS has expressed concerns regarding the quality and safety of outpatient therapeutic services in both this and previous rulemaking, stating that: *"our supervision policy is designed to preserve both the quality and safety of the hospital outpatient services that are paid for by Medicare"* (2012 OPPS Final Rule).

The PRT supports CMS' proposal to add a new paragraph under § 410.27 to provide that: *"Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or non-physician practitioner's service...if they are furnished in accordance with applicable State law."*

CMS' precedent of deferring to State law regarding the delivery of hospital services is well-established, and permits States to determine the policies that are most appropriate to ensure its residents' access to quality hospital care. The PRT concurs that this policy change to the Medicare Conditions of Payment will promote the safety and quality of health care services by ensuring that qualified personnel provide hospital outpatient therapeutic services. It will also provide a mechanism for CMS to deny payment when this requirement is not met.

In the hospital setting, the quality and safety of outpatient therapeutic services are supported by several mechanisms, including the reliance on the order of a physician or non-physician practitioner involved in the patient's care; the quality and safety measures included in the Medicare Conditions of Participation; and the oversight of certifying agencies such as The Joint Commission. The proposed revision to the Medicare Conditions of Payment will provide

CMS with additional and substantive assurances that outpatient therapeutic services are provided by qualified health care personnel operating within their State-granted scope of practice.

Given the additional quality, safety, and enforcement assurances that will be provided by this revision to the Medicare Conditions of Payment, the PRT contends that it is reasonable for CMS to adopt the policy of general supervision as the appropriate level of supervision for outpatient therapeutic services other than pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services performed incident to a physician's or non-physician practitioner's services unless a higher level of supervision is required by State regulations.

A policy of general supervision adopted concurrently with the proposed change to the Conditions of Payment would provide CMS with sufficient assurances regarding the quality and safety of outpatient therapeutic services, and reduce the substantial provider burden and beneficiary access issues inherent in the current policy of direct supervision.

Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

HOP Panel Comments

If CMS does not accept our recommendation on changing the default level to general, as described above, then the PRT requests the agency to reconsider its current process for submitting topics to the Advisory Panel on Hospital Outpatient Payment (HOP Panel) that have been previously reviewed. We have several thoughts on the current process, described below.

First, few requests have been submitted to date, due to providers' difficulty to put forward content in a manner the agency will accept. Second, services that are brought before the HOP Panel are generally simple, high-volume procedures for which clinical practice patterns or techniques rarely change. Third, the PRT is concerned about the extreme difficulty in getting a presentation accepted for a service that has previously been considered by the HOP Panel.

These barriers create an environment that provides minimal opportunity for new information and/or new perspectives on a particular issue to be presented to the HOP Panel.

Therefore, the PRT requests CMS to consider a change in current policy to allow a previously reviewed service to be brought back to the HOP Panel. New evidence may include new information or practice patterns that affect a procedure's safety or a different perspective on a previously presented service. Under current guidelines, it is difficult to advance such information to the HOP Panel because repeat requests are subject to such stringent requirements.

While we initially understood these guidelines, the PRT now finds them to be restrictive and to hamper the agency's receipt of new information on services already brought forth to the

Panel. We could understand limiting presentations if the agency was inundated by multiple requests, but we do not believe this to be the case, based on our participation in these meetings. We fear the current guidelines inadvertently limit the voice of the provider community.

The HOP Supervision Subcommittee was created in order to minimize barriers to delivery of patient care. The PRT further notes that CMS implemented guidelines to prioritize stakeholders' requests for HOP Panel's review of specific services based on service volume, total expenditures, and frequency of requests. CMS also gives priority to services that have not been previously evaluated by the Panel. We believe that providers should have a voice in this process, and should be able to make necessary changes to their current practices based on awareness through proposed and final rules.

If CMS does not implement our recommendation above about changing to a default status of general supervision, **the PRT urges CMS to make the submission process more flexible, to make the guidelines less restrictive, and to facilitate providers' ability to access the HOP Panel to recommend supervision-level changes.**

Non-Enforcement of Physician Supervision in CAH

The PRT appreciates the extension of the non-enforcement requirements for direct supervision of outpatient therapeutic services in CAHs and small rural hospitals, as defined over the last several years. The PRT continues to believe (and support) that non-enforcement includes CY 2009, based on the nature and sheer complexity of the rules in early years.

The PRT strongly requests CMS to accept this request, now that providers in CAH and small rural hospitals have been afforded full disclosure and education on the topic of physician supervision rules in relation to "incident to" physician services.

Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

The PRT understands that CMS seeks feedback and proposals on the best way to collect information on the frequency, type, and payment of services provided in off-campus provider-based hospital departments. We believe this interest stems, in part, from the agency's belief that hospitals and health systems acquire physician practices in order to subsequently convert them to provider-based clinics.

We disagree with this belief, since our experience indicates that, in many cases, hospital-owned physician practices remain freestanding physician practices. In other cases, hospitals and health systems make individual determinations for each practice and location in order to deliver optimal patient care —including being able to offer new services as a benefit to enable patients' better access to high-quality health care. If a hospital chooses to make the investment and develop provider-based clinics, it often represents new services offered within the community; this benefits patients and enables access to integrated health care services that are only available via hospital-based care.

With respect to CMS' interest in gathering data on services delivered through provider-based locations, and its proposals on a process for doing so, the PRT first seeks clarification about how CMS intends to use the collected data. We want to understand if the intended use will justify and offset the *significant* administrative burden providers would face from any new reporting requirements.

Before CMS considers any sort of claim-level or cost reporting data collection, the PRT recommends that the agency mandate the completion of the provider-based attestation for *all* provider-based departments. This attestation is currently voluntary. CMS has already outlined the requirements hospitals must meet for provider-based departments; these requirements contribute to higher costs associated with the greater integration of these clinics with the hospitals that own and operate them.

Costs in the hospital environment, including costs in provider-based departments, are much higher than costs in freestanding physician offices. As previously noted, many of the costs are regulated by CMS to ensure the provider-based clinics are integrated with the hospital that owns and operates them. These costs reflect additional services available to the patients (i.e., emergent care and higher resource utilization, including 24/7 staffing and higher overhead costs that are associated with accreditation). We believe that cost reporting of such clinics under current instructions represents an accurate method to identify costs. We further encourage CMS to clarify instructions for overhead cost allocation to such provider-based departments once the agency mandates the attestation process.

The PRT notes, however, that many of its members have experienced significant delays in their MACs processing the attestations. For this reason, we request CMS to allow providers that believe they meet the attestation criteria for provider-based clinics to bill outpatient hospital claims, and receive APC payments for those locations, after filing the attestation but before receiving formal MAC approval. (This resembles the current process.)

The PRT is also concerned about whether CMS expects modifiers to be used solely for services rendered in off-campus provider-based departments. We are not clear how CMS will track whether there were different services provided in two *separate* provider-based off campus locations on the same day for the same beneficiary. Does CMS want the modifiers to be so specific that it will track each address (or location) where services are rendered, or just whether some services were rendered off-campus (with unmodified services representing services that are delivered on-campus).

In summary, the PRT recommends that, before requiring hospitals to incur the additional burden of reporting claim-level modifiers or making changes to our systems for revenue codes and/or changed cost reporting requirements, CMS should clarify and specify exactly *which services* would require a modifier.

Proton Beam Radiation Therapy (APCs 0664 and 0667)

There are PRT member facilities that are currently in the process of implementing a proton beam therapy program, and we are concerned about providers' ability to receive appropriate payment for these efforts.

The PRT understands that CMS proposes to assign the following four proton beam CPT codes into APC 0667:

- 77520 (Proton treatment simple without compensation)
- 77522 (Proton treatment simple with compensation)
- 77523(Proton treatment intermediate), and
- 77525 (Proton treatment complex)

The PRT is concerned with CMS' proposal, which appears to favor the creation of fewer APC groups without regard to maintaining the groups' clinical meaningfulness and homogeneity. We understand that APC groups should be both clinically meaningful *and* resource homogenous — so we do not understand why CMS seeks to collapse these codes. Doing so will result in a difference of almost *three times* in the cost of the lowest geometric mean and the highest geometric mean. In the current configuration, this is not the case.

Further, we do not believe CMS should compromise clinical homogeneity in favor of creating larger bundles (or groupings) of services, since there are clinical differences in the simple proton beam services and the intermediate and complex proton beam therapy services.

For these reasons, the PRT requests that CMS maintain the current proton beam service APCs. Specifically, for CY 2014, we request that CMS place CPT codes 77520 and 77522 into APC 0664, and place CPT codes 77523 and 77525 into APC 0667.

Proposed Calculation and use of Cost-to-Charge Ratios

Cost Centers and Cost Report

Since CMS has finalized the use of the new standard cost centers for "Computed Tomography (CT)," "Magnetic Resonance Imaging (MRI)," and "Cardiac Catherization" for the Inpatient Prospective Payment System ratesetting, the PRT then supports the use of these cost centers for OPPS rate setting. We ask that CMS require hospitals to report the costs and charges for these services under new cost centers on the revised Medicare Cost Report Form CMS 2552-10.

Doing so will enable CMS to more accurately determine the cost of services provided for these services by carving these costs out of the more generalized cost centers to ensure appropriate reimbursement for these higher-cost, lower-utilized services.

Mental Health Services Composite APC (APC 0034)

Partial Hospitalization Program (PHP)

CMS is considering several possible modifications to the Partial Hospitalization Program (PHP) benefit to ensure the long-term stability of PHPs and improve payment accuracy. CMS seeks to ensure that PHPs serve appropriate patients (i.e., those with acute exacerbation of psychiatric illness) and manage their symptoms in order to prevent hospital admissions and/or re-admissions.

CMS is proposing to continue using four separate APCs to pay for PHP services. Two of the APCs are for services furnished in hospital-based PHPs, with payments calculated using only hospital data; two of the APCs are for services furnished in community mental health centers (CMHCs), with payments calculated using only CMHC claims data.

We agree with this proposal, and appreciate that CMS is making this change.

Physician Recertification

CMS also seeks comments on the current requirements for physician recertification and physician's individualized written plans of treatment. Specifically, CMS seeks input on whether the deadline for the first physician recertification (that a patient would require psychiatric inpatient care absent the PHP) should be a date different from the current standard of the 18th day of partial hospitalization services.

The PRT does not recommend making any changes to the current physician certification requirement.

Requirements for the Written Plan of Action & Quality Indicators

CMS also seeks input on possible additional requirements for the written plan of treatment to best direct PHP resources to appropriate discharges and follow-up services. These may include expedited discharge for patients who are no longer at-risk for inpatient psychiatric hospitalizations, and specific actions to assist patients at discharge (i.e., written instructions describing their medications, having the next appointment with the appropriate Medicare Part B participating practitioner, confirming they have a residence, care coordination information, etc.). In addition, CMS also seeks feedback on quality measures that could be used for a PHP, including the content of the measures and whether the measures should be similar to or the same as those used under the IPF Quality Reporting Program.

The PRT makes the following recommendations on the proposed quality indicators and discharge requirements for PHP.

- **CMS should require PHP programs to identify a specific appointment within 14 days of discharge from the PHP; this discharge continuing care information must be**

provided directly to the follow-up provider.

- **CMS should establish Quality Service Criteria for use in judging performance, including criteria relating to at least the following aspects of care:**
  - Access: The number of program days of scheduled operation from the time of a request for services to the first scheduled day of service.
  - Treatment intensity: The percentage of scheduled attendance consistent with a minimum attendance average of 4 days per calendar week over an episode of care.
  - Discharge planning: The percentage of patients with a scheduled follow-up appointment within 14 days after the date of discharge (as needed).
  - Continuity of care: The percentage of post-discharge continuity of care plans provided to next level of care providers upon discharge.

Proposed Use of Single and Multiple Procedure Claims

Bypass List

For CY 2014, CMS proposes to bypass 179 HCPCS codes. We are puzzled that CMS is proposing to package costs into some evaluation and management (E/M) visit codes but not in others, while, at the same time, the agency is proposing to collapse E/M codes for clinic visits, Type A EDs and Type B EDs. It seems illogical for any E/M visit codes to remain on the bypass list.

The PRT has also heard concerns expressed by the AHA and other industry stakeholders that there may be data problems in CMS' data files, which may have resulted in codes (like the E/M visit codes) being incorrectly included on the bypass list. If the bypass list *is* incorrect, this error will impact all of other proposed APC payment rates for CY 2014 and impact the financial analyses we have examined to date.

We understand that CMS released updated information and data files on August 28th, 2013, but, unfortunately, this late in the comment period timeline, we are unable to begin revising our analyses. Hence, due to the known and unknown data problems, the PRT is unable to make truly meaningful comments on many aspects of the CY 2014 OPPS proposed rule.

Hence, the PRT requests that the agency *not* implement its comprehensive APC, expanded packaging, or E/M visit proposals for CY 2014.

Application of Therapy Caps in CAHs

The PRT does not support including CAHs in Therapy Caps. We note that it is not clear if Congress intends to act to extend the current statutory regulation in this area, which includes CAHs in the beneficiary caps until the end of CY 2013. We do not know what the Congressional action is, and whether it will extend the provisions that subject CAHs to the cap for CY 2014.

The PRT does not support the CMS proposal to place CAH under a different requirement from hospital outpatient departments.

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

We believe that ASP+6% is the *minimum* level of reimbursement that should be provided to cover hospitals' drug acquisition costs. We appreciate CMS' proposal for CY 2014 in this area, and urge the agency to finalize the ASP+6% payment level. Doing so will allow our hospital pharmacies to better cover their drug acquisition costs and minimize provider uncertainty.

We remain concerned about whether ASP+6% is sufficient to cover both acquisition and handling, however. We nonetheless believe that this proposal is preferable to CMS continuing to attempt to determine what level of redistribution from packaged drugs to separately payable drugs should occur on an annual basis. This complex process, which CMS has used for the past several years, results in instability in providers' reimbursement rates and a significant amount of uncertainty from year to year.

The PRT applauds CMS for agreeing to comply with the statute requiring a payment level of ASP+6% for all separately payable drugs.

Proposed Criteria for Packaging Payment for Drugs, Biologicals and Radiopharmaceuticals

Drug packaging threshold

For CY 2014, the PRT understands that CMS proposes to increase the drug-packaging threshold to $90. We continue to disagree with CMS' use of a drug-packaging threshold in the hospital setting while a similar threshold is not used in the physician's office setting.

For this reason, the PRT once again urges CMS to eliminate the drug-packaging threshold. This is a particularly critical step as the agency moves to create parity across sites of service.

If the agency is unwilling to make this change, then the PRT believes that CMS must, at the very least, apply the drug-packaging threshold to all drugs, including diagnostic radiopharmaceuticals.

Diagnostic Radiopharmaceuticals

The PRT once again reiterates that it does *not* support CMS' packaging decision for diagnostic radiopharmaceuticals. We understand the need for packaging, as well as the "efficiency incentives" that CMS hopes to create through larger and larger bundles of payment.

The problem stems from the fact that, like most others across the country, our hospitals consider radiopharmaceuticals to be drugs rather than supplies. As drugs, all radiopharmaceuticals should be reimbursed separately. If CMS does not eliminate the drug-packaging threshold, it should at least apply the threshold in the same manner to all radiopharmaceuticals, in the way that it applies the threshold to all drugs.

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.

This is particularly problematic since the agency describes the fact that pass-through payment is warranted for new diagnostic radiopharmaceuticals as it is for new drugs that receive pass-through payment status. For example, a patient who presents for a bone study requires a radiopharmaceutical that is appropriate for that study even if it is more expensive than a radiopharmaceutical for a soft tissue study. This example alone illustrates the fact that hospitals cannot simply substitute a less expensive radiopharmaceutical for a more-expensive one — unless, of course, hospitals begin restricting the types of patients they treat.

It is the PRT's firm belief that diagnostic radiopharmaceuticals should be treated as drugs rather than as supplies and 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 2014 proposed drug-packaging threshold, if it is finalized at $90.

Proposed Procedures that Would Be Paid Only as Inpatient Procedures

Proposed Changes to the Inpatient List

The PRT continues to be concerned about the Inpatient-Only List and reiterate our belief that it should be eliminated altogether.

As CMS regulations and contractor guidelines both note, the *physician* is responsible for decisions regarding admission status for the individual patient. It is the physician's role to determine whether or not to admit a patient, based on his or her medical expertise and judgment. By utilizing the Inpatient-Only List, CMS takes over this role, determines what constitutes inpatient care, and eliminates the physician's decision-making role in these specific patient specific circumstances.

Yet, CMS continues to reimburse physicians for services that they perform from the inpatient-only list that are rendered on an outpatient basis. Inconsistently, the agency does not provide payment to hospitals in such instances. This policy decision is grossly unfair, as it penalizes

OPPS hospitals and appears to expect that hospitals are somehow able to enforce something that the agency seems reluctant to enforce itself.

Reassignment of Radiofrequency Ablation from APC 0131 to APC 0174

The Food and Drug Administration (FDA) approved Radiofrequency Ablation (RFA) of uterine fibroids on June 15, 2013. This procedure was assigned HCPCS code C9736 (Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intra-operative guidance and monitoring, when performed) effective as of July 2013.

CMS proposes the assignment of this procedure to APC 0131, Level II Laparoscopy. We also that this procedure will be reported on January 1 2014 by new technology CPT code 0336T (Laparoscopy, surgical, ablation of uterine fibroid(s), including the intra-operative ultrasound guidance and monitoring, radiofrequency).

The PRT is concerned about this APC placement and requests this procedure be reassigned to APC 0174. Although we acknowledge that CMS does not yet have claims data on this specific procedure to review for APC placement, claims data *are* available for other services that map to these APCS. We hope the agency will consider this request, which is supported by claims data review in review of claims mapped to these APCs.

APC 131 is made up of Level II laparoscopy services. Upon review of claims data for services in this APC, we found that there are not significant separately billable disposable supplies. Our review of claims mapped to APC 174 finds that there *are* significant cost differences — specifically in the cost of the disposable RFA catheter and other disposable supplies with costs greater than $3400. In addition, claims review also reveals that the average OR time for APC 0174 services averages 47 minutes longer than those services in APC 0131. We also believe that, in addition to the cost differences, APC 0174 contains services that are clinically similar to the RFA uterine fibroids, namely the RFA procedures for liver and renal tumors.

Given the clinical and cost similarities, we ask CMS to place the RFA procedure in APC 0174.

In-Person HOP meeting

In addition, the PRT wanted to comment that its members very much appreciate that the HOP Panel meetings are held in-person, supplemented by telephone/video access for those who cannot travel to CMS for these meetings. We value the ability to attend these face-to-face meetings, and encourage CMS to continue to hold them in this format.

The PRT has attended the HOP Panel (previously APC Panel) meetings for many years and knows first-hand the value generated by these meeting. Panel members often observe the audience's reaction to presentations or proposals, and can call upon individuals for response and discussion. The conversations between sessions are also extremely useful for

communicating provider experiences to the Panel members. These positive effects will be lost if the panel does not meet in-person.

Hence, the PRT wishes to relay its appreciation to CMS for the face-to-face meetings, which benefit concerned providers, CMS staff, and the Panel members alike.

Conclusion

The PRT appreciates the agency's willingness to receive comments from providers on OPPS, and thanks CMS for its consideration of our position. As noted, if you need clarification of any of these points, or would like more information, please contact the PRT via our Chair, Ms. Jennifer Artigue.

Sincerely,

Jennifer L. Artigue, RHIT, CCS
PRT Chair and
Corporate Director, Health Information Management
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Attachment B. Excerpt of Prosthetics, Orthotics and Surgical Dressing from Addendum P That Should Not be Included

HCPCS	HCPCS Descriptor	Proposed 2014 SI	Packaging Policy	DMEPOS Indicator
A4216	Sterile water/saline, 10 ml	N	Supply	OS
A4217	Sterile water/saline, 500 ml	N	Supply	OS
A4280	Brst prsths adhsv attchmnt	N	Supply	PO
A4450	Non-waterproof tape	N	Supply	OS
A4452	Waterproof tape	N	Supply	OS
A4455	Adhesive remover per ounce	N	Supply	OS
A4456	Adhesive remover, wipes	N	Supply	OS
A4461	Surgicl dress hold non-reuse	N	Supply	SD
A4463	Surgical dress holder reuse	N	Supply	SD
A4481	Tracheostoma filter	N	Supply	OS
A4483	Moisture exchanger	N	Supply	
A4606	Oxygen probe used w oximeter	N	Supply	
A4623	Tracheostomy inner cannula	N	Supply	OS
A4625	Trach care kit for new trach	N	Supply	OS
A4626	Tracheostomy cleaning brush	N	Supply	OS
A4629	Tracheostomy care kit	N	Supply	OS
A4634	Replacement bulb th lightbox	N	Supply	
A4651	Calibrated microcap tube	N	Supply	
A4652	Microcapillary tube sealant	N	Supply	
A4653	PD catheter anchor belt	N	Supply	
A6010	Collagen based wound filler	N	Supply	SD
A6011	Collagen gel/paste wound fil	N	Supply	SD
A6021	Collagen dressing <=16 sq in	N	Supply	SD
A6022	Collagen drsg>16<=48 sq in	N	Supply	SD
A6023	Collagen dressing >48 sq in	N	Supply	SD
A6024	Collagen dsg wound filler	N	Supply	SD
A6154	Wound pouch each	N	Supply	SD
A6196	Alginate dressing <=16 sq in	N	Supply	SD
A6197	Alginate drsg >16 <=48 sq in	N	Supply	SD
A6198	alginate dressing > 48 sq in	N	Supply	SD
A6199	Alginate drsg wound filler	N	Supply	SD
A6203	Composite drsg <= 16 sq in	N	Supply	SD
A6204	Composite drsg >16<=48 sq in	N	Supply	SD
A6205	Composite drsg > 48 sq in	N	Supply	SD
A6206	Contact layer <= 16 sq in	N	Supply	SD
A6207	Contact layer >16<= 48 sq in	N	Supply	SD
A6208	Contact layer > 48 sq in	N	Supply	SD

A6209	Foam drsg <=16 sq in w/o bdr	N	Supply	SD
A6210	Foam drg >16<=48 sq in w/o b	N	Supply	SD
A6211	Foam drg > 48 sq in w/o brdr	N	Supply	SD
A6212	Foam drg <=16 sq in w/border	N	Supply	SD
A6213	Foam drg >16<=48 sq in w/bdr	N	Supply	SD
A6214	Foam drg > 48 sq in w/border	N	Supply	SD
A6215	Foam dressing wound filler	N	Supply	SD
A6216	Non-sterile gauze<=16 sq in	N	Supply	SD
A6217	Non-sterile gauze>16<=48 sq	N	Supply	SD
A6218	Non-sterile gauze > 48 sq in	N	Supply	SD
A6219	Gauze <= 16 sq in w/border	N	Supply	SD
A6220	Gauze >16 <=48 sq in w/bordr	N	Supply	SD
A6221	Gauze > 48 sq in w/border	N	Supply	SD
A6222	Gauze <=16 in no w/sal w/o b	N	Supply	SD
A6223	Gauze >16<=48 no w/sal w/o b	N	Supply	SD
A6224	Gauze > 48 in no w/sal w/o b	N	Supply	SD
A6228	Gauze <= 16 sq in water/sal	N	Supply	SD
A6229	Gauze >16<=48 sq in watr/sal	N	Supply	SD
A6230	Gauze > 48 sq in water/salne	N	Supply	SD
A6231	Hydrogel dsg<=16 sq in	N	Supply	SD
A6232	Hydrogel dsg>16<=48 sq in	N	Supply	SD
A6233	Hydrogel dressing >48 sq in	N	Supply	SD
A6234	Hydrocolld drg <=16 w/o bdr	N	Supply	SD
A6235	Hydrocolld drg >16<=48 w/o b	N	Supply	SD
A6236	Hydrocolld drg > 48 in w/o b	N	Supply	SD
A6237	Hydrocolld drg <=16 in w/bdr	N	Supply	SD
A6238	Hydrocolld drg >16<=48 w/bdr	N	Supply	SD
A6239	Hydrocolld drg > 48 in w/bdr	N	Supply	SD
A6240	Hydrocolld drg filler paste	N	Supply	SD
A6241	Hydrocolloid drg filler dry	N	Supply	SD
A6242	Hydrogel drg <=16 in w/o bdr	N	Supply	SD
A6243	Hydrogel drg >16<=48 w/o bdr	N	Supply	SD
A6244	Hydrogel drg >48 in w/o bdr	N	Supply	SD
A6245	Hydrogel drg <= 16 in w/bdr	N	Supply	SD
A6246	Hydrogel drg >16<=48 in w/b	N	Supply	SD
A6247	Hydrogel drg > 48 sq in w/b	N	Supply	SD
A6248	Hydrogel drsg gel filler	N	Supply	SD
A6250	Skin seal protect moisturizr	N	Supply	SD
A6251	Absorpt drg <=16 sq in w/o b	N	Supply	SD
A6252	Absorpt drg >16 <=48 w/o bdr	N	Supply	SD
A6253	Absorpt drg > 48 sq in w/o b	N	Supply	SD

A6254	Absorpt drg <=16 sq in w/bdr	N	Supply	SD
A6255	Absorpt drg >16<=48 in w/bdr	N	Supply	SD
A6256	Absorpt drg > 48 sq in w/bdr	N	Supply	SD
A6257	Transparent film <= 16 sq in	N	Supply	SD
A6258	Transparent film >16<=48 in	N	Supply	SD
A6259	Transparent film > 48 sq in	N	Supply	SD
A6260	Wound cleanser any type/size	N	Supply	SD
A6261	Wound filler gel/paste /oz	N	Supply	SD
A6262	Wound filler dry form / gram	N	Supply	SD
A6266	Impreg gauze no h20/sal/yard	N	Supply	SD
A6402	Sterile gauze <= 16 sq in	N	Supply	SD
A6403	Sterile gauze>16 <= 48 sq in	N	Supply	SD
A6404	Sterile gauze > 48 sq in	N	Supply	SD
A6407	Packing strips, non-impreg	N	Supply	SD
A6410	Sterile eye pad	N	Supply	SD
A6411	Non-sterile eye pad	N	Supply	SD
A6412	Occlusive eye patch	N	Supply	SD
A6441	Pad band w>=3" <5"/yd	N	Supply	SD
A6442	Conform band n/s w<3"/yd	N	Supply	SD
A6443	Conform band n/s w>=3"<5"/yd	N	Supply	SD
A6444	Conform band n/s w>=5"/yd	N	Supply	SD
A6445	Conform band s w <3"/yd	N	Supply	SD
A6446	Conform band s w>=3" <5"/yd	N	Supply	SD
A6447	Conform band s w >=5"/yd	N	Supply	SD
A6448	Lt compres band <3"/yd	N	Supply	SD
A6449	Lt compres band >=3" <5"/yd	N	Supply	SD
A6450	Lt compres band >=5"/yd	N	Supply	SD
A6451	Mod compres band w>=3"<5"/yd	N	Supply	SD
A6452	High compres band w>=3"<5"yd	N	Supply	SD
A6453	Self-adher band w <3"/yd	N	Supply	SD
A6454	Self-adher band w>=3" <5"/yd	N	Supply	SD
A6455	Self-adher band >=5"/yd	N	Supply	SD
A6456	Zinc paste band w >=3"<5"/yd	N	Supply	SD
A6457	Tubular dressing	N	Supply	SD
A6501	Compres burngarment bodysuit	N	Supply	SD
A6502	Compres burngarment chinstrp	N	Supply	SD
A6503	Compres burngarment facehood	N	Supply	SD
A6504	Cmprsburngarment glove-wrist	N	Supply	SD

A6505	Cmprsburngarment glove-elbow	N	Supply	SD
A6506	Cmprsburngrmnt glove-axilla	N	Supply	SD
A6507	Cmprs burngarment foot-knee	N	Supply	SD
A6508	Cmprs burngarment foot-thigh	N	Supply	SD
A6509	Compres burn garment jacket	N	Supply	SD
A6510	Compres burn garment leotard	N	Supply	SD
A6511	Compres burn garment panty	N	Supply	SD
A6512	Compres burn garment, noc	N	Supply	SD
A6531	Compression stocking BK30-40	N	Supply	SD
A6532	Compression stocking BK40-50	N	Supply	SD
A6545	Grad comp non-elastic BK	N	Supply	SD
A7040	One way chest drain valve	N	Supply	PO
A7041	Water seal drain container	N	Supply	PO
A7043	Vacuum drainagebottle/tubing	N	Supply	PO
A7501	Tracheostoma valve w diaphra	N	Supply	OS
A7502	Replacement diaphragm/fplate	N	Supply	OS
A7503	HMES filter holder or cap	N	Supply	OS
A7504	Tracheostoma HMES filter	N	Supply	OS
A7505	HMES or trach valve housing	N	Supply	OS
A7506	HMES/trachvalve adhesivedisk	N	Supply	OS
A7507	Integrated filter & holder	N	Supply	OS
A7508	Housing & Integrated Adhesiv	N	Supply	OS
A7509	Heat & moisture exchange sys	N	Supply	OS
A7520	Trach/laryn tube non-cuffed	N	Supply	OS
A7521	Trach/laryn tube cuffed	N	Supply	OS
A7522	Trach/laryn tube stainless	N	Supply	OS
A7523	Tracheostomy shower protect	N	Supply	OS
A7524	Tracheostoma stent/stud/bttn	N	Supply	OS
A7525	Tracheostomy mask	N	Supply	OS
A7526	Tracheostomy tube collar	N	Supply	OS
A7527	Trach/laryn tube plug/stop	N	Supply	OS