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

Carolinas HealthCare System (NC, SC)

Community Hospital Anderson (IN)

Erlanger Medical Center (TN)

Forrest General Hospital (MS)

Hartford Hospital (CT)

Health First Inc. (FL)

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

Our Lady of the Lake Regional Medical Center (LA)

Robert Wood Johnson University Hospital (NJ)

Saint Joseph's/Candler Health System (GA)

UCLA Healthcare (CA)

University of Pittsburgh Medical Center (PA)

University Health System (TX)

August 31, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1589-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS–1589–P, Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; (Vol. 77, No.146), July 30, 2012.

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the 2013 Outpatient Prospective Payment System (OPPS) Proposed Rule, as published in the *Federal Register* on July 30, 2012.

The Provider Roundtable (PRT) includes representatives from 14 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 **Appendix A.**

Please feel free to contact me at (704) 512-6483 or via email at: *John.Settlemyer@ carolinashealthcare.org*.

Sincerely,

John Settlemyer, MBA, MHA
PRT Chair, and
AVP, Revenue Cycle
Carolinas HealthCare System
PO Box 32861
Charlotte, North Carolina 28232-2861

I. Proposed Updates Affecting OPPS Payments

Proposed Geometric Mean-Based Relative Payment Weights

The PRT understands that CMS proposes to change the basic methodology it uses to calculate relative weights and use geometric mean rather than median cost data. The PRT applauds CMS for seeking a rate-setting method that will improve the agency's cost estimations in order to set outpatient payment rates most appropriately.

The PRT is concerned, however, by CMS' specific proposal since we agree with CMS that medians are generally more stable and less susceptible to extreme data points than means are. CMS' reliance on the geometric mean could result in large payment rate shifts from one year to the next as a result of the changing nature of claims that make it into the rate-setting claims data set. These claims may reflect aberrant coding, billing, or charging practices on the part of just a few providers that will skew the results, especially for APCs with low volumes. Such large APC payment shifts can be seen in the case of APCs 0006, 0007, and 0008.

The PRT disagrees with CMS' statement that using geometric mean will not have widespread financial impact on most hospitals. We believe that certain APCs will experience very large reductions in payment rates as a result of using the geometric mean; we also believe that these large payment shifts should not be allowed. We recommend that CMS conduct further analysis of this issue before implementing a system that may result in payment rate shifts that will impact some hospitals more than others. We note that the hospital's overall bottom line may not be greatly impacted by this change, but departmental bottom lines certainly will be.

The PRT is also concerned that a key driver behind CMS' proposal to use the mean rather than the median is an effort to begin making site of service payment comparisons. CMS indicates as much in the 2013 OPPS Proposed Rule, when it states: *"By adopting a means cost-based approach to calculating relative payment weights under the OPPS, CMS expects to achieve greater consistency between the methodologies used to calculate payment rates under the IPPS and the OPPS, which would allow it to make better cross-system comparisons and examine issues of payment parity."*

The PRT understands CMS' desire to make such comparisons and to achieve consistent payment rates. We note that these sorts of comparisons are only valid if they are "apples to apples" comparisons of like entities. This is not the case at the moment, and it will not be even if CMS uses the geometric mean to set rates in the outpatient setting, because the IPPS and the OPPS rate-setting processes are very different.

For IPPS rate-setting, CMS uses 14 national cost-to-charge ratios; for OPPS, it uses hospital-specific departmental cost-to-charge ratios. The result is that the inpatient system relies on significant averaging among cases and departments, while the outpatient system is much more specific. Implants present just one example: under IPPS, the inpatient MedPar file should be further refined to accommodate a specific break-out of the charges for implants in order to detail information reported under the new implants cost center. No such change is needed for the outpatient MedPar file, which has always contained detailed revenue codes in order for the

"revenue code to cost center" crosswalk to be applied. Merely using a means-based cost estimation rather than a median cost approach will *not, in and of itself,* enable CMS to make comparisons between IPPS and OPPS, despite the agency's desire to do so.

We also note that, in the past, when the PRT has requested that CMS create parity between systems, it has refused to do so and responded that each payment system is different and has its own rules and rate-setting processes. The PRT recommends that CMS maintain consistency in its view that the systems are separate entities.

If CMS now desires to open up the issue of payment system parity for like services, the PRT asks CMS to do so through open and transparent sub-regulatory and regulatory processes established explicitly for this purpose. Only in this way can stakeholders have the opportunity to have open discussion and discourse on the numerous issues and concerns entailed by this policy precedent.

If CMS insists on using the geometric mean as the basis for the CY 2013 relative weight development, the PRT urges the agency to create some sort of dampening mechanism or migration path to mitigate the large payment rate fluctuations that are certain to result. We recognize and appreciate that CMS does not want to create payment rates that are a mixture of the median and the geometric mean, but we urge the agency to weigh this desire against the impact on providers that face APC payment rates that fluctuate by 20% or more.

The PRT has consistently objected to CMS allowing such large payment swings to occur from one year to the next and request that CMS strive to mitigate such swings. Therefore, if CMS finalizes the use of the geometric mean, we believe the agency must use a dampening mechanism so providers are not forced to absorb enormous APC payment rate-changes due to changes in the CMS rate-setting policy.

Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

The PRT appreciates CMS' inclusion of "Implantable Devices Charged to Patients" in its data for CCR calculations, since this makes the data more complete. We agree with the numbers provided in Table 2 and understand the percentage changes in costs. We are pleased that CMS has made this change, which mitigates some of the charge compression; the use of the implantable devices cost centers more appropriately packages device costs into device-related APCs.

In addition, the PRT wishes to thank CMS for sharing the number of hospitals that report revenue code 278. We are concerned, however, that all hospitals may not be using this revenue code for the same items. Based on historical guidance from CMS, hospitals have used revenue code 278 for *any* sterile device that has a HCPCS code, regardless of whether it was implanted or not. Unless hospitals make a concerted effort to review their (often very large) supply charge file, it is probable that lower-priced devices are being reported under revenue code 278.

The PRT encourages CMS to expand its education on the need to correctly code for revenue code 278.

Cardiac Resynchronization Therapy Composite APC (APC 0108)

We are concerned about the status indicator change from "T" to "Q3" for CPT 33225. We do not believe that CMS has a sufficient cost data analysis to allow a composite rate for CPT 33225 and APC 0108. In CY 2012, the AMA issued clarification that CPT 33225 is an ***add-on code*** and we believe that, in the years prior to this clarification, CPT 33225 was frequently misused.

We seek a delay in the implementation of this status indicator change while CMS conducts additional cost data analysis in order to determine if the composite rate and APC 0108 applies to CPT 33225. We believe that CPT 33225 should continue to be assigned to 0655 during this analysis.

In addition, the PRT suggests that CMS consider the assignment of different APCs for upgrades to a pacemaker and cardio-defibrillator based on the number of leads inserted. We believe there are cost difference and more resources utilized to insert two leads compared to three and that the cost of the lead(s) device itself also varies. We request that CMS engage in further cost data analysis on this issue.

Packaged Services

Proposed Changes to Packaging 42 CFR 419.2(b)

CMS proposes to alter language at 42 CFR 419.2(b) to change the word "*included*" to "*packaged*" and add the following language: "*these packaged costs include, but are not limited to the following items and services, the payments for which are packaged into the payments for the related procedures or services*."

The PRT has no issue with changing the wording from "included costs" to "packaged costs." CMS does not propose to add or alter any of the examples of packaged items and services, and the language used already notes that the list provided is not an inclusive one. This is clear and undisputed, in the PRT's view.

The PRT is, however, very concerned about CMS' addition of the phrase: "*the payments for which are packaged into the payments for the related procedures or services."* This addition introduces a new concept — *related procedures or services* — into the packaged costs' regulatory text. For 13 years of OPPS implementation, the text about packaged services has been unchanged. The PRT is concerned that CMS' addition of the word "related" makes the concept of packaged costs much more subjective than it has ever been. Moreover, we are concerned that this addition exposes the regulatory text to broad interpretation.

OPPS is founded on the use of CPT and correct coding principles. These principles often determine what is packaged or not — in other words, they determine what is reported as a separate line item charge with a CPT code that generates OPPS payment. The PRT is concerned that auditors who are unfamiliar with the CPT principles may audit OPPS accounts and may use the proposed regulatory text to broaden the packaging concept beyond accurate CPT coding by using their own, subjective, interpretation of "related."

The PRT adamantly requests CMS to not add the proposed phrase "*the payments for which are packaged into the payments for the related procedures or services"* to this section of regulatory text.

APC 0412, CPT codes 77424 and 77425

The PRT appreciates the fact that CMS has recognized that intraoperative radiation therapy (IORT) CPT codes 77424 (Intraoperative radiation treatment delivery, X-ray, single treatment session) and 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session) are indeed separate and distinct services and should not be packaged into surgical procedure codes. We are pleased that CMS has changed the status indicator for these codes from "N" in CY 2012 to "S" for CY 2013.

We are, however, concerned with the placement of these services in APC 0412, IMRT. IORT is not clinically similar to IMRT, nor do the two require similar resources. Hospital's resource costs for IORT are *much* greater than for traditional radiation therapy. This is due to IORT being delivered in a single fraction in the operative suite after the tumor has been resected, and being delivered by the radiation oncology team. Once this radiation is delivered, the operative surgeon resumes closure of the incision. Another important difference is the fact that the capital equipment for this service cannot be used to perform traditional radiation therapy, as the equipment is *only* designed for this intraoperative radiation delivery.

The IMRT and the HDR treatments are used for many different patients each day and the actual treatment time per session is much shorter. We understand that rate-setting is not based upon the cost savings that stem from performing IORT as opposed to traditional radiation therapy modalities. Nonetheless, based on current APC payment rates and industry-standard average courses of treatment, aggregate average payment for traditional radiation therapy treatments are as follows:

o IMRT	35 sessions	$19,464
o External Beam	35 sessions	$9,274
o HDR	*10 sessions*	$16,581

As it relates to IORT, cost data from one of the PRT member providers indicates that the costs to render this service range from $4,042 to $5,600 per case. The PRT want CMS to know that the monumental capital expense of providing this service is spread across many fewer treatments, thus resulting in higher per-charge single encounters as opposed to multiple lower per-charge encounters spread out across the course of traditional fractional radiation-therapy delivery.

Because CMS does not have sufficient claims data at the present time, the PRT urges the agency to place CPT codes 77424 and 77425 in an appropriate New Technology APC that will provide reimbursement in the range of our observed costs of approximately $5500 per case; this figure aligns with our cost data as well as the cost information provided to the HOP Panel. A sufficient payment level must be provided so that hospitals can offer this important service, which is more beneficial to specific patient populations and represents cost savings to the Medicare program for the entire episode of care.

Recommendations of the APC Panel - Sacroiliac Injections

We appreciate that CMS acknowledged the APC Panel's recommendation that the agency provide data regarding the APC and status indicator assignment for Sacroiliac Injections. We are deeply disappointed that CMS did not accept this recommendation and urge the agency to reconsider its decision.

We believe the confusion rests with the description of G0260, *"Sacroiliac Injection with or without arthrogram"*. When a sacroiliac injection is performed *with* an arthrogram, we understand that it is bundled into the same HCPCS codes for G0260 as a therapeutic injection. When a sacroiliac injection is performed *without* arthrogram, and fluoroscopy or CT imaging is used, the CPT codes for Fluoroscopy (CPT 77003) or CT (CPT 77012) are both packaged items.

CPT codes 77003 and 77012 that are coded with G0260 have a NCCI edit with an indicator of 1. We cannot report CPT 77003 and 77012 with modifier 59 because the imaging guidance is not separate and distinct — it is part of the procedure. This means that providers cannot accurately report the cost of the imaging guidance (either Fluoroscopy or CT) due to the CCI edits and the fact that HCPCS code G0260 descriptor does not indicate if either Fluoroscopy or CT imaging are bundled into the procedure code.

We request that CMS issue a new HCPCS code to describe the sacroiliac injection procedure performed with imaging (Fluoroscopy or CT), which would also allow for further cost data analysis. Alternatively, we recommend that CMS allow the reporting of CPT code 27096 and revise the status indicator from "B" to "T".

II. Proposed APC Group Policies

New Category 3 CPT Codes

CPT 0304T

We believe the APC assignment for CPT 0304T is incorrect and that this CPT belongs in APC 0107, rather than APC 0090, based on providing like services. CPT 0304T describes the insertion or removal and replacement of a device, which is similar to CPT codes 33262 – 33264 and 33227 – 33229. Services in APC 0090 are described as repositioning, removal, or repair — except for CPT 33224.

We note that CPT 33224 describes removal, insertion, and/or replacement of a generator, so it is also is better aligned with APC 0107, due to describing like services.

CPT 0305T and 0306T

Although CPT 0305T and 0306T are assigned to like services — for example CPT 93279 and 93292 — there is a great disparity in APC 0690 between the minimum cost ($2.56) and maximum cost ($3741.71); the median cost is $34.51. We request that the rate for APC 0690 be set to the median cost and not below, as is currently the case with the rate of $33.92.

We also ask CMS to conduct additional cost data analysis, given the great disparity between the minimum and maximum cost in APC 0690, based on the 2012 Median Cost Data File. We believe the cost disparity in APC 0690 may be attributed to three basic types of services: Programming Device Evaluation, Interrogation Device Evaluation, and an initial set-up and programming as described by CPT 93745.

CPT 0307T

We agree that CPT 0307T is assigned to the correct APC, APC 0105, which describes removal of devices. Yet, we are concerned by the great disparity between the minimum cost ($66.33) and maximum cost ($87,993.06) contained in the 2012 Median Cost Data File.

We request that CMS conduct additional cost data analysis to determine if there is greater resource utilization for some of the procedures within APC 0105 that is captured by the cost disparities, and that may indicate relocating some of the procedures to a different APC.

2 Times Rule

The PRT believes that there are several CPTs that violate the 2 times rule, as described below. Some of these may be low-volume (i.e., they do not meet CMS' claims volume significance test for the 2 times rule), but we remain concerned about their APC placement nonetheless.

APC 0604

In the proposed rule's discussion of Extended Assessment and Management APCs, CMS mentions that the Hospital Outpatient Payment (HOP) Panel recommended that the Visits and Observation Subcommittee review the claims data for HCPCS G0379 (Direct referral of patient for observation care) and consider the appropriate APC group for the code.

The PRT was pleased to see this comment because we have long been concerned that placing G0379 within APC 0604 violates the 2 times rule. We had requested that CMS reassign HCPCS code G0379 in our comments on the 2012 OPPS Proposed Rule. In addition, at the February, 2012 HOP Panel meeting, we asked the Panel to recommend that CMS reassign this code.

CMS did not accept our proposal when it finalized the CY 2012 rule. The agency rationale was that historical guidance dispensed in 2003 is still relevant regarding the placement of HCPCS G0379. The 2003 guidance related to old HCPCS codes for direct referral that no longer exist, which were necessary to facilitate then-current Observation payment policies/concepts that also no longer exist. At the August 27-28, 2012 HOP Panel meeting, the PRT asked the Panel to recommend that CMS move HCPCS G0379 from APC 0604 (Level 1 Hospital Clinic Visits) and to reassign G0379 to APC 0608 (Level 5 Hospital Clinic Visits). Below, we provide the information on which we based this request (we note this request varies from the one the PRT made in comment to the 2012 OPPS Proposed Rule).

The geometric mean costs indicate that the resources used for G0379 resemble those expended for high-level clinic visits more than resources for low-level clinic visits. We note that CMS' claims logic for composite APC 8002 treats G0379 similarly to high-level clinic visit codes CPT

code 99205 and 99215. Furthermore, under composite APC logic, both of these codes are assigned to the Level 1 Extended Assessment Composite APC 8002. Yet, when claims processing requirements are not met for the composite (i.e., the eight-hour time frame is not met), the APC grouping for G0379 is forced to a low-level E/M APC group, which is *inconsistent* with the resources involved (as demonstrated by cost data).

When providers are paid outside of the composite APC logic, the current payment is insufficient to cover the resources expended for the direct referral intake. This is illustrated by the following example: when a patient requires physician-ordered observation services, the patient arrives at the hospital nursing unit directly from a physician's office or their home setting. The nursing staff must complete the registration information, review the physician orders and other documentation pertinent to the visit, complete the patient's comprehensive nurse assessment and nursing care plan, enter physician orders for any diagnostic tests, establish and/or reconcile medication administration records, and coordinate care activities related to diagnostic tests. As this list clearly demonstrates, there is a high-degree of work value expended on the intake of each Observation patient. This work is reported on direct referral to observation claims using HCPCS code G0379.

The PRT urges CMS to trust provider claims data that clearly delineate G0379 as interchangeable with a "high-level clinic visit." This also aligns with CMS' manual instructions, which state: *"Each hospital's internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes. Hospitals should ensure that their guidelines accurately reflect resource distinctions between the five levels of codes."* We believe that many facilities have included G0379 in their clinic leveling guidelines.

For this reason, the PRT asked the HOP Panel to recommend to CMS that it assign HCPCS G0379 to the same APC as CPT code 99205 when the Composite APC 8002 criteria is not met. Specifically, we request that CMS reassign HCPCS G0379 from APC 0604 to APC 0608. We believe this is appropriate because the geometric mean cost (from the 2013 OPPS proposed rule supporting files for CPT codes 99205 and G0379) is *very* similar: the geometric mean of CPT code 99205 is $176.54 and the geometric mean cost of G0379 is $180.71.

Placement of G0379 within APC 0608 would resolve the 2 times rule violation for APC 0604 and more appropriately align the resources with a high-level hospital visit when the criteria for Composite APC 8002 are not met. If CMS does not make this change, providers will continue to be under-paid when the services provided and claims processing requirements for Extended Assessment and Management APC 8002 are not met for a "direct referral." The HOP Panel agreed with the PRT and advanced this recommendation to CMS, and the PRT urges CMS to accept the Panel's recommendation.

APC 0623

CPT 36260 appears to violate the 2 times rule within ACP 0623. The median cost of CPT 36260, $6034.38, is higher than two times the lowest median cost, which is $1132.14. We do not believe that CPT 36260 belongs to APC 0623, as it has a very low frequency of utilization. We request that CMS conduct a cost data analysis to investigate this situation and assign CPT code 36260 to

a more appropriate APC.

APC 0229

We believe that both CPT codes 37183 and 37210 appear to violate the 2 times rule and are incorrectly assigned to APC 0229. The highest median cost in the APC is $11,297 (for CPT 37206) and the lowest cost is $3,818.18 (for CPT 37183) and $5,219.85 (for CPT 37210). We believe that both CPT 37183 and 37210 should be assigned to APC 0083, Coronary Angioplasty, Valvuloplasty and Level 1 Endovascular Revascularization of the Lower Extremity.

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

CMS proposes to pay hospitals an additional $10 per dose to cover the cost of purchasing 100% non-Highly Enriched Uranium (HEU) radioisotopes used in diagnostic TC99m scan radiotherapy. The hospital must certify that the Tc99m source is a non-HEU supply of radionuclides, using the full-cost recovery accounting methodology. Hospitals are instructed to report a special HCPCS Q-code (*QXXXX*) on the claim to make this certification and receive the $10 payment.

The PRT supports this initiative in general, but we are concerned that the $10 payment may be far less than the actual costs hospitals would incur to purchase non-HEU radioisotopes. CMS has stated that the agency will adjust this payment based on future cost reporting; if CMS does this, it will alleviate the PRT's concerns. We also support the three options CMS provides to document the purchase of 100% non-HEU radioisotopes, and we appreciate the simplicity and low administrative costs involved in this process.

We are confused by one aspect of the payment process, however. In the proposed rule, CMS states that it: "*would adjust the payment for HCPCS QXXXX code accordingly, reducing the payment for the scans by the amount of cost paid through HCPCS QXXXX code payment.*" We are perplexed by this statement, which seems to be in conflict with the very purpose of the payment. It appears to indicate that CMS will pay for non-HEU isotopes' extra costs, and then deduct that amount from the payment for the scan. This does not make sense to us and we request that CMS explain the reasoning behind this proposal.

In addition, with regard to the *QXXXX* code itself, the PRT advocates using a different approach. We suggest that CMS create specific HCPCS codes to distinguish between HEU and non-HEU Tc99m radioisotopes. (Currently, HCPCS codes do not distinguish between HEU and non-HEU production.) To give an example of this proposal, we provide the following example using HCPCS code A9502, which describes "Technetium TC-99m Tetrofosmin Diagnostic Per Study Dose." We propose to create *two parallel HCPCS codes* to report Tetrofosmin; one to report Tetrofosmin from a HEU source, and the second to report Tetrofosmin from a non-HEU source.

Implementation of two codes for each radioisotope (one non-HEU, one HEU) would provide CMS with specific cost information relating to the radioisotope being used, and simplify hospital reporting — since only one HCPCS code would be needed on the claim. Without having two HCPCS codes available, we suspect that hospitals will not report the additional *QXXXX* code as

proposed, since their radiology charge systems may likely have difficulty incorporating a second charge ($1) for the same service. Even if the hospital's billing systems allow a second reportable code, providers are likely to fail to enter the second charge ($1).

Finally, our hospitals report that their suppliers state that there is no availability of non-HEU isotopes and that this shortage will exist for at least two more years. If and when non-HEU isotopes become available, we believe that hospitals will work with the manufacturers to utilize these sources.

III. Devices

FB / FC Modifier

CMS proposes that the FB/FC modifier apply to "costly devices" and that the APC payment adjustment apply to a specific set of costly devices. The proposal is intended to ensure that the adjustment is not triggered by the implantation of an inexpensive device whose cost does not constitute a significant proportion of the total payment rate for an APC.

The PRT understands the concept of assigning the FB/FC modifier for device-dependent procedures that have devices with Full or Partial Credit. We request clarification regarding the assignment of FB/FC modifier to devices that providers receive at no cost or at an "*inexpensive*" cost, however.

Providers lack clear guidelines or criteria to determine what is meant by "*inexpensive*" and note that interpretation of this term is highly subjective. We also note that there are inconsistencies between the FB/FC modifier procedure listing and the list of procedures CMS provides in Table 21 of the proposed rule (entitled, "Device-dependent Listing"). The FB/FC listing is not an inclusive listing of all device-dependent procedures.

The PRT requests CMS to provide a *complete and explicit list* of procedures that are subject to the FB/FC assignment. Providers must have this clarification in order to prevent any subjective interpretation by the OIG or Medicare contractors of the term "*inexpensive*"; provide clear operational instructions to staff; and facilitate CMS' receipt of uniform and consistent claims data.

IV. Payment for Drugs, Biologicals, and Radiopharmaceuticals

Payment for Separately Payable Drugs

The PRT applauds CMS for agreeing to comply with the statute requiring a payment level of ASP+6% for *all* separately payable drugs. 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 2013 in this area, and urge the agency to finalize the ASP+6% payment level, which 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.

Drug Packaging Threshold

For CY 2013, the PRT understands that CMS proposes to increase the drug-packaging threshold to $80. 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 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" which CMS hopes to create through larger and larger bundles of payment. The problem stems from the fact that our hospitals (like most others across the country) 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 does 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. 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 2013 proposed drug-packaging threshold, if it is finalized at $80.

V. Visits

Critical Care

CMS states that the 2011 claims data do not show a decrease in the median cost for CPT code 99291 and that CMS lacks confidence in the claims data needed to re-cost critical care exclusive of bundled procedures.

CMS' policy towards bundled procedures with critical care changed partway through 2008 and was formalized in policy and APC pricing in 2009. In 2011, the AMA changed the definition of CPT code 99291 to exclude any bundled procedures when billed by facilities. CMS continued conditional packaging of bundled procedures when billed with 99291 until claims data were available.

The PRT argues that median costs for critical care show no patterns before or after implementation of the bundled policy. Both the mean and median costs increase and decrease during the period of time when the bundled policy changed. (See chart, below.)

Year	CPT Code	SI	APC	Single Frequency	Total Frequency	Mean Cost	"True" Median Cost
2008	99291	S	0617	27219	123817	550.41	477.22
2009	99291	S	0617	21771	110867	$589.84	$501.63
2010	99291	S	0617	21080	107110	$597.70	$518.77
2011	99291	S	0617	25150	107058	$568.99	$491.72
2012	99291	S	0617	21654	104932	$596.09	$493.26
2013	99291	Q3	617			$534.44	$520.16

The PRT is concerned that, if the bundled payment policy continues, it will negatively impact smaller rural hospitals and their provision of critical care services. Hospitals with trauma centers typically admit critically ill patients as inpatients; therefore, the critical care services are no longer applicable to the OPPS. We believe that many OPPS claims for critical care services come from smaller, rural hospitals that provide critical care and associated ancillary services to patients who are subsequently transferred to another facility.

If CMS distrusts the claim data for CPT code 99291, it can easily use 2008 claim data (from before the bundling policy) and update them with overall inflation factors. It is important for CMS to adhere to its CPT policy in making OPPS payment. The distinct ancillary services performed by separate departments during a critically ill encounter do not meet CMS' packaging policies.

Transitional Care Management: Proposed *GXXX1*

The PRT would like to thank CMS for its proposal for a new GXXX1 code, defined as "*all non-face-to-face services that are related to the transitional care management that are furnished by the community physician or non-physician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing facility, and inpatient rehabilitation facility; hospital outpatient for observation services or partial hospitalization services; and a partial hospitalization program at a CMHC, to community-based care*." The PRT believes that having a code specifically for reporting post-discharge transitional care management services will allow providers to report the care provided across the continuum and result in better reporting of both services that are currently provided and services that will be provided in the future.

We note that — in the case of many integrated delivery networks and hospitals with provider-based clinics — when the care is being transitioned to the patient's treating physician or non-physician practitioner, that provider is performing care management services in outpatient hospital departments (i.e., provider-based clinic). In these cases, the costs for supporting staff and other resources are borne by the hospital operating the provider-based clinic; these represent legitimate outpatient hospital costs. Therefore, it is important that these costs be reported correctly with the new proposed G-code. Reporting these costs with separate charges and this proposed G-code on outpatient hospital claims from the hospital's clinics means that the costs can *no longer* be included in hospital E/M clinic visit guideline criteria.

The PRT is aware that many hospitals include care coordination in their E/M facility-level guideline criteria and, as a result of this new code, will realize a drop to a lower-level visit code. A drop in the visit level and reporting the G-code with a status indicator "N" will result in hospitals seeing a decrease in payment. Hospitals cannot be recognized for these legitimate costs. Conversely, when a free-standing clinic bills the GXXX1 code, it will receive separate payment, per the Medicare Physician Fee Schedule's proposed rule. Yet, when an outpatient hospital clinic bills this code on its institutional claim, it will receive no separate payment.

In fact, if the code is billed at the end of the 30-day period (as CMS proposes) and it was the only service billed, the claim will be rejected as a claim with an "N" status-only charge and code on the claim. By definition, this code reflects the non-face-to-face services, and is designed to recognize the facility's resources used for services performed in provider-based clinics. To this end, the PRT believes that the code should have a status indicator of "S", with APC payment, and that it should *only* be billed when the care coordination is performed by a qualifying physician or non-physician practitioner in a hospital-based outpatient department.

We do not believe CMS has had an opportunity to think this policy through from the perspective of provider-based clinics. We recommend that CMS follow its current policy of *not* receiving 1500 claims unless the physician or non-physician practitioner provides face-to-face professional services. If CMS wants to track this code for services provided by the physician or non-physician practitioner on the 1500 claim from a provider-based clinic, then the agency needs to explicitly define this goal. Furthermore, when the place of service is 22 for outpatient hospital on the 1500 claim, there should be no separate payment — since the correct policy is that the hospital receives payment under OPPS for this provider-based clinic service.

VI. Inpatient-Only List

The PRT continues to be concerned about the Inpatient-Only List and reiterate our belief that it should be eliminated altogether. It is the physician's role to determine whether or not to admit a patient, based on medical expertise and judgment. By utilizing the Inpatient-Only List, CMS is taking over this role, determining what constitutes inpatient care, and eliminating the physician's decision-making role in these specific circumstances.

The PRT requests that CMS clarify for hospitals and the RAC whether the inpatient-only list is going to be maintained. If it is, we urge CMS to provide clear guidance to the RAC entities to *immediately* stop denying inpatient admissions that meet these inpatient-only criteria. We discuss this issue further below.

APC Placement for Procedures Removed from IP Only List

The PRT makes recommendations about services to remove from the Inpatient-Only List based on our institutions' belief that these services are clinically appropriate to perform in the outpatient setting. Although we often cannot make a recommendation on the APC placement for these CPTs, when we can do so, the recommendation is based on our facilities' cost data. The PRT is concerned about CMS' method for determining APC placement when a procedure is removed from the Inpatient-Only List; in this situation, by definition, CMS has very limited outpatient claims data to use for rate-setting and risks under-valuing these APCs.

For example, based on a request from the PRT, CMS removed CPT 43770 (Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device such as gastric band and subcutaneous port components) from the Inpatient-Only list for CY 2012. Although we did not make a specific APC assignment recommendation to CMS for this CPT code, we fundamentally disagree with CMS placing it in APC 0131, with a proposed payment rate of $3500. This action would significantly under-represent the total costs associated with this procedure.

To assess this view, two of the PRT's member facilities researched their costs for providing this procedure and determined that the supply cost alone for the band ranges from $2700 to $3100. We reviewed one member's average total cost for this service, which is $5,300; the cost of the band ranges from $2700 to $3100. CMS' own geometric mean and median cost calculations for CPT code 43700 estimates the *total cost* to be around $7300. This estimation of the total procedure cost is significantly more reflective of our own estimation of total cost for this procedure.

This analysis highlights that the proposed payment rate of $3500 for CY 2013 is grossly insufficient. The PRT requests CMS to reconsider placement of this procedure into a more appropriate APC.

In addition, we urge CMS to develop an inclusive methodology for APC placement when procedures are removed from the Inpatient-Only List. In general, when a procedure includes a high-cost device, we also urge CMS to work closely with the manufacturer, which is likely to

have received claim and cost information from hospitals that can be of assistance to CMS in accurate rate-setting.

CPT 22856 and 27447

The PRT has always maintained that the Inpatient-Only List should be eliminated, and support removal of any services from this list. We believe that the physician should *always* make the determination of where services are most appropriately performed. For this reason, the PRT agrees with CMS that CPT codes 22856 and 27447 should be removed from the Inpatient-Only List so that physicians can select the most appropriate location for them to be performed. We also agree that the status indicator should be changed to "T" for both codes.

In addition, the PRT provides the following list of additional CPT procedure codes that we believe CMS should remove from the inpatient-only list, since we believe they can be safely performed in the outpatient setting.

Inpatient Only Procedures Recommended for Change from Status Indicator C				
CPT/ HCPCS	**Code Description**	**Milliman (16th Edition)**	**2012 InterQual**	**Comments**
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel		Outpatient	Requested previously in 2012 comments
20661	Application of halo, including removal; cranial			Requested previously in 2012 comments
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta), requiring general anesthesia			Requested previously in 2012 comments
20936	Autograft for			Requested

	spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)			previously in 2012 comments
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction, without bone graft			Requested previously in 2012 comments
21196	Reconstruction of mandibular rami & body with sag split & int fix			Requested previously in 2012 comments
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar			Requested previously in 2012 comments
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 (List separately in addition to code for separate procedure)	Ambulatory if 1-level or 2-level fusions, fusions at or below C4-5, patient wo myelopathy or subjective large neck; Inpatient multilevel fusions/unstable medical comorbids may require overnight		APC Panel recommended removal at August, 2011 meeting. Requested previously in 2012 comments
22558	Arthrodesis, anterior interbody technique, including minimal	Inpatient	Inpatient	APC Panel recommended removal at August, 2011

	discectomy to prepare interspace (other than for decompression); lumbar			meeting. Requested previously in 2012 comments
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)	Inpatient - lumbar; Some OP and IP indications for cervical (see 22548)		Add on code. Can be used with codes that have both IP and OP recommendations. Requested previously in 2012 and 2010 comments
22855	Removal of anterior instrumentation			Requested previously in 2012 comments
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar			Requested previously in 2012 comments
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)			Requested previously in 2012 comments
23472	Arthroplasty, glenohumeral joint total shoulder (glenoid and proximal humeral replacement)	Ambulatory wo history chronic opioid use/dependence, wo serious active medical	Inpatient	Requested previously in 2012 comments

		comorbidities, and wo significant non-shoulder functional limitation and able to receive ambulatory nerve block anesthesia regimens postop; Inpatient if not appropriate for ambulatory nerve block regimens		
35221	Repair blood vessel, direct; intra-abdominal			Requested previously in 2012 comments
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral			Requested previously in 2012 comments
35721	Exploration (not followed by surgical repair), with or without lysis of artery; femoral artery			Requested previously in 2012 comments
35800	Exploration for post op hemorrhage, thrombosis or infection; neck			Requested previously in 2012 comments
37182	TIPS procedure			Requested previously in 2012 comments
37617	Ligation, major artery; abdomen			Requested previously in 2012 comments
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic			Requested previously in 2012 comments
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury			Requested previously in 2012 comments
44300	Open jejunostomy following a diagnostic laparoscopy			Requested previously in 2012 comments

44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)			Requested previously in 2012 comments
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)			Requested previously in 2012 comments
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)			Requested previously in 2012 comments
44602	Suture of small intestine accidental laceration			Requested previously in 2012 comments
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)			Requested previously in 2012 comments
49255	Omentectomy, epiploectomy, resection of omentum			Requested previously in 2012 comments
51840	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); simple	Ambulatory: laparoscopic suspensions, sling procedures, minimally invasive procedures (eg, tension-free vaginal tape); Inpatient: open procedures, multiple repairs, or procedures performed in conjunction with other surgical procedures	Outpatient except inpatient for Burch Culposuspension.	Requested previously in 2012 comments
56630	Vulvectomy, radical, partial;		Inpatient - radical/ hemivulvectomy. Outpatient - partial vulvectomy.	Requested previously in 2012 comments
61624	Transcatheter			Requested

	permanent occlusion or embolization, percutaneous, any method; central nervous system			previously in 2012 comments
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)	Ambulatory: minimally invasive, some standard single level and some elective multiple level procedures; Inpatient: some nonelective or multilevel procedures or patients with major comorbidities or complications		Requested previously in 2012 comments
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	Ambulatory: Patients undergoing limited or minimally invasive procedures. Inpatient: Nonelective or extensive surgery patients (eg, 2 or 3 spinal levels).		APC Panel recommended removal at August, 2011 meeting. Requested previously in 2012, 2011, and 2010 comments
63710	Dural graft, spinal			Requested previously in 2012 comments

RAC Denials

The PRT also wishes to raise an additional issue with CMS: inpatient denials by RAC reviewers when the patient receives a procedure that CMS has designated as "Inpatient Only." We are concerned that RACs appear to be applying medical necessity criteria to their reviews, despite the fact that no CMS regulations require the "medical necessity" criterion to be separately met for inpatient admissions. CMS' contractors are also inappropriately using the Inpatient-Only list to deny short-stay cases that are performed as inpatient stays, merely because the procedure has been removed from the Inpatient-Only List.

We know of cases where this has occurred, necessitating appeals to the Administrative Law

Judge level to have erroneous denials overturned, which constitutes an enormous waste of resources. The PRT requests that CMS address this problem and consider how a facility could be reimbursed for a medically necessary procedure designated as "status C" (inpatient only) if the RAC is allowed to deny the admission as not being medically necessary.

We urge CMS to stress, in both regulatory language and transmittals, that procedures with APC payment rates *can* be performed, covered, and paid by Medicare on an inpatient basis when medical necessity is documented and the physician has ordered inpatient status.

VII. Supervision

In the proposed rule, CMS notes that the supervision requirements under §410.27 do not apply to services provided by OPPS hospitals or Critical Access Hospitals (CAHs) when the services are professional services billed under the MPFS or are PT, SLP, and OT services billed by the hospital as therapy services and paid at the applicable MPFS amount. The exception to this rule is the small subset of services considered "sometimes therapy services"; when these services are provided under a therapy plan of care, the conditions under §410.27 do not apply, When these services are provided by another discipline and not under a therapy plan of care, however, they *are* subject to supervision rules noted in §410.27.

The PRT appreciates CMS clarifying that these instructions apply equally to OPPS and CAHs. We also wish to express our appreciation to CMS for extending the non-enforcement of direct physician supervision requirements for CAHs through CY 2013.

The PRT supports the change from *direct* to *general* supervision for services that were recommended at the HOP Panel at the Panel's August 2012 meeting (i.e., G0008, G0009, G0010, G9141, 51700, 51702, 51705, 51798, 11719, G0127, 29580, 29581, 36000, 36591, 36592, 96360, 96361, 96365 -96376, 96521, 96523, and G0379). The PRT believes that it is *extremely* important for CMS to respect the recommendation of the Panel and implement this recommended change in supervision level.

The PRT is concerned that CMS is using the direct supervision requirement for Part B coverage not as a coverage policy, but rather as a patient safety and quality policy. In fact, the physician supervision requirement is a requirement for coverage and payment of outpatient hospital therapeutic services. We believe that the Hospital Conditions of Participation appropriately and adequately address patient safety and quality issues. As CMS advocates for accountable care, it is very important that payment systems support the most appropriate site of service for care and access to care. We believe that the current default to *direct* supervision for outpatient therapeutic services is a barrier to accountable care.

Therefore, for Part B coverage purposes, the PRT asks that CMS place *all* outpatient therapeutic services under general supervision.

VIII. Outpatient Status — Solicitation of Public Comments

The following comments are specific to CMS' solicitation of public comments on Outpatient (OP) Status. The PRT applauds CMS' willingness to evaluate this complex issue and we urge

CMS to ensure that all policy changes meet critical objectives of protecting beneficiaries from financial liabilities and reduced benefits, **and** of protecting providers from financial burdens stemming from administrative burden as well as denials.

We note that there is a need for additional discussion and data analysis of the various options. We urge CMS to conduct discussions and analyses in an open and transparent manner with all stakeholders. The PRT members would all be interested in serving on a task force that CMS may appoint to explore options. Our comments on this area follow:

- CMS should eliminate observation status entirely and implement a policy to pay a percentage of the MS-DRG for short-stay cases.

- If CMS does not eliminate observation status, the agency should clarify for RACs, MACs, and hospitals the national, evidence-based criteria to determine inpatient admissions' medical necessity.

CMS states: "*In some cases, when the physician admits the beneficiary and the hospital provides inpatient care, a Medicare claims review contractor, such as the Medicare Administrative Contractor (MAC), the Recovery Audit Contractor (RAC), or the Comprehensive Error Rate Testing (CERT) Contractor, determines that inpatient care was not reasonable and necessary under section 1862(a)(1)(A) of the Act and denies the hospital inpatient claim for payment."*

Inpatient status may not be the issue in this case; rather, the issue may lie with observation status. Patients in "observation" receive the exact same care as do patients who are formally admitted as inpatients to the hospital. The physician's orders for clinical services are determined based on the patients' *clinical needs*, not on the patient's *status*. In many hospitals, no specific unit for observation patients exists that differs from the inpatient unit, and usually the same nurse takes care of both "inpatients" and "observation patients." These patients receive a complete assessment on admission and on a regular basis throughout their hospital stay; medications, diagnostic services, care coordination, education, and discharge planning and instructions are provided regardless of their status.

In hospitals' day-to-day world, the decision to admit individuals as inpatients or keep them under observation is made as a matter of regulatory compliance, but this decision does <u>not</u> impact the clinical care provided to the patient. There is virtually *no* distinction between the two other than the provider's reimbursement and, of course, the beneficiary's co-payment liabilities.

Observation was initially intended for use for those patients who present to the Emergency Department with symptoms that needed to be evaluated but that have high likelihood of being resolved within a 24-hour period, such as asthma, congestive heart failure, and chest pain. In order to provide the best care possible, observation status was used to rapidly assess, treat, and discharge these patients without their having to be admitted to the hospital.

With the implementation of the Recovery Audit Contractors (RAC), the newest mechanism to extract reimbursement from providers, the concepts of medical necessity and short-stay admissions have spiraled out of control. Hospitals are now subjected to hundreds of record

requests on a recurring cycle and the review process can often take over a year from beginning to end. In addition, these Medicare review organizations perform retrospective reviews that can occur many years after the patient received care.

- CMS can gather needed information on hospitals' utilization review (UR) programs by creating a new condition code for hospitals to apply when their UR staff has verified the inpatient status with criteria. This will enable CMS to validate several issues around denials of short-stay cases.

In order to avert denials and avoid being targeted by CMS' review entities, many hospital facilities have been forced to create specific departments devoted to processing audits, appeals and refunds, and reviewing inpatient admissions to determine if the care provided meets the medical necessity requirement in the inpatient setting. This work, which is being conducted *solely* to meet CMS' regulations, does not contribute to patient care outcomes.

It does, however, increase the cost of providing health care to Medicare beneficiaries because the hospital staff involved in this review are professional-level personnel who have specialty certification in case management / Utilization Review. They also include either a staff Hospital Physician Advisor or individuals hired under contract with a company that provides these services. (An entire industry has arisen to respond to facilities' burdens related to CMS audits and appeals, which has greatly increased facilities' costs; we are sure this was not CMS' intent.) The resource burden is compounded by the fact that, for smaller facilities, review services are typically only available during the workweek (Monday through Friday), and not on weekends and holidays. As a result, hospitals often lack the ability to review the appropriateness of inpatient admissions prior to short-stay patients' discharge.

The review process itself suffers from a significant number of reviewer inconsistencies and a lack of clear guidance from CMS to both review entities and hospitals. Because the RAC audit process also involves the MAC as the fiscal intermediary, providers experience significant problems getting accounts paid when denials are overturned and the entities fail to communicate with one another. Beyond the time-consuming frustration created by having to follow-up with both entities (and being told that the *other* is responsible for correcting the issue), hospitals that succeed in gaining resolution often have the accounts cross over more than one fiscal year, which has significant cost-reporting implications.

The PRT knows that hospitals without dedicated resources often give up fighting for their due reimbursement despite having provided patients with needed care and services. It is unfair that providers are forced to cease pursuing their just reimbursement because they cannot battle the fiscal intermediaries' and/or RAC's delays and obfuscation. The PRT is concerned by the RACs' recent focus on short-stay admissions and the large number of denials that are being received with inconsistent and incorrect rationale from these review entities. Individually, we have contacted our State Hospital Associations, expressed our questions and concerns to CMS in the Hospital Open Door Forum, and contacted our RAC Regional officers directly.

If CMS does not eliminate observation status, then the PRT urges CMS to provide review entities and hospitals with *clear* information about the evidence-based criteria to be used to deny claims.

In addition, if CMS does not eliminate observation status, we agree that the agency will benefit from additional information about hospitals' utilization review (UR) programs. To this end, we suggest that the agency create a new condition code that hospitals can use on any case where its UR staff have verified the inpatient status with criteria. This will enable CMS to validate several issues, including whether there are more short-stay denials of cases that lack UR review and whether there are fewer MAC/RAC denials of cases that have had UR review.

- CMS should work with Congress to eliminate the three-day qualifying stay requirement for skilled nursing benefits. We note that for numerous DRGs, the geometric mean length of stay is less than three days. CMS wants to encourage the lowest cost setting for patient care. Conversely, if this cannot be changed, then we encourage the agency to consider outpatient observation time as also qualifying the patient for needed skilled nursing benefits.

The issue for the three-day qualifying stay is that the hospital may place a patient in observation for 24 hours in order to determine if there is a need for inpatient care. If this is the case, the individual is formally admitted as an inpatient for two days, which meets the medical necessity requirement. Upon discharge, if the patient needs skilled rehabilitation, however, he or she will *not* be eligible due to having been in observation for one day (and being classified as an outpatient) and then having only been an inpatient for two days.

We recommend that CMS re-evaluate the necessity for the three-day qualifying stay. With the push to decrease length of stay (LOS) and move patients to less-costly outpatient settings, the three-day stay rule is a barrier to needed care. If the three-day stay rule continues, we recommend that the hours spent by the patient in observation count toward the qualifying stay, given that these patients receive similar care as if they had been admitted as an inpatient.

- CMS should work with Congress to address the problems posed by non-covered self-administered drugs and to further neutralize beneficiaries' financial liability when they are admitted to a room and bed.

Patients who go to a bed do not understand why they get billed for self-administered drugs on one occasion (when they are in observation) and not on another occasion (when they have been admitted as an inpatient). The Part D benefit for these drugs is burdensome for patients and does not cover their out-of-pocket costs.

The PRT urges CMS to work with Congress to further "neutralize" beneficiaries' financial liability when they are placed in a room/bed for outpatient observation services and to address the problems posed by non-covered self-administered drugs.

- The PRT does not support the idea of prior authorization. We are concerned with the administrative burden and cost this would add to both CMS and providers.

Layering further administrative costs into the health system by CMS' contractors' providing 24/7 utilization review for prior authorization of inpatient admissions would not improve patient care. It will, however, rather drain precious resources from CMS and providers alike. Furthermore, such a process will not be viable without national criteria, which have yet to be developed.

- The PRT applauds the AB Demonstration Project, but objects to providers having to sacrifice their appeal rights and express our concern about the complexity and administrative burden of billing requirements to produce Part B claims, per the demonstration requirements.

The PRT supports the concept of the AB Demonstration Project, but disagrees that hospitals should have to sacrifice their right to appeal cases that the RACs arbitrarily deny without a sound clinical basis.

A key benefit in this demonstration project is that beneficiaries are held harmless from the financial impact when their case changes from a Part A to a Part B stay. This has critical implications with respect to deductibles, co-pays, and self-administered drugs.

As CMS recognizes, much of the Part A and Part B distinction for acute hospital care stems from the technological advancement of medicine. In many respects, the inpatient Part A and outpatient observation Part B distinction is an artifact of Medicare's having been created in the 1960s. Beneficiaries do not differentiate Part A from Part B when they are admitted to a nursing unit in the hospital; the patient knows (rightly) only that he or she was admitted to the hospital and stayed in a bed. If the patient needs acute inpatient or outpatient hospital care for a three-day length of stay, and meets post-acute requirements for skilled nursing care, then he or she should be covered by Medicare for the skilled nursing benefit.

IX. Hospital Outpatient Department Quality Measures

The PRT understands — and supports — the need to report quality indicators for Medicare outpatients. We believe the quality indicators required by CMS 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 provides medical assessments, diagnostic studies, treatments, and evaluations to determine if admission is warranted.

The PRT once again endorses the concept of further selection of measures for the HOP QDRP. We reiterate that CMS *must* 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.

Furthermore, the PRT recommends that any quality measure selected should have an easily identifiable correlation to clinical outcomes and the patient's experience of care.

Background

The PRT appreciates CMS' clear description of the "National Quality Strategy" principles for development of quality measures. The PRT appreciates that CMS' goal is to align hospital Outpatient Quality Measures (OQM) program with the IQR and ASCQR programs as well as the HHS and CMS Strategic Plans. Such consistency will reduce the operational burden of complying with quality measures.

We were particularly interested that "*person and caregiver experience of care*" is included in the selection criteria. We recognize that other "pay for performance" programs include measurements of patient satisfaction, but wish to note that patient satisfaction is a *highly* subjective measure.

We appreciate the public-private collaboration afforded in the Measure Application Partnership (MAP). We believe that input from stakeholders who encounter health care's everyday operational challenges is vital to the selection of measures that align with best practices.

The PRT requests CMS to clarify the patient population for which OQM apply. The OPPS proposed rule appears to be inconsistent by discussing submission of data about Medicare patients *and/or* Non-Medicare patients. We also seek clarification if, in the topics that are specific to Medicare patients only, CMS refers just to patients covered by "traditional" Medicare or if the measures also apply to "Medicare Advantage" and/or "Medicare Replacement" beneficiaries.

The PRT firmly believes that CMS quality measures should be based solely on data derived (either through claims or data abstracting) on the Medicare population — not all patients treated in the outpatient setting — and look forward to receiving clarification on the above question.

Publication of HOP QDRP Data

The PRT agrees with CMS' statement in the proposed rule that information reported on the Hospital Compare website may not be easily understood by the public. PRT members ourselves have been confused when reviewing data on the Hospital Compare website. If these data are confusing to providers who work in the system every day, we can only imagine how perplexed the average Medicare beneficiary must be.

The PRT is also concerned that the website's information may be misleading to the public, and we question the data's applicability, given their age and the past time-frame in which it was collected. We doubt that Medicare beneficiaries will be able to make informed health care decisions based on data that are old, such as those presented on the Hospital Compare website.

Removal or Suspension of Quality Measures from the Hospital OQR Program Measure Set

The PRT supports CMS' proposal to change the term "*retirement*" to "*removal*" to avoid any misunderstanding about the process. We support using the same criteria for measure removal as are used in the Inpatient Quality Review (IQR) program. Consistency across quality programs makes managing the quality measures process more straightforward for providers.

Suspension of One Chart-Abstracted Measure for CY 2014 and Subsequent Years' Payment Determinations

In principle, the PRT supports the suspension of OP-19 (Transition Record with Specified Elements Received by Discharged Patients). In prior comment letters, we have expressed our concerns about this measure.

Despite this support, we have issues with the process for communicating this suspension, as described in the proposed rule. CMS explains that notices were sent out through Memorandum on 4/2/12 and on 4/12/12 to clarify the agency's intent to not use the data submitted on this measure for payment determination, public reporting, or in validation. The PRT does not think this is a very effective notification method, and we recommend alternative and additional approaches. Elsewhere in the proposed rule, CMS discuss sending e-mail notification to specified hospital staff. The PRT requests that CMS consider a similar notification process for the Outpatient Quality Reporting program.

The PRT also questions the requirement that hospitals continue to be required to submit data on the "suspended" measure. It is not clear to us why hospitals should be required to report chart-abstracted data when CMS does not intend to use these data. What is even more perplexing is that CMS instructs hospitals to report data on the suspended measure by populating "*the submission field with a value that is not meaningful*" and to not submit a null value. We note that not only are hospitals uncomfortable with purposefully reporting invalid data, but also that doing so makes no sense.

In addition, these reporting recommendations are both difficult to comply with and place providers at considerable risk. Submitting meaningful data in the field could lead to data rejection, thereby impacting facilities' ability to meet the requirements for full OP hospital payment update. The PRT recommends that CMS cease collecting data on this measure completely; if it must collect data it does not intend to use, the agency should <u>not</u> instruct hospitals to provide non-meaningful information.

Deferred Data Collection of OP-24 Cardiac Rehabilitation Measure (Patient Referral from an Outpatient Setting) for the CY 2014 Payment Determination

The PRT has voiced concern about this measure and we are relieved that CMS has deferred data collection for Patient Referral from an Outpatient Setting. We understand that this measure is already being captured by NQF and agree that including it in the OQR as well is duplicative and unnecessary.

The PRT suggests that CMS evaluate the option for these data to be considered for implementation as a claims-based measure, rather than as a chart-abstracted measure.

Quality Measures for 2015 Payment Determination

As CMS is well aware, CY 2013 and 2014 will be periods of great challenge for both the provider community and CMS alike. The implementation of ICD-10 will be a monumental task and all of our resources (both providers' *and* CMS') will be focused on the complete overhaul of our coding, reporting, and data collection systems.

We appreciate CMS' consideration in not adding any new measures for collection during CY 2014 for the CY 2015 payment determination. This will allow all of us to spend the necessary time to focus our resources on implementing ICD-10 and providing the training required by such a tremendous change.

In this proposed rule, CMS clarifies the deferral of claims-based measure OP-15 (Use of Brain CT in the ER for Atraumatic Headache). As noted by the PRT in prior comment letters, we are concerned that CMS will not gain complete data for this measure. Coders do not typically code signs and symptoms associated with a conclusive diagnosis, so the codes for associated symptoms that qualify as exclusions may not be available on the claim.

Collection of Data from EHRs

The PRT agrees that the evolution and infrastructure of Electronic Health Records (EHR) will increase the capacity for the electronic reporting of measures, and foster elimination of the burdensome chart-abstraction data submission method.

While the PRT approves of the concept of using data that are collected from electronic health records, we do not support CMS having direct access to a facility's EHR for data abstraction. We support CMS having access within our facility system's firewalls *only* to data in the EHR that specifically address the quality measure. We do not support the use of a direct portal by which CMS gains open access to all data within a patient's EHR.

We encourage the development of functionality by which hospitals can submit specific data elements in electronic format. We believe that a system of this type can be developed that will enable hospitals to provide the necessary information electronically and not increase their burden. We support the terms in the EHR Incentive Program, which provides a foundation for hospitals to send (and for CMS to receive) quality measures through electronic submission.

Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program

We reiterate that requirements to report *any* additional measures in CY 2014 will be extremely burdensome, as providers will be addressing issues arising from ICD-10 implementation. CMS should also consider the quality of the ICD-10 data it will receive during the initial implementation phase, as most of the measures under consideration are code-driven. The PRT requests that CMS consider delaying further expansion in light of ICD-10 implementation.

The PRT appreciates CMS' proposal to initiate a call for input to access the measure domains including Clinical Quality of Care, Care Coordination, Patient Safety, Patient & Caregiver Experience of Care, Population/Community Health and Efficiency. We approve of this approach and urge CMS to include representation from the provider community when gathering input.

Proposed Payment Reduction for Hospitals that Fail to Meet the Hospital OQR Program Requirements for CY 2013 Payment Update

Extraordinary Circumstances Extension or Waiver

The PRT commends CMS on its proposal to continue to grant extensions automatically for the entire locale involved in natural disasters without requiring action on the part of the affected facilities. Several of the PRT member's facilities have recently encountered these extraordinary

circumstances as a result of natural disasters; we understand first-hand the difficulty in requesting an extension under such conditions.

We support CMS' proposal to modify the current process to state that the "*CEO or other hospital designated personnel*" may sign the waiver. The PRT requests that CMS also consider providing a similar extraordinary circumstance waiver in relation to Recovery Audit Contractor (RAC) requests while hospitals recover from a natural disaster.

Form, Manner, and Timing of Data Submission - Generalized Requirements

The PRT asks that CMS consider standardizing the reporting timeframes across all measures. Requiring that some measures be reported each quarter and other measures be reported only during specific quarters is confusing and creates opportunities for missed deadlines. To receive the full OPD fee schedule increase factor, hospitals must comply with submission requirements for chart abstracted data, population and sampling data, claims-based data, and structural quality measure data including all patient volume data.

The PRT reiterates our belief that CMS' quality measures should be based strictly on data derived (either through claims or data abstracting) on the Medicare population – not on all patients who are treated in the outpatient setting.

Proposed Chart-Abstracted and Claims-Based Measures Data Requirements

For chart-abstracted measures, CMS proposes to use data from 3rd Quarter 2013 for the CY 2014 payment determination. For claims-based measures, CMS uses claims from CY 2010 for the CY 2013 payment determinations, and claims from CY 2011 for the CY 2014 payment determination. The PRT questions the need for such a long delay in claim utilization.

In addition, we once again note the inconsistency in the use of Medicare claims versus data from all patients. CMS states that it will use only Medicare FFS claims for structural measures, but proposes to use data from *all* patients (e.g. including non-Medicare patients) for other measures.

Proposed Structural Measures Data Requirements

The PRT appreciate the extension of data submission from 7/1/13 — 8/15/13 to 7/1/13 — 11/1/13. The PRT continues to have concerns regarding some of the structural measures slated for data submission in 2013.

Safe Surgery Checklist

The PRT supports the implementation of a structural measure for facilities to indicate their use of a safe surgery checklist, as long as the reporting requirement is only a "yes" or "no" submission. We do not support the collection of these data on an individual patient or procedure-detailed level. These data are already being collected for accreditation purposes by most facilities.

Hospital Outpatient Volume for Selected Outpatient Surgical Procedures

The PRT again voices our concern about the timeframe for implementation of this data-reporting requirement. Data submission on eight categories of procedures with a wide range of CPT codes will be required between 7/1/13 and 11/1/13, which is right in the midst of the anticipated ICD-10 implementation date in October 2014. Providers' administrative burden of the data collection and reporting will be *extraordinarily* high.

The PRT also points out that the low volume of procedures performed by a facility is often the result of a shortage of specialists in the provider's geographical area. For this reason, we question the validity of the data captured by this measure. At a minimum, hospitals should report the number of performing physicians along with the number of procedures to give better insight into the volume data.

If CMS insists on moving forward with this data submission requirement (despite the ICD-10 implementation burden and concerns about the measures), the PRT requests that CMS reduce the number of categories selected for initial submission. We remain concerned about CMS' intent for hospitals to report "*all patient volume data*" and feel strongly that the data should apply only to the Medicare population for which CMS is responsible.

Proposed Data Submission Requirements for OP-22: ED-Patient Left Before Being Seen for the CY2015 Payment Determination

The PRT appreciates CMS making the timeline for submission of measure OP-22 consistent with that of other structural measures.

The PRT continues to have fundamental issues with this particular measure and remains concerned about the consistency of the data that CMS will gather through this measure. Our concern stems from the differences in facilities' record-keeping practices for patients who leave the facility prior to being seen. At many facilities, if a patient leaves prior to registration, no official medical record is created.

We also request that CMS define what "*being seen*" means more specifically. Specifically, we seek information about what point a patient is considered to have "*left without being seen*" — e.g., before or after triage. We seek clarification about whether CMS is attempting to measure the volume of patients who are being triaged or the volume that is actually being treated.

Some facilities have triage performed by a physician, advanced practice nurse, or physician's assistant. Technically, the intent of this measure can be met if a patient is "evaluated by a physician/advance practice nurse/physician's assistant"; yet, in these cases, no treatment has been rendered to the patient. And, a patient may leave the facility between being triaged and actually receiving any treatment; it is not clear if CMS would consider this patient as having "*left without being seen*." The PRT requests that CMS clarify these questions so that providers can better understand the intent and provide more accurate data to the agency.

Proposed Population and Sampling Data Requirements for the CY2014 Payment Determination

The PRT disagrees with CMS' assertion that sampling requirements should apply based on both

Medicare and non-Medicare cases. We believe that CMS should focus *only* on the population of patients for which the agency is responsible.

Proposed Hospital OQR Program Validation Requirements for CY 2014 Payment Determination and Subsequent Years

Randomly Selected hospitals

The PRT commends CMS on reducing the number of randomly selected hospitals from 800 to 450. Like providers, CMS will be preparing for ICD-10 implementation, and additional validation will increase the burden on both facilities and CMS staff. We once again request that CMS recognize the strain under which hospitals will be operating during this difficult transition period.

Proposed Use of Targeting Criteria/Proposed Targeting Criteria for Data Validation Selection

In general, the PRT believes that the proposed targeting criteria are reasonable and we agree with CMS' decision to limit the criteria for targeted selection to only 1) fails the validation requirements that applies to CY 2012 payment determination, or 2) has an outlier value on the data it submits.

We appreciate CMS' consideration of prior comments regarding the additional targeting criteria that had been proposed previously.

Encounter Selection

The PRT believes that CMS' proposed validation requirements are reasonable and would be acceptable to providers if they were the *only* Federal data submission requirement. We are deeply concerned, however, that these record requests will supplement those that are already established as part of the Federal integrity audit processes (e.g., RAC, Medicaid Integrity, ZPIC, MAC).

While these programs were developed by CMS to serve specific purposes, the end result will be that facilities will receive multiple requests from each contracted entity. These requests will be made concurrently and meeting them will significantly increase hospital providers' labor investments and costs. The PRT encourages CMS to review the validation process with respect to other data requirements, rather than seeing it as a single request, and to consider the operational impact that receiving multiple audit entity requests will have on any single provider.

Because of the volume of Federal audits and reviews, the PRT requests that record request documents clearly identify whether the review is as a result of random selection or is a targeted selection.

Validation Score Calculation

The PRT appreciates CMS' acknowledgement of our request last year to keep the timeframe for submission of medical record documentation consistent with other CMS contractor (i.e. RAC), at

45 days. Managing different submission timeframes may lead to inadvertently missing deadlines, which no provider wants to do.

The PRT also agrees with CMS' proposal that the CMS contractor's letter should be addressed to hospital medical record staff that are identified in the IP Quality Reporting program to the state QIO. Consistency in mail delivery will aid hospital staff to comply with reporting deadlines.

The PRT also requests that CMS consider an alternative way of communication, such as e-mail, to acknowledge reconsideration requests. E-mail is a standard method of communication in many facilities and we urge CMS to explore the use of e-mail notification.

Proposed Hospital OQR Reconsideration and Appeals Procedures for the CY 2014 Payment Determination and Subsequent Years

The PRT agrees with the proposal to provide a new method of notifications in relation to reconsideration and appeals. We believe it would be beneficial for CMS to provide e-mail acknowledgement to the designated hospital personnel that the reconsideration request was received, and to provide a formal response to the same designee with outcome of the reconsideration request.

Ambulatory Surgical Centers (ASC) Quality Reporting Program

The PRT applauds CMS' efforts to develop equity in reporting requirements by including ambulatory surgical centers (ASCs) in a quality reporting program. As the PRT has frequently commented to CMS, it is appropriate to assure quality of care to Medicare beneficiaries in *all* settings that provide outpatient services — including ambulatory surgical centers.

Considerations in Selection

The PRT appreciates the harmonization of ASC Quality Measures with Outpatient Quality Measures with respect to the principles used in selection of measures. We agree that quality measures should focus more on the needs of a patient with a particular condition than on the setting where care is provided.

ASC Measures for CY14 Payment Determination

The PRT appreciates CMS's decision to implement only five of the eight ASC Measures proposed in the previous proposed rule.

The PRT requests that CMS clarify why the ASC quality measures process differs so greatly from the proven process that has been implemented in the hospital outpatient department setting. If CMS' initiative seeks to improve health care outcomes, safety, quality, efficiency and satisfactory patient experiences, we question the decision not to implement the process consistently across sites of service.

While the measures proposed are not an issue, the PRT is deeply concerned by the process for data capture. The PRT continues to oppose the submission of data via a "Quality Data Code" and

application of payment indicator "M5." This proposal will impose an administrative burden on ASCs and be operationally difficult to manage. Although many of the same measures are currently submitted by hospitals (some as inpatient quality measures), these facilities are not using a QDC to identify them. The PRT does not understand why the reporting method for identical measures differs so dramatically from one site of service to another.

ASC Measures for CY15 Payment Determination

The PRT understands the ASC measures for CY 2015 and notes that they are similar to measures proposed for reporting the CY 2014 payment determination for hospitals. But, the categories of surgical CPTs are different. The ASC table does not include the range of Cardiovascular codes or the range of Respiratory codes, although the procedures represented by these codes are regularly performed in the ASC setting. We recommend that CMS keep the categories consistent and standardize categories for both hospitals and ASCs.

We also note, once again, the inconsistency in the dates for data collection and submission. For the Safe Surgery Checklist use, ASCs will participate in data collection from 7/1/13 — 8/15/13. Requiring data submission consistently (by quarters) across all measures and across sites of service would assure adherence to deadlines and increase the integrity of the data submission.

Again, the PRT wishes to note that this data collection occurs in the midst of ICD-10 implementation and urges CMS to consider the burden that this proposal will impose.

Proposed ASC Measures for Future Consideration

The PRT reiterates our previous comments about the proposed HAI measure that is specific to Influenza Vaccination Coverage Among Health care Personnel. Our concerns about the availability of vaccinations and the overlap with all patient vaccination requirements apply in the ASC environment as well. (See below.)

Influenza Vaccination Coverage Among Healthcare Personnel

This measure concerns the PRT for several reasons. First, as CMS states, the Centers for Disease Control and Prevention (CDC) already collect these data. We believe that it is a duplication of effort for CMS to include this measure, given that another government entity is already collecting these data.

Second, we are also concerned with CMS' definition of "*health care personnel*" (HCP), because it includes employees who are not directly involved in patient care — specifically, clerical and billing personnel. In today's health care environment, many clerical and billing personnel are located in offices outside of the hospital's health care facility. It is not clear to us why these employees are included in the requirement, or where CMS draws the line for HCP inclusion among various categories of personnel.

Third, we are concerned about the apparently annual shortage of influenza vaccines. The potential for vaccine shortage is compounded by the recent CMS proposed rule, "CMS 3213-P Medicare & Medicaid Program: Influenza Vaccination Standard," which was issued on 5/4/11.

This proposed rule would require that hospitals offer vaccinations to *all* patients during the 2011-2012 flu season as a Condition of Participation (COP). The availability of vaccine products will be compromised if CMS implements the requirement that *all* health care personnel and *all* patients receive vaccination.

As indicated in comments by the American Hospital Association (AHA), this is an "unfunded mandate in the midst of a difficult economic climate." The PRT wholeheartedly agrees with the AHA about this, and requests that CMS seriously evaluate the impact on the health care industry that would arise from implementation of this measure.

The PRT appreciates CMS' recognition of the time and effort involved in planning for quality reporting in its decision not to add any measures for CY 2014, CY 2015, CY 2106, or subsequent years at this time.

Technical Specifications – Data Publishing

The PRT supports publication of both ASC and hospital data, but once again voice our concern about the interpretation of the data by the public. The PRT is concerned that the information may be misleading since we ourselves sometimes have difficulty understanding it. As noted, we question the applicability of the data due to their age and the past timeframe during which they were collected. We are concerned that Medicare beneficiaries will be able to make informed health care decisions using data that are old.

CMS has acknowledged the difficulty in understanding the data and the PRT is certain that the agency will take steps to provide more clarification to users of this important quality data.

X. Revisions to Quality Improvement Organization (QIO) Regulations

The PRT supports the proposed immediate advocacy process that would enhance hospital quality improvement organizations' ability to better meet the needs of Medicare beneficiaries. The PRT agrees that the proposed changes are a positive step to improve aspects of the Quality Improvement Organization (QIO)'s review activities that have been deemed to be problematic, and to enable the QIOs to improve this program.

The changes proposed would give QIO the authority to send and receive secure transmission of electronic versions of medical education. The PRT supports giving the QIO this authority. We agree that a complaint that is submitted electronically to the QIO meets the requirement for written submissions. We believe that this process will speed up the process so that beneficiaries' concerns can be resolved in a timely manner and save the cost of copying records.

The PRT agrees that it is appropriate to limit the time-period for submitting a written complaint, but we suggest that three years from the original date of service is still too long a time frame. Beneficiaries should be encouraged to report quality of care issues as soon as possible in order to enable a through and timely review and resolution to complaints. The longer the timeframe is to report these concerns, the more burdensome to providers and practitioners the process becomes. It also complicates the process as details about the case may become stale and less memorable over time. For those reasons, the PRT recommend a shorter timeframe of 18 months instead. We

believe that this timeframe is better aligned with the goal of facilitating and improving the timeliness of efforts to address complaints.

In addition, in order to address beneficiaries' complaints and to facilitate a continuous quality review for care, the PRT believes that allowing the QIO to use its authority *in lieu* of a written complaint to respond allegations is appropriate.

The changes proposed would also provide more detailed and improved procedures for QIOs when completing Medicare beneficiaries' complaint reviews and general quality care review, including procedures related to a new alternative dispute resolution process called "immediate advocacy." The PRT appreciates and supports this concept as an informal alternative dispute resolution process that can quickly resolve an oral complaint made by a beneficiary or his/her representative about the quality of health care received. The concept has the potential to greatly decrease the length of current process. We agree that it is appropriate to allow the QIO to determine that the complaint includes concerns that could be deemed significant, substantial, or gross and flagrant violations of the standard of care to which beneficiaries are entitled.

The PRT believes that the six-month timeframe is sufficient for submitting complaints electronically. This will allow the QIO to respond in a timely manner to reported quality issues, which, in turn, will minimize the process's timeframe. The PRT also agrees that the use of an oral consent will streamline the process by eliminating the need to process additional paperwork and fostering a timely response to beneficiaries' concerns.

The PRT believes that, in order to conduct a thorough investigation, it is appropriate to allow the beneficiary to submit additional concerns after his/her initial submission of a written complaint. We also support giving beneficiaries the right to consider additional concerns either during the same complaint review or as a separate complaint. The proposal gives the QIO the authority to separate a beneficiary's concerns into separate complaints if the QIO determines the concerns relate to different episodes of care. This proposal will facilitate the identification of all potential concerns and allow a more directed approach to isolating issues. We recommend that the investigation use an evidence-based standard of care to determine standards of care and allow an unbiased evaluation of providers. This aligns with other quality and data initiatives to which providers adhere in their day-to-day operations.

The PRT strongly disagrees with the proposal to allow the QIO to interpret best practice and/or available norms to establish measurements of whether the care was appropriate. This is especially troublesome when the provider is denied due process by being unable to appeal. We feel strongly that allowing the QIO to interpret the standards for care will lead to overly subjective determinations and negate the physician's care decisions that were based on an assessment of the patient's situation and health care needs.

The PRT also believes that it is also important for CMS to maintain the requirement that QIOs utilize individuals who have active staff privileges in one or more hospitals. The clinical practice standards that stem from new, evidence-based standards are rapidly changing and can *only* be evaluated by an actively practicing clinician.

Finally, the PRT believes that standardization of response timeframe is beneficial and we support

the requirement that the QIOs issue its interim initial determination within seven calendar days after receiving all medical information. It is important for providers to be able to discuss a determination *before* it is finalized and to submit additional medical evidence, as well. We agree that records management should facilitate a through and timely response, but there are instances when additional information may be found in the course of the hospital's investigation. When this occurs, hospitals should be allowed to submit this new information for consideration during the QIO's final review.

XI. Other Areas of Comment

Although CMS does not discuss its proposal for new HCPCS G-codes or modifiers to report therapy services in its CY 2013 OPPS Proposed Rule, the PRT has comments related to this area, since this proposal will impact our hospital facilities. We have also submitted these concerns in our MPFS comment letter.

Therapy Services

The PRT is disturbed that CMS has singled out outpatient rehabilitation services for application of onerous and overly complicated billing requirements. While we understand that the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA) required CMS to develop a "claims-based data collection strategy," we assert that the billing and coding process for therapy services is already sufficiently complex to accomplish this requirement.

It should be noted that Physical Therapists (PT), Occupational Therapists (OT), and Speech Therapists (Speech) are in extremely short supply and facilities across the nation have very tight budgets. These factors make it impossible for hospitals and other therapy providers to simply hire more therapists to comply with the proposed regulations, which are extremely resource-intensive.

The PRT respectfully requests that CMS consider facilities' restrictions in both staffing and budgets when it considers methods for implementing the MCTRJCA regulations. Our goals are consistent with the agency's — both the PRT and CMS seek to maintain access to needed services and provide effective, high-quality services to the Medicare beneficiaries we serve. The proposed regulations would hamper efforts to achieve those goals.

Use Diagnoses Codes to Capture Functional Status

CMS proposes this new system because it believes that the diagnoses codes are insufficient to capture the patient's functional status. The agency states, in its discussion about various methods for collecting data, "*…we believe that the primary diagnosis on the claim is a poor predictor for the type and duration of therapy services required*."

The PRT agrees with CMS, when *only* the principal diagnosis is used. This is not necessarily the situation, however. Secondary diagnoses *also* appear on the outpatient claim and provide additional information regarding the patient's clinical condition. They can also indicate functional limitations, for example, when hemiparesis is coded as a secondary diagnosis. In addition, the imminent implementation of the ICD-10 system will advance the use of diagnoses

to better define the patient's clinical picture.

The PRT believes that, since diagnosis coding has long been a part of the billing process, diagnoses codes should be used to assist in data collection activities. This is preferable to CMS implementing a new system that relies on additional and onerous documentation and claims coding, as is the case with the proposed system of G-codes plus severity modifiers.

Furthermore, we note that the "Development of Outpatient Therapy Payment Alternatives" (DOTPA) is due to be published during the second half of CY 2013. The PRT suggests that CMS continue with the current payment cap with medical review for requested exceptions until *after* the DOTPA report has been published and analyzed. Otherwise, CMS runs a very large risk that it will implement this radically new process in January 2013 and then be forced to change the process upon review of the DOTPA report. It would be unfair and burdensome to force providers to change systems twice in such a short period of time (and it would be particularly challenging for institutional providers who are just now coming under the payment cap regulation).

We request that CMS use diagnoses codes as part of the data collection process, and then create a viable system that responds to the findings of the DOTPA report during CY2013. The current process of requesting an exception to the set cap payment amount only applies to a small percentage of the patient population. The exception process to the payment cap would be much more manageable for hospitals and other providers than applying multiple G-codes and modifiers to every claim.

CMS' Proposal to Report G-Codes and Modifiers Regarding Beneficiary Status is Overly-Complex

The PRT believes that the proposed system of reporting HCPCS G-codes along with severity modifiers is too complex and will likely result in CMS receiving consistently poor information *at least* during the first two to three years of its use. This overly complex process will require a significant level of education and time to implement in a compliant manner – and consume time and resources that hospitals simply cannot spare. We suspect that it will take several years of practice, provider education, and revisions to providers' documentation systems before CMS will be able to consider the data reliable enough to use in making future payment decisions.

The PRT suggests that CMS will have better success in capturing functional status and severity through the use of a quality data registry rather than attempting to capture it via claims data. To illustrate this problem, the PRT provides the following summary of the G-code proposal's complexity:

- First, the therapist must submit the correct CPT-4 therapy procedure code for the service ordered, provided, and documented.
- Then the therapist must simultaneously submit <u>both</u> a "current status" G-code (which may be a generic functional limitation code or a specific functional limitation code) at the initial encounter and after either the 10th treatment day or 30 calendar days (whichever is less) *and* a projected "goal status" G-code.
- At the end of treatment, a third type of G-code (the "discharge status" code) must be

submitted along with another "goal status" G-code.
- To each of the G-codes (current, goal, or discharge status), the therapist must calculate a modifier that appropriately reflects the severity or percent of limitation being reported.

CMS proposes only two sets of three functional limitation G-codes: one set of primary codes and one set of secondary codes. Yet, a patient often has three, four, or more functional limitations. Under the proposed system, the therapist will *only* be able to treat two functional limitations at one time. In order to treat additional functional limitations, the therapist must wait until the primary and/or first of the secondary limitations is resolved. At that point, the therapist can stop coding on that limitation, and begin coding the third functional limitation — using the same set of codes that had been used for the now-resolved functional limitation.

Yet, this does not reflect that way in which therapy services are actually provided. Therapists who identify a patient as having more than two functional limitations never treat the first two limitations until they are resolved and *then* begin treating additional limitations. This would be bad patient care and unnecessarily extend the treatment period with absolutely no benefit to the patient. Initiating the proposed system with just two sets of functional limitation codes is counter-productive to CMS' goal to increase efficiency and reduce unnecessary services.

A second problem is presented by the fact that, for <u>each</u> of these G-codes, the provider must calculate and attach a modifier that describes the patient's severity and/or percent of limitation. Because CMS is not going to recommend or prescribe any specific functional assessment, therapists will select what they believe, in their professional estimation, to be the most appropriate assessment tools — but then will have to convert the scores captured by those tools to correlate with the percentage range of one of the 12 severity modifiers that CMS proposes.

A third problem is presented by the fact that therapists do not always need to use formal assessment tools for secondary limitations. Therapists often identify that a patient has more than one functional limitation at the onset of therapy, and develop related treatment goals for these limitations. They may not, however, need to use a formal assessment tool in order to do so. For this reason, the PRT requests that CMS <u>not</u> require the reporting of secondary functional limitations. Therapists should be allowed to select the most clinically significant functional limitation to be reported and not be overloaded by being required to perform additional and unnecessary tests.

CMS also requested comments on the three separate pairs of G-codes discussed in the CY2011 PFS rule. We agree with CMS' assessment that these G-codes are "*potentially redundant and confusing*" and add that, in our view, they will provide the agency with little meaningful data.

Assessment Tools

CMS asked for comments on assessment tools that are used to assign the modifier percentage of limitation. Feedback from the PRT facilities' clinical therapists indicates that many, varied assessment tools are available and used by therapists in their daily work. The specific assessment tool used depends on the body part and/or the functional limitation of focus. It should be noted that Physical Therapists, Occupational Therapists, and Speech Therapists all use different

assessment tools. For these reasons, one assessment tool cannot be applied to all situations in order to apply a modifier.

The use of multiple assessment tools also presents complications under the proposed system. Each of the many assessment tools that are regularly used by therapists would require the measure score to be converted to the percentage scale of the specific modifier in order to assign the correct severity modifier. Whenever a therapist used a new assessment scale, the therapist would have to understand how to correctly convert the results to the correct modifier percentage scale. Electronic medical records might be able to convert assessment scales to the correct modifier but it takes time and resources modify documentation programs and depending on the assessment scale used, the conversion calculations would differ from tool to tool.

Regardless of whether CMS uses a 5-point, 7-point, or 12-point scale, assignment of the modifiers will be burdensome for clinical therapists. While therapists use assessment tools every day, they have never before been required to convert one scale reading to another in order to assign a modifier to a G-code on the patient's claim. This process is confusing, overly complex, and certain to generate faulty data. As previously noted, the PRT believes that CMS will capture more accurate and complete data through a process that does not rely on claims data, such as a registry.

Adaptation for G-Codes by Select Categories of Functional Limitations

If CMS decides to use "Select Categories of Functional Limitations" rather than generic G-codes, the PRT urges the agency not to require therapists to report more than the primary functional limitation. A set of generic codes to indicate the primary functional limitation will be easier and less complicated to implement than requiring multiple sets of category codes with associated sets of G-codes ("current status," "goal status," and "discharge status"). This type of data collection is needlessly complicated and will be burdensome to therapists. As the PRT has noted, it is not appropriate for the claims process and should be handled via a quality reporting mechanism instead.

PRT members discussed CMS' Table 19 with clinical therapists to gauge their reaction. The response was that a patient's functional limitation may very well fit in *more than one category*. Therapists are as varied in their approach to assessment and treatment as the individual patients are unique in their needs. Using the categories presented in Table 19 might require a therapist to use three sets of codes to describe one functional limitation. For example, for a patient with a post-operative hip fracture, the functional limitation can appropriately be captured by the"Walking and Moving Around", the "Changing and Maintaining Body Position", and the "Self Care" categories. If forced to choose one category, one therapist might code the limitation as "Walking and Moving Around," while another therapist might choose one of the latter codes. Neither therapist would be wrong in their categorization. Without extremely clear definitions and guidelines for these categories' use, different therapists are likely to use different categories. CMS will be deprived of reliable and consistent data and will not be able to use the information to design a better payment system.

In addition, CMS does not specify why it proposes to require a third G-code for "discharge status". The PRT believes that using a "current status" code and a "goal status" code will suffice.

The last "current status" and "goal status" code that are reported accurately represent the end of treatment and record the patient's progress just as well as a "discharge status" code would. If the patient requires further treatment, another evaluation code would be submitted with "current status" and "projected goal status" codes. The evaluation code provides an indication that this is a new treatment period and a new "goal status" is being submitted.

Reporting Frequency

CMS has proposed that the "current status" code be reported every 10 treatment days, or 30 calendar days after treatment day one, whichever is shorter. We recommend that CMS change the reporting of "current status" to coincide with the last treatment day in the calendar month or the last day of treatment — whichever comes first.

Many providers bill recurring outpatient therapy claims on a monthly basis and this reporting schedule would fit into therapy providers' systems and processes. It would be much easier to implement edits to identify and stop claims that lack the appropriate status codes than to try to edit for every 10^{th} treatment day.

CMS has indicated that the 10/30 frequency is consistent with provider documentation requirements, since progress notes are required in the same time frame. Many providers have included the needed elements of the progress report in their daily treatment notes. For these providers, remembering to submit a "current status" code every 10^{th} treatment day would not coincide with documentation and would create an extra step for therapists to take. For consistency, progress note requirements can be changed to the last treatment day of the calendar month or the last day of treatment, whichever comes first.

As previously discussed, the "discharge status" codes are unnecessary, since the "current status" that is reported on the last day of treatment essentially reports the same information.

Implementation Date

While CMS has proposed a six-month testing period, the PRT feels that a minimum of a full year is more appropriate and will ensure that CMS gains accurate information from this system.

Summary

The process CMS proposes is, in our view, too complex and will requires a significant amount of education and time for hospitals to implement in a compliant manner. The system of reporting functional status and severity is more suited to a quality data registry. This is not a goal that can be easily accomplished via claims data. For this reason, we recommend that CMS use a registry in conjunction with primary and secondary diagnosis codes, and not rely on additional documentation and claims coding to capture this information.

If CMS insists on implementing this proposal, the Provider Roundtable makes the following recommendations, which we believe are necessary to minimize the confusion, poor quality data, and provider burden that the proposed system will create:

- CMS should maintain the current payment cap with medical review for requested exceptions until after the DOTPA report is published and analyzed (and not implement a short-term system that will require revision based on the DOTPA report's outcomes).

- CMS should not use "discharge status" codes, which are unnecessary and add too much complexity to the proposed system. We recommend that CMS only use the "current status" and "goal status" G-codes.

- CMS should not require secondary functional limitations to be reported. Therapists should be allowed to select the most clinically significant functional limitation to be reported as the primary functional imitation.

- CMS should not develop and/or recommend one specific assessment tool for therapists to use in assigning the appropriate modifier, as this is not reflective of how therapists actually work.

- CMS should change the reporting frequency for the "current status" G-code to coincide with the last treatment day in the calendar month or the last day of treatment, whichever comes first.

- CMS should allow a full year to implement the new codes and modifiers to ensure that the new system generates compliant and accurate coding and billing.

Provider Roundtable: c/o Carolinas Healthcare System, Attn: John Settlemyer, AVP Revenue Cycle,
PO Box 32861, Charlotte, NC 28232-2861
704-512-6483 or 704-222-0399 | *John.Settlemyer@carolinashealthcare.org*

Attachment A. 2012 Provider Roundtable Members

Jennifer L. Artigue, RHIT, CCS
Director, Medical Records,
Health Information Management
Our Lady of the Lake Regional Med Center
5000 Hennessy Blvd.
Baton Rouge, LA 70808
225-765-8847 (W)
337-923-8865 (M)
Jen21306@ololrmc.com

Kathi L Austin, CPC, CPC-H, CCP
Corporate Executive Director
Revenue Integrity
Mercy Health System
645 Maryville Center Ste 100
St. Louis, Missouri 63141
314-364-2520 (W)
314 223-5700 (M)
314-364 – 3625 (F)
kathi.austin@mercy.net

Freda Brinson, CPC, CPC-H, CEMC
Compliance Auditor,
Corporate Compliance
St. Joseph's/Candler Health System
5353 Reynolds Street
Savannah, GA 31405
912-819-8964 (W)
912-247-0177 (M)
brinsonfr@sjchs.org

Kathy L. Dorale, RHIA, CCS, CCS-P
VP, Health Information Management
Avera Health
3900 W. Avera Drive
Sioux Falls, SD 57108
605-322-4731 (W)
605-261-9110 (M)
605-322-4522 (F)
kathy.dorale@avera.org

Janet V. Gallaspy, BS, RN, MPH-HSA
Corporate Compliance Operations Manager
Corporate Compliance
Forrest General Hospital
PO 16389
Hattiesburg, MS 39404-6389
601-288-4462 (W)
601-606-5458 (M)
jgallaspy@forrestgeneral.com

Jerry Hill, MA
Chargemaster Coordinator
University Health System
Business Center, 355-2 Spencer Lane
San Antonio, Texas 78201
210-358-9260 (W)
210-279-0233 (M)
jerry.hill@uhs-sa.com

Yvette Marcan, RN, MA, RHIA, CCS
Clinical Reimbursement Specialist
Health First Inc.
3300 Fiske Blvd
Rockledge FL 32955
321-434-5168 (W)
321-917-1448 (M)
yvette.marcan@health-first.org

Victoria McElarney RN, MBA, FACHE, CPC-H
Director, Revenue Integrity & Improvement
Robert Wood Johnson University Hospital
1 Robert Wood Johnson Place
New Brunswick, NJ 08903
732-418-8423 (W)
908-208-6623(M)
victoria.mcelarney@rwjuh.edu

Diana McWaid, MS, RHIA, CCS, CPC
Director, Medical Coding & Revenue Integrity
UCLA Healthcare
924 Westwood Blvd, Suite 720
Los Angeles, CA 90059
310-794-6230 (W)
dmharrah@mednet.ucla.edu

Kathy Noorbakhsh, RN, BSN, CPC, CPC-H
Project Manager, Finance/ Compliance Officer
UPMC Mercy / Magee-Women's Hospital of UPMC
300 Halket Street
Pittsburgh, PA 15213
412-641-3849 (W)
412-983-0820 (M)
noorkj@mail.magee.edu

Terri Rinker, MT (ASCP), MHA
Revenue Cycle Director
Community Hospital Anderson
1515 N. Madison Ave
Anderson, IN 46011
765-298-2110 (W)
317-414-7852 (M)
trinker@ecommunity.com

Anna Santoro, MBA, CCS, CCS-P, RCC
Revenue Cycle Integrity Manager
Hartford Hospital/Hartford Healthcare
80 Seymour Street
Hartford, CT 06102
860-972-2335 (W)
amsanto@harthosp.org

John Settlemyer, MBA, MHA
AVP, Revenue Management /
CDM Support
Carolinas HealthCare System
PO Box 32861
Charlotte, NC 28232-2861
704-512-6483 (W)
704-222-0399 (M)
John.Settlemyer@carolinashealthcare.org

Julianne Wolf, RN, CPHQ
Revenue Integrity Manager
Erlanger Health System
975 E. Third St Suite 708-B
Chattanooga, TN 37403
423-778-4771 (W)
423-432-2875 (M)
julianne.wolf@erlanger.org