



Provider Roundtable

Asante Health System (OR)

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)

Our Lady of the Lake Regional Medical Center (LA)

Robert Wood Johnson University Hospital (NJ)

Saint Joseph's/Candler Health System (GA)

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

UCLA Healthcare (CA)

UPMC Mercy / Magee Women's Hospital of UPMC (PA)

University Health System (TX)

August 30, 2011

Donald Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Dr. Berwick,

Re: ***CMS-1525-P, Medicare and Medicaid Program; Proposed Changes to the Hospital Outpatient Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement on Patient Notification Regulations for Calendar Year 2012 Rates***

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the 2012 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on July 18, 2011.

The Provider Roundtable (PRT) includes representatives from 15 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, 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 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

Cost Reporting

Magnetoencephalography (MEG)

For the new revenue codes 086x for Magnetoencephalography (MEG), CMS proposes to utilize cost center 3280 (Electrocardiogram [ECG], and Electroencephalography [EEG]) as the primary center and cost center 5400 (Electroencephalography [EEG]) as the secondary center. The PRT believes the prioritization of these two cost centers is reversed and recommends that CMS adopt cost center 5400 as primary and 3280 as secondary.

At the August meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups, it was noted that one Medicare Administrative Contractor (MAC) has granted a non-standard subscribed cost center on the cost report specific for MEG (line 54.01). This is a subscribed line to cost center 5400 and supports the PRT position that 5400 should be the primary cost center.

The PRT urges CMS to adopt this non-standard subscribed cost center line nationally for all hospitals performing MEG. We further ask CMS to evaluate and publish the data from the subscribed cost center line. We request that CMS outline, for all hospitals, the method by which more discrete cost center lines can be requested for capital expensive services having their own unique National Uniform Billing Committee (NUBC) revenue codes. In addition, we believe that MACs should notify CMS when they grant new, non-standard subscribed cost center lines so that the agency can evaluate the information in light of its use of cost center and claims data under both the OPPS and IPPS.

Implantable Devices Charged to Patients & Other New Cost Centers

In recent years of OPPS rulemaking, CMS has greatly improved the information it provides to the public, such as the median cost files. In the spirit of improving the transparency of the OPPS rate-setting methodology, the PRT seeks additional data regarding hospitals' reporting of revenue codes and cost centers.

We encourage CMS to publish information on the range of cost to charge ratios (CCRs) for the "Implantable Devices Charged to Patients Cost Center" for the 437 reporting hospitals (or for the updated number of such hospitals when the final rule is issued). Doing so will enable the public to assess whether, at least for these hospitals collectively, reporting under this new cost center is resulting in higher CCRs as was originally expected. In addition, the PRT asks CMS to publish data regarding the number of hospitals reporting revenue code 0278 on their claims. We are interested in learning whether CMS intends to apply the newly resulting CCR only to revenue center 0278.

In addition to data related to this new cost center, the PRT requests that CMS publish additional data on hospitals reporting the other new non-standard cost centers and the corresponding revenue codes — including 3120 for Cardiac Catheterization Laboratory, 3230 for CAT Scan, and 3430 for MRI.

The PRT would also like to suggest a format by which CMS can share information about all hospitals reporting various revenue codes and cost centers. Our suggestion is for CMS to simply add a few rows to the Revenue Code to Cost Center crosswalk already publicly available. This will provide the additional information we are requesting related to the number of hospitals reporting claims data under certain individual revenue code and the number of hospitals having a corresponding primary, secondary or tertiary cost center on their cost reports.

We have attached a sample version of the Revenue Code to Cost Center crosswalk with the additional rows being requested along with yellow highlighted cells where we are asking CMS to report the collective number of hospitals reporting the revenue codes on their claims and cost centers on their cost reports. Below, we provide a redacted version of the crosswalk for very common revenue codes and primary cost centers to illustrate our suggestion. Providing this information on the CMS web site will further improve the transparency of the OPPS rate-setting process.

Revenue center ID & # of Hospitals Reporting	Description	Used in 2010 OPPS	Primary cost center source for CCR	Primary cost center name
0250	Pharmacy	Y	5600	Drugs Charged to Patients
Add # of hospitals			Add # of hospitals	
0260	IV Therapy	Y	4800	Intravenous Therapy
Add # of hospitals			Add # of hospitals	
0270	Medical/Surgical Supplies	Y	5500	Med Supplies Charged to Patient
Add # of hospitals			Add # of hospitals	
0278	Medical/Surgical Supplies: Other implants	Y	5500	Med Supplies Charged to Patient
Add # of hospitals			Add # of hospitals	
0320	Radiology - Diagnostic	Y	4100	Radiology-Diagnostic
Add # of hospitals			Add # of hospitals	
0360	Operating Room Services	Y	3700	Operating Room
Add # of hospitals			Add # of hospitals	
0390	Blood Storage/Processing	Y	4700	Blood Storing, Processing, & Trans.

Add # of hospitals			Add # of hospitals	
0391	Blood: Administration (e.g. Transfusion)	Y	4700	Blood Storing, Processing, & Trans.
Add # of hospitals			Add # of hospitals	
0450	Emergency Room	Y	6100	Emergency
Add # of hospitals			Add # of hospitals	
0481	Cardiology: Cardiac catheter lab	Y	3120	Cardiac Catheterization Laboratory
Add # of hospitals			Add # of hospitals	
0510	Clinic	Y	6000	Clinic
Add # of hospitals			Add # of hospitals	
0610	Magnetic Resonance Tech. (MRT)	Y	3430	Magnetic Resonance Imaging (MRI)
Add # of hospitals			Add # of hospitals	
0636	Drugs Require Specific ID: Drugs requiring detail coding	Y	5600	Drugs Charged to Patients
Add # of hospitals			Add # of hospitals	
0750	Gastrointestinal	Y	3340	Gastro Intestinal Services
Add # of hospitals			Add # of hospitals	
0762	Treatment/Observation Room: Observation room	Y	6201	Observation Beds (Distinct Part)
Add # of hospitals			Add # of hospitals	

II. A. 2. e. (6) Cardiac Resynchronization Therapy Composite APC (APCs 0108, 0418, 0655, and 8009) AND

III. D. 6. Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes (APC 0108)

The PRT generally supports the creation of Composite APC 8009 for CRT-D and the restructuring of existing APCs 0108, 0418 and 0655. We are fundamentally opposed to the introduction of a “capping mechanism” based on another payment system, however. In a significant departure from longstanding policy, CMS proposes to introduce the concept of a

“payment cap” on existing APC 0108 and new APC 8009 by limiting payment to the lesser of the calculated APC median cost or the standardized payment rate for IPPS MS-DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization and without Medical Complications and Comorbidities). The agency has stated that this proposal stems from its belief that it is not equitable to pay more for these services under the OPPS than under the IPPS.

As CMS has frequently reminded the APC Panel, hospital providers and other stakeholders, each payment system (IPPS, OPPS, MPFS, etc.) is unique and should not be compared to one another. The methodology to develop Inpatient MS-DRG rates is vastly different from the claims based methodology used under OPPS. Furthermore, there is much debate in the Inpatient community regarding the vast variation in cost by geographic area. These are significant reasons not to look across payment systems to establish a cap. Furthermore, we are unclear why CMS would assume that the inpatient rate setting methodology is more accurate than the outpatient methodology, especially since CMS has put several mechanisms in place for device-dependent APCs to ensure improved accuracy of claims data, such as the procedure-to-device and device-to-procedure edits. These same types of claims protections are not applied to INPATIENT claims. We do not even know if the devices are accurately reported on IP claims — it is questionable, at best.

CMS believes its proposal of a payment cap to APCs 8009 and 0108 is appropriate based on the assumption that outpatients who receive these services would not have complications or comorbidities (CCs) or major complications or comorbidities (MCCs) and are, therefore, less acute and resource-intensive to treat in the outpatient setting. This assumption is invalid. Hospitals have worked very hard to educate physicians to select the inpatient versus outpatient site of service on a case-specific basis. In addition, the coding concept of CCs and MCCs does not apply to outpatients. CMS knows full well that complications and comorbidities exist in outpatient populations. We would have expected CMS to conduct and publish rigorous coding analysis on the OP claims data before bringing this proposal forth. Furthermore, we remind CMS that the decision about patient status rests solely with the intent and ordering authority of the attending physician.

Therefore, it is inappropriate for CMS to depart from its usual rate-setting methodology and propose to pay APC 0108 or APC 8009 at the lesser of the APC median cost or the IPPS standardized payment rate for MS-DRG 227. Utilization of a stable and consistent APC rate-setting methodology is *critical* to maintain provider confidence in Medicare’s payment systems. CMS has consistently instructed the provider community of the need to code and bill completely and accurately, since claims data alone are used to set future payment rates. To not use claims data because the agency “*suspects potential site of service enticements*” is not an appropriate rationale for limiting the payment for APC 8009 or APC 0108. It is particularly inappropriate when CMS is not using the same rationale to review payment rates of *other* APCs.

The PRT strongly encourages CMS to study the data further before making assumptions about outpatient vs. inpatient costs. In addition, the PRT recommends that CMS:

- Analyze geographic practice patterns for inpatient versus outpatient procedures;
- Analyze geographic cost patterns of the implant cost;
- Wait for 2013, when new CCRs from the specific implant cost center will provide more accurate information for median cost development.

If enacted as proposed, CMS could completely disregard provider outpatient claims data, which both the Panel and CMS have consistently put forth as the basis for calculating OPSS payment rates. With this proposal, CMS is dismissing the provider claims data it has and is, instead, looking across care settings to create “parity”. CMS has not done so before, even when the agency has been asked to do so.

CMS cites authority under section 1833(t)(2)(E) of the Act as the rationale for this proposal: *E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.* The PRT firmly believes this citation applies only to adjustments made within the OPSS and does not give CMS unilateral authority to make equitable adjustments across payment systems.

The PRT expects CMS to set the payment for newly proposed APC 8009 and existing APC 0108 based solely on the use of outpatient claims data and not to limit the outpatient APC payment rate to the inpatient MS-DRG rate. If CMS proceeds with its proposal, we would expect an immediate “parity” adjustment to the payment for drugs under OPSS whereby CMS would remove the drug packaging threshold and pay separately for all drugs as it does in the physician office setting.

Two-Times Rule: APC 604 and HCPCS Code G0379

The PRT requests that CMS analyze why APC 0604 is consistently in violation of the two-times rule and why this violation continues to be unresolved. The claims file shows that the cost associated with HCPCS code G0379 (Direct admission of patient for hospital observation care) is much higher than the cost of the other codes within APC 0604 (see chart below).

Proposed Median Costs for Hospital Outpatient Services, by HCPCS code for CY 2012										
HCPCS	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean cost	Median Cost	CV
99201	V	0604		135142	135805	\$4.35	\$771.66	\$84.36	\$52.01	112.431
99211	V	0604		4006379	4295457	\$4.69	\$651.54	\$74.35	\$49.92	100.262
G0101	V	0604		25542	25961	\$3.66	\$633.87	\$61.30	\$45.67	75.828
G0245	V	0604		31	31	\$18.15	\$253.85	\$65.41	\$70.49	80.419
G0379	V	0604		18294	54846	\$36.11	\$4,064.73	\$493.69	\$367.41	89.935

Because HCPCS code G0379 is reported only in the scenario of a direct admit for hospital observation services, the clinical homogeneity of G0379 is more similar to the services represented by the higher-level E&M codes than to those represented in the lower levels. The median cost data support this statement. Based on CMS' median cost data calculated from provider claims data, the median cost for G0379 is closest to the median cost calculated for CPT 99285 (Emergency Department Visit Level 5) as noted in the chart below. For this reason, the PRT recommends reassignment of G0379 to APC 0616.

Proposed Median Costs for Hospital Outpatient Services, by HCPCS code for CY 2012										
HCPCS	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	Median Cost	CV
99285	V	0616		901868	2304824	\$88.22	\$1,845.96	\$445.06	\$370.90	57.047
G0379	V	0604		18294	54846	\$36.11	\$4,064.73	\$493.69	\$367.41	89.935

If CMS does not agree with assignment to APC 0616, the PRT alternately recommends CMS create a new APC and assign G0379 as a single code to this separate APC. The clinical similarity with the higher E&M level codes also supports that G0379 should be assigned to the composite APC for Level II Extended Assessment and Management (8003) along with CPT codes 99284 (Emergency Department Visit Level 4), 99285 (Emergency Department Visit Level 5), 99291 (Critical Care First Hour), and G0384 (Level 5 Hospital Type B ED Visit). The median costs for CPT 99205 (Office/Outpatient Visit New Level 5) and 99215 (Office/Outpatient Visit Established Level 5) are significantly lower than the median cost for G0379 and would therefore remain with composite APC Level I Extended Assessment and Management (8002). (See chart below)

Proposed Median Costs for Hospital Outpatient Services, by HCPCS code for CY 2012										
HCPCS	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	Median Cost	CV
99205	V	0608		80907	89547	\$20.63	\$1,416.18	\$200.60	\$177.77	72.859
99215	V	0607		575837	660265	\$14.23	\$1,171.74	\$158.08	\$137.94	77.700

In summary, the PRT recommends that the two-times rule violation for APC 0604 be resolved by reassigning G0379 to APC 0616 and assigned to the composite APC 8003.

Computed Tomography of Abdomen and Pelvis (APCs 0331 and 0334)

The PRT sincerely thanks CMS for rectifying the error made in assigning new CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material), 74177 (Computed tomography, abdomen and pelvis; with contrast material) and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions) to the single Computed

Tomography APCs for 2011. As we have stated since publication of the 2011 Final Rule, the services described by CPT codes 74176 — 74178 are not “new services”. They are existing services now being described by new codes that describe a combination of services that have been historically provided and reported with two distinct legacy CPT codes.

We appreciate the validation of the merit of our view presented during the winter 2011 APC Panel meeting. In addition, we are grateful for the efforts and support of the American Hospital Association and the American College of Radiology on this issue.

We agree with the use of predecessor CPT code claims data for the creation of new APCs 0331 (to which CPT 74176 would be assigned) and 0334 (to which CPTs 74177 and 74178 would be assigned). The data analysis and cross-mapping of legacy codes (in which CMS describes the use of 2009 codes and claims data in combinations that are thought to represent the new codes, to simulate payment for the new codes) are consistent with the rationale CMS described for Endovascular Revascularization of the Lower Extremity. We believe this approach is precisely the one CMS should have employed from the outset for the APC assignment of the new CPT codes for CT Abdomen and Pelvis.

For consistency with other Imaging Composite APCs (although the PRT still does not support all of the Imaging Composite “rules”) we agree that all other composite imaging rules should apply as described, and we support the claims preparation approach described (in which CMS did not use this subset of data to create the medians for the other composite APCs).

As the CPT Editorial Panel moves forward with the creation of additional “new codes” to describe a combination of services that have historically been reported with two or more legacy CPT codes, we expect CMS to continue using the same logic as employed for Endovascular Revascularization and for CT Abdomen and Pelvis to establish median costs that are commensurate with the legacy claims data.

APC 0040 Level 1 Implantation / Revision / Replacement of Neurostimulator Electrode

The PRT agrees with CMS’ proposal to reassign CPT codes 63663 and 63664 from APC 0687 to APC 0040 in order to resolve the two-times rule violation within APC 0687.

Based on CMS’ claims analysis, since 61% of claims containing CPT codes 63663 or 63664 did not contain device HCPCS codes C1778 or C1897, the PRT recommends the creation of two *new* HCPCS codes to specifically identify the replacement of neurostimulator electrodes percutaneous array(s) and the replacement of neurostimulator plate and paddle(s). These two new HCPCS codes will allow for the differentiation between revision and replacement procedures in the claims data, and foster analysis of the cost differences between replacement and revision. Identification of cost differences between these procedures will yield more appropriate analyses for calculating future median costs for the procedures and an evaluation of whether they should be assigned to the same APC group. We also seek device-to-procedure and procedure-to-device edits to ensure the device code is reported so that complete cost is calculated in future analysis.

Proposed OPSS Payments to Certain Cancer Hospitals

The PRT understands that the 2010 Affordable Care Act (ACA) required CMS to conduct a study to determine if, under OPSS, the costs incurred by Cancer Hospitals exceed those of other hospitals. The ACA also authorized the Secretary to provide an appropriate adjustment to the Cancer Hospitals to reflect any identified higher costs.

In the 2012 Proposed Rule, CMS describes a study indicating that Cancer Hospitals are paid 64 cents on each dollar, while other OPSS hospitals are paid 91 cents on each dollar. Although some of the differences between Cancer Hospitals and other OPSS hospitals may be explained by differences in patient population and technology, the PRT struggles to understand why the difference is so large. We wonder if the difference would remain as significant if an updated PCR was used and compared against other hospitals.

The PRT believes that Congress' goal is to protect beneficiary access to care related to cancer services, rather than to protect specific hospitals. We do not believe that either CMS or Congress wants to undermine access to care by taking money from the OPSS payment system and moving it to Cancer Hospitals. The proposed rule would do exactly that, however, thereby aiding Cancer Hospitals at the expense of all other providers. We believe this proposal fails to recognize differences in the Cancer Hospitals' relative efficiencies. We are also concerned for the beneficiaries, since increasing the APC payment rate will also increase the beneficiaries' co-pays.

For these reasons, the PRT opposes redistributing money from other hospitals to implement this positive adjustment for Cancer Hospitals, but does believe that CMS should identify a different mechanism for making this adjustment. Alternate methods must be examined so that all other hospitals and beneficiaries are not penalized. One such approach is having Congress study and update the payment-to-cost ratios for those Cancer Hospitals outside of the normal OPSS updating process. Ultimately, we believe that Congress, rather than CMS, must address this issue and that new funds may be required to protect Cancer Hospitals, all other hospitals, and beneficiaries.

Wage Index Changes

The PRT recommends that CMS make no changes to the wage index methodology for OPSS calculations and that the agency works to address the systemic issues within the wage index calculations. The causes of the fluctuations are rooted in the independent changes made over time to affect payment for a subset of hospitals, and now the methodology has many pieces and is complex. The PRT believes that CMS needs to simplify the system to correct for the fluctuations without creating two distinct methodologies for payment calculation on the facility provider side.

OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

Reimbursement for Separately Payable Drugs (Average Sales Price)

The PRT understands and appreciates that CMS proposes to continue using the redistribution process it started in CY 2010 to move some dollars from packaged drugs to separately payable drugs in order to compute an average sales price (ASP) -plus payment amount for separately payable drugs.

CMS' current proposal results in a proposed ASP plus four percent (ASP+4%) payment level for separately payable drugs for CY 2012, compared to the ASP+5% hospitals receive today. Both of these payment levels fall short of what the PRT has consistently requested: for CMS to provide reimbursement for *all* separately payable drugs using at least ASP+6%. We continue to believe this to be the *minimum* acceptable payment level to cover the acquisition cost for drugs.

Although CMS can be commended for creating a reallocation methodology to create appropriate payment levels for separately payable drugs, the PRT believes this methodology is unnecessarily complex and that instead CMS could simply comply with the statute that calls for a payment level of ASP+6% for *all* separately payable drugs to cover drug acquisition costs, and then provide a separate appropriate payment to address pharmacy handling/overhead costs. Providing payment of at least ASP+6% for separately payable drugs in CY 2012 would allow CMS to comply with the statute and reimburse providers appropriately for drug acquisition costs.

If CMS elects to continue with a reallocation process, the PRT requests CMS to move a greater percentage of dollars from uncoded packaged drugs to separately payable drugs in order to achieve at least a payment level of ASP+6% for all separately payable drugs. We believe this is appropriate, given that a disproportionate amount of pharmacy handling/overhead costs are currently being associated with both coded and uncoded packaged drugs instead of with separately payable drugs. As CMS knows, charge compression leads to an under-estimation of the cost pool associated with separately payable drugs that, in turn, leads to an unacceptably low ASP-plus percentage.

Currently, CMS appears to be comfortable moving approximately 23% (\$161 million) of costs from coded packaged drug to separately payable drugs, while only moving about 11% (\$54 million) of uncoded packaged drug costs. The PRT believes that CMS can — and should — redistribute the same portion of total costs from uncoded packaged drugs as it has proposed for coded packaged drugs, as both pools of packaged drugs behave similarly with respect to the impact of charge compression.

Coded and uncoded packaged drugs are handled similarly when it comes to drug mark-up practices. In fact, one could argue that uncoded packaged drugs are likely to be even *lower* in cost than coded packaged drugs, and possibly subject to even *higher* mark-ups. This results in even more pharmacy handling/overhead costs being associated with these drugs than with either coded or separately payable drugs. Therefore, the PRT believes that CMS should use the same redistribution approach for coded and uncoded packaged drugs and move 23% of the costs from

both pools to separately payable drugs before computing the ASP-plus percentage for separately payable drugs.

Finally, if CMS continues with the reallocation process, the PRT believes that CMS will receive more complete and accurate data from hospitals if it simply *requires* providers to report HCPCS codes for all drugs under OPPS that have HCPCS codes. In general, it is no longer burdensome for providers to report HCPCS codes, since many state Medicaid programs mandate reporting both HCPCS codes and NDC numbers/codes. The PRT noted this at the recent APC Advisory Panel meeting and we hope CMS will take this fact under consideration. The PRT believes that, by making such a “requirement”, CMS will clearly signal to hospitals that this is a priority and not an option. This will result in an increase in the number of HCPCS-coded packaged drugs hospitals report, particularly if hospitals understand that CMS uses a portion of the coded packaged drug data to help set future reimbursement rates for separately payable drugs.

Since hospitals are now required to have a HCPCS code in order to report an NDC number/code to Medicaid programs (including using J3490 as miscellaneous), mandating HCPCS code reporting for all drugs with a HCPCS code and reporting J3490 for all drugs without a HCPCS code will not present any additional burden to providers.

The PRT also recommends that CMS leave revenue code reporting to the discretion of hospitals and mandate that contractors accept detail coding on revenue code 25X reported line items, if utilized. The PRT acknowledges that hospitals and the American Hospital Association (AHA) are concerned about additional requirements that increase hospitals’ operational burden, but with the advent of Medicaid NDC reporting requirements, the PRT strongly believes that this is no longer a relevant issue. For this reason, we encourage CMS to discuss this in detail with the AHA and at a minimum ask the provider community for its input on this type of requirement in the 2012 OPPS Final Rule.

Drug Packaging

For CY 2012 the PRT understands CMS proposes to increase the drug packaging threshold from \$70 to \$80. We have a fundamental problem with CMS’ continued use of a drug packaging threshold in the hospital setting when 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. If this is not feasible, we urge CMS to maintain the current drug packaging threshold of \$70 rather than to raise it.

Diagnostic Radiopharmaceuticals

Once again, the PRT wishes to reiterate that it does not support CMS’ packaging decision for diagnostic radiopharmaceuticals and contrast agents. Although we understand conceptually that packaging creates “efficiency incentives”, we firmly believe that CMS should *only* package low-cost items and supplies. This is particularly true for items and supplies with substitutes, so providers can make efficient choices without compromising patients’ clinical care.

We do not understand why CMS seems to consider diagnostic radiopharmaceuticals to be “supplies” rather than “drugs”, despite the fact that the statute considers diagnostic radiopharmaceuticals to be drugs. As such, it is our firm belief that diagnostic radiopharmaceuticals should be treated as drugs rather than supplies.

Radiopharmaceuticals are not ordered in bulk, do not sit on a shelf waiting to be used, and are not interchangeable. We refute CMS’ assertion that packaging diagnostic radiopharmaceuticals gives providers flexibility to select the most efficient products, services, care delivery, etc. This assertion is simply not true. For example, a patient who presents for a bone study requires a radiopharmaceutical appropriate for that study — even if that specific diagnostic radiopharmaceutical is more expensive than one used for a soft tissue study. CMS must recognize that hospitals cannot select the least-expensive radiopharmaceutical and substitute it for a more expensive one — unless, of course, we restrict services provided to our patients and only serve those who need certain types of scans.

Therefore, the PRT again urges CMS to provide separate reimbursement for all diagnostic radiopharmaceuticals with a median cost greater than the current drug packaging threshold.

Hospital Outpatient Department Quality Measures

The PRT understands and supports the need to report quality indicators for Medicare outpatients, who are typically in our hospitals for 24 hours or less. During that time, hospital staff provide medical assessments, diagnostic studies, treatments, and evaluations to determine if admission is warranted. We believe the quality indicators required by CMS must be *very* specific and must relate to the patient’s current outpatient visit.

While the PRT endorses the concept of further selection of measures for the HOP QDRP, we believe it is vital for CMS to provide information about how reporting a specific measure will affect the measurement of hospital quality, and how facilities can ensure the data are captured efficiently. Only then will providers be able to understand how the proposed standards will specifically measure quality, and how reporting the measures will affect the hospital’s ability to capture the data elements efficiently. The PRT also recommends that any quality measures selected have an easily identifiable correlation to clinical outcomes and to the patient’s experience of care.

The PRT appreciates CMS’ clear description of the new principles for development of quality measures and was especially interested that “patient’s experience of care” was included in the selection criteria. We recognize the fact that other “pay for performance” programs include measures of patient satisfaction, but wish to note that patient satisfaction is a *highly* subjective measure.

In addition, in general, the PRT requests clarification on some of CMS’ proposed principles. In the first principle, CMS states: “*to the extent practicable and appropriate, outcome and patient experience of care measures should be adjusted for risk factors or other appropriate patient population or provider characteristics.*” The PRT is unclear about this statement and requests

CMS to provide examples of how the adjustments would be applied. We appreciate CMS' indication that it intends to align measures with best practices among other payers and urge CMS to work with other payers, as providers struggle with the lack of alignment between CMS' requirements and other payers'.

The PRT also requests clarification from CMS about the patient population for which Outpatient Quality Measures apply. The OPSS Proposed Rule appears to contain inconsistent information about submission of data on Medicare patients and/or non-Medicare patients. In the topics specific to Medicare patients only, we request that CMS clarify if it is referring only to patients covered by "traditional" Medicare, or if these measures also apply to "Medicare Advantage" or "Medicare Replacement" policyholders. The PRT firmly believes that CMS' quality measures must be based strictly on data related to the Medicare population (derived either through claims or data abstracting) rather than on *all* patients treated in the outpatient setting.

The following are our comments on specific proposals about quality measures:

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 have encountered confusion when reviewing data on the Hospital Compare website, and we are well-versed in this content area. If the data are confusing to providers, we can only imagine how perplexed the average Medicare beneficiary will be when trying to use the site.

The PRT is concerned that the information may be not only confusing but also misleading to the public. We question the applicability of the data due their age (based on the timeframe during which it was collected, several years earlier) and our concern that Medicare beneficiaries may not be able to make informed healthcare decisions using data that potentially may no longer reflect a hospital's quality of care. The PRT requests CMS to consider using a more current timeframe for HOP QDRP, in order to provide beneficiaries with access to the most timely and accurate information for making their healthcare decisions.

Proposed Revisions to Measures Previously Adopted for the Hospital OQR Program for CY2012 Payment Determination

Patients Left without Being Seen

The PRT appreciates the proposed requirement to submit only numerator and denominator counts once per year in an effort to decrease data collection burdens. We are concerned, however, with the consistency of the data that CMS will gather using that approach.

The PRT is additionally concerned about this specific measure due to a lack of clarity on CMS' part and differences in facilities' record-keeping practices for patients who leave without being seen. We request that CMS provide a more specific definition of "being seen" and clarify the point at which a patient would be considered to have "left without being seen" for data collection

purposes; specifically, does this occur before or after triage? At many facilities, no official medical record is created for an individual who leaves prior to registration. In this case, it would be impossible to report that the individual had left without being seen.

It would also be helpful to know if CMS' goal is to measure the volume of patients triaged or the volume actually treated. For example, in some facilities, triage is performed by a physician, an advance practice nurse, or a physician's assistant. In these cases, the patient would meet CMS' stated intent if the measure is designed to assess the volume of patients who are "*evaluated by a physician/advance practice nurse/physician's assistant*". Yet, no treatment might be rendered at that point. A patient may leave the facility after being triaged but prior to receiving treatment. The PRT requests CMS to clarify if such a patient would be considered in the counts of patients having "left without being seen". While this may appear to be a small issue, the manner in which the data are reported can greatly impact the information posted about a facility's quality of care.

Proposed New Quality Measures for CY2014 and 2015 Payment Determinations

Considerations in Expanding and Updating Quality Measures

The PRT supports the criteria CMS describes for assigning priority to quality measures. CMS' statements that priority is assigned based on "*greatest mortality and morbidity in the Medicare population*" and "*conditions that are high volume and high cost for the Medicare program*" support the PRT's opinion, noted above, that measures must be reported *only* for the Medicare population.

Collection of Data from Registries

The PRT supports the use of registries to collect data for future quality measures as an alternative to chart abstraction. We appreciate CMS' detailed definition of "registry" in the proposed rule. The PRT believes that any and all registries should be required to obtain CMS' approval and/or sponsorship in order to be considered for data-gathering activities. Further, if registry participation becomes a requirement, hospitals must be given adequate time to implement processes and registrations for registry participation.

Collection of Data from EHRs

The PRT supports the concept of using data collected from electronic health records (EHRs), but opposes CMS having direct access to a facility's EHR for data abstraction. We believe that a process to foster specific data submission from the EHR can be developed to provide the necessary information electronically without increasing hospitals' operational burdens.

We support access within our facility systems' firewalls to data in the EHR that only and specifically addresses quality measures being required for reporting. We do not support a direct portal by which CMS gains open access to all data in a patient's electronic health record. The PRT encourages the development of functionality for hospitals to submit specific data elements using an electronic format.

Proposed New Hospital Outpatient Quality Reporting (OQR) Measures for CY2014 payment determination

As CMS is well aware, CY 2013 is going to be a year of enormous challenges for both the provider community and the agency itself. The implementation of ICD-10-CM/PCS will be a monumental task and all of our resources (both providers' and CMS') will be focused on successful completion of the overhaul of our entire coding, reporting, and data collection systems.

For this reason, we strongly suggest that CMS consider delaying *any* expansion of the OQR Program that would require additional reporting during Calendar Year 2013. This would be similar to the freeze applied to new ICD-10-CM codes in order to get the system implemented. We request that CMS allow all providers and its own agency the necessary time to focus resources and energies on the implementation and training efforts that this tremendous change will require. We believe this is in the best interest of everyone involved, including beneficiaries, to ensure all new measures can be considered and data collection implemented accurately.

Proposed New NHSN HAI Measures – Surgical Site Infection

The PRT appreciates CMS' thorough description of the rationale for including this new HAI measure and the attempt to align quality measures across programs. We are unsure, however, about the number of healthcare facilities that currently report through the existing NHSN infrastructure. CMS indicates that twenty-one (21) states currently require data submission on this measure, but the statistics indicate that less than half of the states are currently required to report. We seek clarification from CMS on how the agency proposes to collect data from non-NHSN-participating facilities.

CMS states in the proposed rule, “*We are proposing that hospital outpatient departments use the existing NHSN infrastructure and protocols that already exist for this proposed measure to report it for Hospital OQR Program purposes.*”

The PRT wishes to point out that NHSN instructions for surgical site infections designate procedures by ICD-9-CM procedure codes; but outpatient procedures are coded using CPT codes due to the fact that ICD-9-CM procedure codes are not a HIPAA-compliant transaction set for outpatient claims. Most outpatient facilities do not assign ICD-9-CM procedure codes to outpatients because of HIPAA. Yet, CMS proposes to make the NHSN instructions applicable to outpatient reporting. CMS appears to be suggesting that hospitals have to not only code a non-HIPAA compliant code set in order to report this quality measure, but also to “double code” an outpatient claim in order to report the data under the code set already adopted by NHSN's infrastructure. Current reporting of surgical site infections through NHSN require between 22 and 30 specific data elements on *each* surgical procedure identified. The PRT requests that CMS consider the enormous administrative burden caused by such a comprehensive data-abstracting measure on facilities that are already struggling to meet all of their reporting requirements.

We also note that CMS states that this measure will reflect “*surgical site infections occurring within 30 days after an NHSN-defined operative procedure*”, but does not address the fact that there are approximately 84 procedures defined by NHSN! The volume of data abstraction required for this proposal was not clearly described in the proposed rule, and mandating such a large number of procedures to be reported will be tremendously burdensome. For this reason, the PRT proposes that CMS select a *limited* number of surgical procedures for which data submission is required in order to increase data integrity and accuracy while minimizing providers’ burdens.

Proposed New Chart-Abstracted Measures

Diabetes

The PRT notes that these measures are focused primarily on services provided in a physician’s office or physician-based clinic (“primary care measures”), rather than in a hospital outpatient facility. Moreover, we do not believe these measures are applicable to the outpatient setting. CMS agreed with our comments in the 2008 OPPTS rule, noted the patient challenges associated with this measure, and decided not to implement these measures. In the CY 2012 proposed rule, CMS acknowledges the challenges faced by hospitals amid implementation of different programs, and we ask CMS to consider these issues once again.

The PRT recommends that CMS explore the option to apply these measures *only* in settings where primary care services are provided, since the measures appear to be more applicable in a physician hospital-based clinic setting rather than in traditional outpatient ancillary departments.

Should CMS determine that this measure is applicable to the entire outpatient population, the PRT believes that more specific details on the agency’s intent are needed. Specifically, we are concerned about the high volume of patients in various hospital departments (including the ER) who have diabetes coded as a diagnosis on their claim. The sad reality is that there is a diabetes epidemic in this country, and a large number of our patients have this disease. It is not clear, however if the measure would only be applicable when diabetes is the *first* listed diagnosis, or if diabetes appears in *any* position on the beneficiary’s claim. We also seek clarification regarding scenarios such as a patient who is seen in the Emergency Department for a fracture and is subsequently discharged, but who has diabetes coded as a secondary diagnosis: would such a case be subject to this measure?

Should CMS move ahead with the proposed diabetes measure, the PRT asks CMS to consider delaying implementation until after meaningful use implementation and wider adoption of the EHR.

Cardiac Rehab

We understand that the measure under consideration by CMS for inclusion in the OQR Program (“Cardiac Rehabilitation: Patient Referral From an Outpatient Setting”) is already being captured by NQF. Inclusion in the OQR is, therefore, a duplicative requirement for data submission. The PRT suggests that CMS evaluate the option for these data to be considered for a claims-based measure, rather than as a chart-abstracted measure.

Proposed Structural Measures

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

Once again, the PRT wishes to voice our concern about the timeframe for implementing this data reporting requirement. Data submission on eight categories of procedures with a wide range of CPT codes will be required between July 1 and August 15, 2013, a mere six weeks prior to the ICD-10 implementation date (October 1, 2013). The administrative burden of data collection and reporting will be extreme and occurs at a very bad time for providers.

If CMS insists on moving forward with this data submission requirement despite the ICD-10 implementation burden, the PRT requests that, at a minimum, CMS either reduce the number of categories selected for initial submission, or expand the submission window beyond the indicated 45-day time period.

The PRT also would like to note that a low volume of procedures performed by a facility is often the result of a shortage of specialists in the facilities’ geographical area, which calls into question the validity of this data capture measure. Furthermore, it is just as important to report the number of physicians as the total number of procedures. CMS should collect the number of procedures in each category and the number of physicians. To assess quality, it is imperative that the volume of procedures be compared to the volume of physicians performing such procedures. A hospital reporting 1,000 procedures in a category with 50 physicians is very different from a hospital reporting the same 1,000 procedures with 500 physicians.

Finally, we are concerned about the intent for hospitals to report “*all patient volume data*”. The PRT believes that the data should apply strictly to the Medicare population for the reasons noted above.

Proposed Hospital OQR Measures for CY15 Payment Determination

Proposed New NHSN HAI Measure

Influenza Vaccination Coverage Among Healthcare Personnel

This measure raises several concerns for the PRT. CMS states that these data are currently being collected by the Centers for Disease Control and Prevention (CDC). The PRT therefore believes that it is an unnecessary duplication of effort for CMS to also collect this information.

In addition, we are concerned with CMS' definition of healthcare personnel (HCP) as including employees who are not directly involved in patient care (i.e., clerical and billing personnel). In today's healthcare environment, many clerical and billing personnel are located in offices outside the hospital facility. It is not clear to us why these employees should be included in the vaccination requirement. Further, it is unclear where CMS is drawing the line for inclusion: all HCP versus those HCP who on occasion must be in the hospital facility, etc.

Another issue of grave concern to the PRT is the recurrent shortage of influenza vaccines. It is not clear what the penalties will be for facilities that are unable to ensure HCP vaccination during times of shortage. The likelihood of a vaccine shortage is compounded by CMS' recent proposed rule, *CMS 3213-P Medicare & Medicaid Program: Influenza Vaccination Standard* (issued on May 4, 2011), which proposes to require hospitals to offer vaccinations to all patients during the 2011-2012 flu season as a Condition of Participation. The availability of vaccine products will be compromised if CMS implements these requirement that all HCP be vaccinated, and that all patients be offered the vaccination.

The PRT concurs with the comments submitted by the American Hospital Association (AHA) that this proposal is an "unfunded mandate in the midst of a difficult economic climate". The PRT asks CMS to recognize this measure's potential negative impact on the healthcare industry and to retract it.

Possible Quality Measures Under Consideration for Future Inclusion

The PRT appreciates that CMS provides a list of measures under consideration for future inclusion in the OQR program, but notes that it is difficult to assess their impact due to the vague descriptions provided in the proposed rule. CMS has not provided any rationale or specific details on the measures, making it impossible to comment on them at this time. The PRT will reserve comment until more detailed descriptions of the measures are provided and the timeframe for reporting approaches. We would like to stress, once again, that the requirement to report *any* additional measures in CY 2014 will be burdensome, as the industry will be addressing issues arising from the October 2013 ICD-10 implementation. We suggest that CMS also consider the quality of the ICD-10 data that 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.

Proposed Payment Reduction for Failure to Meet Program Requirements

Extraordinary Circumstances Extension or Waiver

The PRT commends CMS on the proposal to grant extensions automatically for entire locales that are involved in natural disasters without requiring action by the affected facilities. Several of the PRT member facilities have recently encountered such extraordinary circumstances due to natural disasters; we understand first-hand the difficulty in requesting an extension under such circumstances. The PRT requests that CMS also consider providing a similar extraordinary circumstance waiver for Recovery Audit Contractor (RAC) requests for facilities recovering from natural disasters.

Proposed Requirements for Reporting Data for CY13 and Subsequent Years

Form, Manner, and Timing of Data Submission

The PRT appreciates the definition of “encounter”, “episode” and “episode of care”.

The PRT asks CMS to consider standardizing the reporting timeframes across all measures. Requiring some measures to be reported each quarter while others are reported only during specific quarters is confusing and may lead to missed deadlines.

Eligibility to Voluntarily Sample / Exception for Low-volume

In principle, the PRT supports the opportunity for providers to sample when there are a significant number of encounters in a measure. We believe, however, that this stipulation should apply to hospitals with less than five Medicare claims, rather than being applied to hospitals that have less than five claims across all payers.

Population and Sampling Data Requirements CY13 and Subsequent

The PRT disagrees with CMS’ assertion that sampling requirements should apply based on both Medicare and non-Medicare cases. CMS should focus only on the population of patients for which the agency is responsible. Providing data on all individuals served by a facility will create a significant burden for providers without giving CMS any additional data on its own beneficiaries.

Hospital OQR Program Validation Requirements – Validation Approach for CY13 Payment Determination

Randomly Selected Hospitals

The PRT commends CMS on its recommendation to reduce the number of randomly selected hospitals from 800 to 450. Like providers, CMS must prepare for ICD-10 implementation, and additional validation will increase the burden on both facilities and CMS staff. We again request

that CMS take into consideration the strain under which hospitals will be operating during this difficult transition.

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

In general, the PRT believes that the proposed targeting criteria are reasonable. Our only concern is to ensure equitable selection of the 50 randomly selected hospitals based on targeting criteria. Under the current targeting criteria design, it is possible for the same hospitals to be selected year after year. The PRT asks CMS to consider limiting the frequency with which a hospital can be “randomly” selected for validation based on targeting criteria.

Encounter Selection

The PRT believes that CMS’ proposed validation requirements are reasonable and would be acceptable to providers if it were the *only* Federal data submission requirement. We are deeply concerned, however, that these record requests will supplement those already established as part of the Federal integrity audit processes (e.g., RAC, Medicaid Integrity, ZPIC, and 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 as a single request, and to consider the operational impact that receiving multiple audit entity requests will have on a provider.

Validation Score Calculation

The PRT requests that CMS keep the timeframe for submission of medical record documentation consistent with other CMS contractors (i.e. RAC) at 45 days. Managing different submission timeframes may lead to inadvertently missing deadlines. Given the volume of contractors that currently request medical record documentation, the PRT believes that a 30-day turn around for record submission is unreasonable.

Additional Data Validation Conditions under Consideration for CY2014 and Subsequent Years

Because the validation-targeting criteria proposed for CY 2014 are consistent with prior years, the PRT supports the proposal to target facilities that were not selected for validation in the previous three years and facilities with a low number of submitted encounters relative to population size.

Instead of targeting hospitals that report a significant number of “unable to determine” elements, however, the PRT suggests that this is an opportunity for CMS to provide education regarding the abstracting of these data elements. If many hospitals are abstracting “unable to determine” on

the same data elements, it indicates a lack of clear instruction and/or understanding about CMS' intent. The PRT requests that CMS provide assistance in clarifying these issues prior to proceeding with targeting validation.

Electronic Health Records

As indicated previously in our comments, the PRT supports the concept of using data collected from electronic health records, but does not support CMS having direct access to a facility's EHR for data abstraction. We wish to reiterate that data submission should be restricted to limited EHR data elements only for purposes of quality measure reporting. We support the terms in the EHR incentive program that provide a foundation for hospitals to send, and CMS to receive, quality measures through electronic submission.

2012 Medicare EHR Incentive Program Electronic Reporting Pilot

Proposed Electronic Pilot

The PRT once again ask CMS to consider the administrative burden of implementing ICD-10 when making decisions regarding introduction of new initiatives. We would appreciate clarification from CMS on the purpose of this pilot, which appears to duplicate other quality measurement programs that are already in effect or are proposed for implementation.

Clinical Quality Measures (CQM) Reporting Under Pilot

The Clinical Quality Measures proposed under this pilot appear to be more comprehensive and repetitive than the current measures being reported by hospitals. In addition, the proposal is to submit *patient-level* CQM data for Medicare patients only. The PRT wishes to highlight this inconsistency: this proposal applies only to Medicare patients, as opposed to other CQM measures that apply to *both* Medicare and non-Medicare cases. The proposal to submit patient-level data differs from the Final Rule for Medicare & Medicaid EHR Incentive Program, which requires submission of aggregate data.

Proposed Ambulatory Surgery Center (ASC) Quality Reporting Program

The PRT applauds CMS' efforts to finally develop equity in reporting requirements by including ASCs in a quality reporting program. As the PRT has frequently commented to CMS, it is extremely appropriate to assure quality of care to Medicare beneficiaries in all settings that provide outpatient services, including ACSs.

Considerations in Selection

The PRT appreciates the alignment of ASC Quality Measures with HOPD Quality Measures in relation to the principles used in the selection of measures. We again note the subjectivity of measures of "patient satisfaction", but realize this aligns with the Value-Based Purchasing implementation plan.

Proposed ASC Measures for CY14 Payment Determination

The PRT wishes to highlight the extremely short timeframe for ASCs to prepare for submission of quality measures. The proposal requires claims-based submission on the initial eight measures to begin on January 1, 2012. Yet, the final OPPS Rule is expected to be released only few weeks before that date and the PRT is concerned that ASCs will not have adequate time to prepare.

The PRT requests that CMS clarify why ASCs' quality measures process differs so significantly from the process that has been successfully implemented in the hospital outpatient department setting. If CMS' initiative seeks to improve healthcare outcomes, safety, quality, efficiency, and satisfactory patient experiences, it seems odd not to implement the process consistently across all sites of service.

While the proposed measures are not an issue, the PRT is deeply concerned about the proposed data capture process. Data submission via a "Quality Data Code" and application of payment indicator "M5" will impose administrative burden on ASCs and will be operationally hard to manage. Although many of the exact measures are currently submitted by hospitals (some as inpatient quality measures), hospitals do not use a QDC for identification. The PRT does not understand why the reporting method for identical measures differs so dramatically for various sites of service.

The PRT also wishes to note that ASCs do not currently participate in any abstracting or data submission requirements. Unlike hospitals, ASCs do not have established Quality Departments that can participate in quality measurement initiatives without adequate opportunity to plan and develop internal programs.

Proposed ASC Measures for CY2015 Payment Determination

The PRT understands the measures proposed for ASCs' in CY 2015 and notes that they are similar to measures proposed for reporting for the CY 2014 payment determination for hospitals. We would like to comment, however, on the fact that 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. The PRT suggests that CMS keep the categories consistent and standardize categories for both hospitals and ASCs.

We highlight, once again, the potential problems stemming from inconsistency in the data collection and submission dates. For the Safe Surgery Checklist use, ASCs will participate in data collection from July 1, 2013 to August 15, 2013. Requiring data submission consistently (e.g., by quarters) across all measures and across sites of service is preferable, as it will not only ensure compliance with deadlines but also increase the integrity of the data submission.

Again, the PRT wishes to note that this data collection is proposed to occur in the midst of ICD-10 implementation, and requests that CMS consider the burden that this timeframe will impose on providers.

Proposed ASC Measures for CY16 Payment Determination

The PRT reiterates our previous comments about the proposed HAI measure specific to Influenza Vaccination Coverage among healthcare personnel. Our concerns about the shortage of availability of vaccinations and the overlap with all patient vaccination requirements apply in the ASC environment, as well.

Measures for Future Consideration

The PRT notes there are significant differences in the measures proposed for future consideration for hospitals versus ASCs. We encourage CMS to create alignment and consistency by implementing the *same* measures across these two sites of service. Collecting the same data elements will enable CMS to ensure that its beneficiaries receive the same quality of specific services, regardless of the setting.

In addition, the PRT notes that some of the proposed future measures will impose significant data gathering and reporting burden on ASCs. The PRT reserves further comment on these future measures until CMS provides more descriptive definitions of the measures. We plan to provide input during future comment periods.

Technical Specifications — Data Publishing

The PRT supports publication of both ASC and hospital data, but once again voice our concerns about the public's interpretation of these data. The PRT is concerned that the information may be misleading and also question the usefulness of data that are old (e.g. that were collected several years earlier). It is not clear that Medicare beneficiaries will be able to make informed healthcare decisions based on data that are old and/or poorly communicated. CMS itself acknowledges the difficulty in understanding these data. The PRT supports CMS taking steps to provide more clarification to users of these important quality data.

Value-Based Purchasing (VBP)

The PRT understands and supports CMS' initiatives to measure the quality of care provided to Medicare beneficiaries. It is clear that CMS intends to connect provider reimbursement to quality and outcome measures. In general, the PRT supports this effort and the measurements proposed for CY 2014, since they are measures that providers currently collect and report to CMS via data abstractions or claims data. Those data-gathering processes have already been established and do not pose an additional burden on hospital facilities.

The PRT has some general questions regarding the VBP, however. Specifically, we seek clarification from CMS on the following questions:

1. With the upcoming implementation of ICD-10, has CMS conducted a crosswalk between ICD-9-CM and ICD-10 for HACs and other outcome conditions? The provider community would appreciate CMS sharing its findings from such an analysis and information it has about there being more specificity with ICD-10.

2. Given the burden on facilities associated with implementing ICD-10, is CMS considering a delay in enforcement of the measures?
3. Does CMS plan to integrate the outpatient measures with the inpatient measures for actual facility reimbursement impact?
4. What processes exist for challenging the CMS value-based (VB) incentive payment? Hospitals are to be informed of their estimated FY 2013 VB incentive payment in approximately August or September 2012, with expected final VB incentive payment amount communicated in November 2012. If hospitals' calculation of their VB incentive pay differs from CMS' calculation, how will these discrepancies be addressed?

Proposed 2014 Measures

The PRT supports Clinical Process of Care proposed measures for 2014 including the addition of SCIP inf 9 (Post-op urinary catheter removal on post-op day one or two). The PRT also supports CMS' use of Mortality Outcome, AHRQ, and HAC measures. The PRT supports CMS' proposal not to consider HAC measures under the "topped out" criteria.

The PRT requests CMS to assess the use of a more current timeframe for HCAHPS data, however. The data that was reported in April 2011 began to be collected in July 2009, almost two years earlier. In order to be most relevant for beneficiaries' use in making decisions about their care, data should be validated and reported in a timeframe closer to the data collection period.

Medicare Spending per Beneficiary Calculation

The PRT recommends that CMS include all Medicare payer plans (and specifically Medicare Advantage) in the calculation in order to create an "apples to apples" comparison. Failing to do so may result in skewed results since healthier beneficiaries tend to be enrolled in the Advantage plans, when compared to those in the traditional Medicare program. In addition, the PRT believes CMS must case-mix adjust or otherwise risk-adjust/standardize this calculation otherwise hospitals with high case-mix indices may "appear" more costly when they are not. CMS does not describe its approach for case-mix adjusting this measure, but the PRT strongly believes the agency must release details on this for comment prior to finalizing this measure.

VPB Scoring and Validation

The PRT agrees with the proposed domain weight for the FY 2014 VBP measures: patient care experience stays at 30%; clinical process of care decreases from 70% to 20%; outcome measures stay at 30%; and the new efficiency measure is set at 20%.

HAC Validation Accuracy

The PRT agrees that HACs are an important component in measuring patient quality of care. We note, however, that the 2010 Affordable Care Act (ACA) establishes a separate payment adjustment for HACs starting in fiscal year 2015. After that time, hospitals that score in the top

quartile for the rate of HACs, compared to the national average, will be penalized by reduced Medicare payments for all MS-DRGs. It is, therefore, duplicative and unnecessary to include HACs in the VBP effort. Before proceeding with this proposal, the PRT asks CMS to analyze these inter-related payment penalties and share its results with the public.

If CMS proceeds with this process, the PRT recommends delaying development of the HAC validation process until further education is provided to facilities. Given the various large-scale initiatives CMS has required of hospitals in recent years (including RAC, 5010, and meaningful use), we believe providing education is a necessary first step before CMS places another burden on facilities for validation and/or data collection activities.

Validation and Publication of Submitted Data

The PRT is concerned about CMS' publication of quality data, even given the process in place to validate quality measures. A recent example is provided by the incorrect data that were originally published for HAC measures, which CMS had to remove and republish. Further, CMS has acknowledged that the Hospital Compare website may be difficult for beneficiaries to understand in terms of OPSS quality measures. The PRT is concerned about how the VBP scores will be communicated to ensure widespread public use and correct interpretation by beneficiaries. We ask CMS to provide additional information on the steps the agency plans to take to educate Medicare beneficiaries about the Value-Based Purchasing data, including the media that will be used to do so.

Inpatient-Only List

The PRT reiterates its request that CMS examine Medicare Advantage claims data when evaluating whether to remove procedures from the inpatient-only list. We made this request at the APC Panel meeting on August 10, 2011, and received some indication from CMS that this may be possible.

In the proposed rule, CMS discusses that a "physician professional society" agrees that many of the procedures designated as "inpatient only" should be performed appropriately and safely only in the inpatient setting. The PRT does not disagree with this statement. We do, however, assert that there are many procedures on the inpatient-only list that are performed appropriately and safely in the outpatient setting on a daily basis in hospitals across the nation. The PRT recommends that CMS develop a process to more quickly evaluate procedures for removal from the inpatient-only list outside of the rule-making process. More frequent updates to the inpatient-only list would allow CMS to be more responsive to OPSS provider requests, which are usually triggered by physician and patient desires for procedures to be performed in the outpatient setting.

The PRT notes that, currently, there are no ramifications to physician payment when inpatient-only procedures are ordered and performed in the outpatient setting. An inpatient level of care is not ordered when the procedure can be done as an outpatient in the physician's judgment and giving consideration to the individual patient's clinical picture. The physician drives the

decision-making process (as they should) — but the hospitals are penalized. As we have stated since our inception, the PRT believes that physician payment (or lack of payment) for inpatient-only procedures should mirror the hospital's: unless the site of service on the physician claim is inpatient, Medicare payment should be denied for any inpatient-only procedure performed on an outpatient basis. As CMS regulations and contractor guidelines note, the physician is responsible for decisions regarding admission status for the individual patient, and the PRT wholeheartedly agrees with this. Yet, CMS continues to reimburse physicians for services they perform from the inpatient-only list that are rendered on an outpatient basis, but will not provide payment to hospitals. This policy decision is grossly unfair as it penalizes OPPS hospitals and appears to expect that hospitals are somehow to enforce something the agency seems reluctant to enforce. As CMS knows, hospitals have little influence over physicians and/or the opportunity to intervene when a physician makes a decision on the appropriate site of care for patients to receive services.

The PRT encourages CMS to push A/B MAC Medical Directors to develop local coverage determinations (LCD) that define when selected procedures should be performed as inpatient or outpatient. These policies can then be consistently applied to both Part A hospitals and Part B physician providers consistently. This will move the decision-making process into the physician's realm and ensure that decisions are based on the individual beneficiary's needs and clinical presentation, and away from an inflexible "list" approach.

The PRT agrees with and supports the Advisory Panel on APC Groups' recommendation during the August, 2011 meeting to remove 63267, 22551, 22552, 22554, and 22558 from the inpatient-only list. The following table includes additional codes the PRT recommends for removal from the inpatient-only list and a change from status indicator C to an appropriate OPPS payable status indicator. The recommendations from Milliman and InterQual criteria are provided when available. (Note: Many procedures are not included and consequently do not have a recommendation in one or both of the criteria sets.)

Inpatient Only Procedures Recommended for Removal			
CPT/ HCPCS	Code Description	Milliman Recommendation (15th Edition)	InterQual Recommendation version 10.0 15, 2011
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel		Outpatient
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)		
20661	Application of halo, including removal; cranial		
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		

20930	Allograft for spine surgery;morselized		
20931	Allograft for spine surgery only; structural (List separately in addition to code for primary procedure)		
20936	Autograft for spine surgery only (includes harvesting the graft); local (ie, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)		
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction, without bone graft		
21196	Reconstruction of mandibular rami & body with sag split & int fix		
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar		
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)		
22855	Removal of anterior instrumentation		
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar		
22840	Posterior non-segmental instrumentation (ie, 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)		
23472	Arthroplasty, glenohumeral joint total shoulder (glenoid and proximal humeral replacement)	Ambulatory except inpatient for patients not appropriate for ambulatory nerve block regimens	Inpatient
27702	Arthroplasty, ankle; with implant (total ankle)		
32662	Thoracoscopy, surgical; with excision of mediastinal cyst, tumor, or mass		Outpatient for pleural lesion; all others inpatient
35221	Repair blood vessel, direct; intra-abdominal		
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral		
35721	Exploration (not followed by surgical repair), with or without lysis of artery; femoral artery		
35800	Exploration for post op hemorrhage, thrombosis or infection; neck		
37182	TIPS procedure		

37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed		Outpatient except: urgent procedure, anticoagulation planned, or kidney failure.
37617	Ligation, major artery; abdomen		
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic		
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	Ambulatory	Inpatient
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	Ambulatory	Outpatient - lap adjustable gastric banding (LAGB), LapBand, Realize adjustable gastric banding. All others inpatient.
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury		
44300	Open jejunostomy following a diagnostic laparoscopy		
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)		
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)		
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)		
44602	Suture of small intestine accidental laceration		
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)		
49255	Omentectomy, epiploectomy, resection of omentum		
51840	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); simple	Ambulatory: lap suspensions, sling procedures, minimally invasive procedures (eg, tension-free vaginal tape). Inpatient: most open procedures, including procedures performed in conjunction with other surgical procedures.	Outpatient except inpatient for Burch Culposuspension.
56630	Vulvectomy, radical, partial;		Inpatient - radical/hemivulvectomy. Outpatient - partial vulvectomy.
61624	Transcatheter permanent occlusion or embolization, percutaneous, any method; central nervous system		Not included in IQ criteria.

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	Not included in IQ criteria.
63710	Dural graft, spinal		Not included in IQ criteria.

Visit Distributions

The PRT is interested in CMS’ comment that, from 2005 to 2010, the agency noticed a slight shift in the proportion of level 4 and level 5 visits, when compared to level 4 and level 5 Type A visits. CMS noted that, in the aggregate, charges seem to be increasing and asked if this shift could be attributed to hospitals refining facility visit guidelines based on CMS’ principles.

In order to respond to CMS’ request for comment on this issue, the PRT asks CMS to provide additional visit information. In particular, the PRT requests that CMS provide data regarding whether it has observed any shift in reporting “new” versus “established” patient visits after instituting the new definition of established patient in CY 2009. We note that CMS has two years of claims data since the definition change. If hospitals changed their reporting based on the new definition, the data should reflect a shift, since more patients would have been “established” patients under the new definition.

The PRT contends that, if CMS has *not* noticed this shift in the proportion of new and established patient visits beginning with 2009 claims, it suggests that hospitals may not have begun applying the revised definition. In the same vein, a shift in level 4 and 5 visits may have occurred more in response to the increasing trend of co-morbid conditions in Emergency Department (ED) visits than from hospitals response to CMS’ visit guidelines. The PRT would like to know if CMS has evaluated secondary diagnoses on level 4 or 5 Type A ED visit claims. This would be one indication that the acuity of those patients is increasing, and support the higher-level visits.

The PRT has submitted comments on this particular subject to CMS on numerous occasions and our objections remain the same. We continue to believe that the length of time between a patient’s hospital visits has no bearing on services or resources provided during a specific hospital visit. The fact that a patient has been seen in a hospital outpatient department, or has been admitted as an inpatient “within the past three years”, has *absolutely no impact* on the resources required to evaluate, manage, and treat the patient’s current condition or reason for the current visit.

The PRT acknowledges that CMS’ claims data indicate a new patient visit involves more resources than an established patient visit. Yet, we continue to believe these data are flawed,

since it is almost impossible for hospitals to operationalize CMS' definition of a "new patient".

Therefore, we believe that the "new patient" visit codes may simply be reported as a matter of course, rather than through a thoughtful charging practice. We also believe that providers report "new patient" visits even when fewer than three years have elapsed since the patient was last treated at the hospital, which also contributes to the cost differences observed by CMS. Simply put, the PRT does not trust the data providers are reporting to CMS given our own experiences, the extreme challenges in using the "new patient" codes, and our knowledge of the inherent obstacles to correct reporting observed within our own facilities.

While keeping these codes in place and reporting them would generate better payment rates for some providers, the PRT would much prefer to take a reduction in APC payment rates by using *only* the "established" visit codes and blending the median costs for new and established patients, than having to adhere to CMS' required definition of "new patient".

If CMS chooses to continue requiring hospitals to report both "new" and "established" visit codes, the PRT strongly urges CMS to change the definition of an "established" patient by removing the verbiage: "created within the past three years". We urge CMS to return to its original definition, published in 2000: "*If the patient has a hospital medical record, that patient is considered an established patient to the hospital.*"

Physician Supervision

Independent Review Process

The PRT agrees with the use of the current APC Panel and the creation of a separate sub-committee process to further develop and maintain physician supervision rules. We also support CMS' proposal to add two to four additional members to the Panel to represent critical access hospitals (CAHs) during the discussions and decision-making process related to level of supervision. We agree that these members should have membership on the subcommittee and their input be limited to the discussions surrounding physician supervision issues. In other words, they would not be fully active APC Panel members, just as CAHs are not subject to the OPSS. The PRT members strongly recommend these members include at least three (preferably four) CAH physicians or other clinical disciplines to represent CAHs and rural communities. The PRT suggests that CMS consider CAH Emergency Department physicians and qualified non-physician practitioners (NPP) for membership on this panel.

The PRT conceptually agrees with CMS on the proposal of a sub-regulatory process to enable stakeholders to request changes in supervision levels more than once a year. We support the creation of a process to foster more rapid supervision decisions/changes for individual CPT codes through a process consistent with the sub-regulatory process for diagnostic services under the MPFS that has been adopted for hospital outpatient settings. However we expect maximum transparency from CMS wherein the public requests, Panel recommendations, public comments,

and CMS decisions are fully published. In other words, we expect the process to be “formal” in nature and we expect it to be “official” in the way that rule-making is.

The PRT also agrees that there is a potential for administrative burden in reconsidering requests for evaluation, but we strongly believe that such a process is necessary. Changes to clinical evidence, new technology, and/or new techniques for delivering patient care are among the indications for allowing reconsideration — but these should not be the *only* reasons. We urge CMS to allow reconsideration of unique circumstances without specifying at this moment what these reconsiderations might be. For example, future requests may concern advances in telemedicine and telehealth. We do not believe that CMS should create a specific, defined set of principles about changing circumstances at the risk of preventing a service from being re-evaluated by the sub-regulatory committee at a later date.

The PRT requests some clarification on specifics about the sub-regulatory committee, however. We presume that the committee would meet with a frequency that is consistent with the charter of the APC Panel (i.e. traditionally twice per annum). We feel strongly that twice annually is the *minimum* timeframe for making recommendations, obtaining CMS approval, and publishing updates in transmittals. The PRT also seeks clarification that the sub-committee process will provide the same opportunities for testifying on issues as does the APC Panel meeting. We would expect presentations, discussions and recommendations related to physician supervision take place during the open public agenda of the APC Panel Meeting. We encourage CMS to ensure the same level of access for individuals to engage with the physician supervision sub-regulatory committee on physician supervision rules. We hope that hospitals will have similar opportunities to raise issues with this body as we have with the APC Panel for OPSS. The PRT strongly encourages CMS to allow stakeholders and providers the opportunity to submit requests throughout the year with consideration by the subcommittee at least twice a year.

The PRT also recommends that CMS establish a listserv to alert the public when new information is published, and an online comments submission process. We believe that CMS will gain more detailed information for its future rule-making if the agency establishes an anonymous request process so that providers feel at ease asking questions about potential services or asking for the review of certain services without the fear that doing so will trigger a red flag from a regulatory audit standpoint.

The proposed rule is unclear regarding whether final decisions would be effective in July or January following the most recent APC Panel meeting, or only in January of the upcoming payment year. CMS notes that public comment on the proposed level of supervision is desired after the sub-committee has made its recommendations. The PRT recommends a 45- to 60-day comment period. Since the volume of items to be considered and commented on would be small compared to a proposed rule, this schedule should offer providers, stakeholders, and other interested parties adequate time to comment. The PRT recommends implementation of the supervision changes in January, as with changes to the OPSS (following the recommendations made at the summer Panel meeting) and again in July (following the recommendations made at the winter Panel meeting.) This allows for a 45- to 60-day comment period to follow each Panel meeting, time for CMS to publish guidance based on the sub-committee’s recommendations and

the rationale for the level of supervision, publishing a transmittal and for hospitals to implement any change internally. The PRT appreciates CMS providing specific and detailed clarification on how the sub-regulatory logistics will occur.

CMS proposes to charge the panel with recommending a supervision level (i.e., general, direct, or personal) to ensure an appropriate level of quality and safety for delivery of a given service, as defined by the CPT code. The panel would assess four specific points of consideration: complexity of service; acuity of the patients receiving the service; probability of unexpected or adverse patient event; and expectation of rapid clinical changes during the therapeutic service or procedure. The PRT requests that CMS not lock into these four specific criteria but rather recommend that the agency make allowances for other exceptions based on changes in technology.

The PRT recommends that all therapeutic procedure CPT codes start with the default assignment of *general* supervision, and allow the subcommittee to assign a higher level of supervision when there is a significant clinical or quality rationale for doing so. Furthermore we recommend that the assignment of general supervision not be preceded by direct supervision at the initiation of the procedure. At the time the sub-regulatory process is initiated, we would ask CMS to retire the concept of “nonsurgical extended duration therapeutic services”. We also request CMS to restate in the final rule that the level of supervision assigned via the APC Panel sub-regulatory committee will apply to outpatient facility providers *only*.

To highlight the rationale described above, we offer the following example. The PRT is concerned that “visit codes” will require unnecessary direct supervision, when general supervision is more appropriate for these “incident to” services. Specifically, in the hospital outpatient setting, a physician may order an enema treatment for a patient who has a constipation diagnosis. Since this service is not identified with a specific CPT code, the service would be classified with a hospital E&M code based on facility-specific criteria. Based on current standards of care, the service is safely performed “incident to” a physician service, without requiring direct physician supervision.

The PRT does not believe the level of *personal* supervision is necessary. Those procedures that are performed directly by physicians inherently include the appropriate level of care, thus negating the need for “supervision”.

The proposed rule suggests that individual codes must be submitted to the panel for review and that there will be a limit and prioritization based on volume and expenditures. The PRT recommends, when appropriate, CMS allow categories of codes to be submitted so that an individual code(s) will not be left out of the equation due to infrequent usage when the code(s) have similar resources and value as other codes submitted within the category.

The PRT also recommends that CMS begin to include an indicator of the specific level of physician supervision required for each HCPCS code in Addendum B of the OPFS final rule, similar to the MPFS, for ease of use by hospital providers.

Although CMS implemented a process for certain extended services to start with *direct* physician supervision and change to *general*, hospitals with greater access to physicians and non-physician practitioners are continuing to require direct supervision without the option to change to general for the “extended services” due to lack of standardization of documentation practices. This could lead to their vulnerability in an audit, if the documentation is not found to be as expected by an individual reviewer. For this reason, some hospitals will require “direct” supervision throughout the performance of the “extended services”, in order to avoid audit and vulnerability. Hospitals are concerned about subjective reviews based on differing opinions and interpretations of documentation and do not “trust” the current system implemented for hospitals. The vulnerability is a greater concern for the rural and CAH hospitals that cannot accommodate direct level of physician supervision throughout the entire service, such as observation. The hospital community is concerned about the majority of CPT codes being assigned to “direct” supervision as the default.

We are also concerned with services that lack a defined CPT code, such as recovery room services. The PRT believes that a patient is able to move into a general level of supervision after phase 1 recovery, based on the American Society of Anesthesiologists (ASA) guidelines. In addition, it is not clear how a hospital can comment on service lines that lack CPT code distinctions.

Further, we note that CMS has not resolved the CAH problem of nurse-initiated services that are ordered by a physician in order to begin treatment on a patient prior to the physician’s arrival in the ED. Nursing protocol and scope of practice allow clinicians to carry out the physician’s order in such situations. The PRT seeks clarification from CMS about the hospital’s responsibility and vulnerability for billing such services. In addition, the PRT asks CMS to further clarify clinical practice issues related to billing practices. CMS should consider that hospitals will ultimately do what it takes, regardless of payment, to take care of their patients — even if it means a revenue loss. The PRT does not believe that hospitals should be expected to take a direct reimbursement hit when they are attempting to best serve the beneficiary.

We agree with the need to move forward with a definition for personal and general supervision for clarity across provider settings. Because the rule addresses outpatient facility services, we ask CMS to confirm that, after ASA guidelines are met for discharge from recovery care, general supervision is the standard. The PRT asks CMS to confirm that, following ASA guidelines, personal supervision by a physician is required until the end of phase 1 recovery. Pursuant to ambulatory anesthesia and surgery guidelines, a licensed physician should be in attendance in the facility (or, in the case of overnight care, immediately available by telephone) at all times during patient treatment and recovery and until the patient is medically discharged. Staff should be adequate to meet patient and facility needs for all procedures performed in the setting, and should consist of professional staff (including physicians and other practitioners) who hold a valid license or certificate and are duly qualified (including nurses who are duly licensed and qualified). In order to prevent confusion among the provider community, the PRT would appreciate confirmation from CMS about this understanding of recovery room supervision. Such a clarification will also prevent CMS from being inundated with questions about this issue.

Finally, the PRT requests that physician supervision rules applied to hospital outpatient settings also be applied to ambulatory surgery centers (ASCs). The PRT urges CMS to treat ASCs the same as hospital outpatient surgeries. This is important in order to treat all provider settings fairly across similar services and ensure consistent quality care provided to the beneficiaries. The PRT is concerned that, once again, CMS appears not to describe a direct physician supervision requirement for ASCs related to care provided in the post-acute care unit (PACU). The CoPs merely require a surgeon to create a discharge summary before the patient is released. Because there is no requirement or specified expectation of the timing of this summary, the assessment could be written two hours after the surgery or two hours before the patient is discharged (which, beginning in CY 2010, could be up to 22 hours post-surgery). In addition, patients may stay in an ASC for up to 24 hours, but CMS does not require direct physician supervision or for a physician to be immediately available.

This policy creates significant variations and inequalities between hospital outpatient departments and ASC facilities, despite the fact that they provide many of the same services. The PRT believes that CMS is allowing existing CoPs to guide ASC practices without adding any separate requirements related to physician supervision. We ask for the same latitude for *all* hospitals and their outpatient departments. In other words: if CoP guidance is sufficient for ASCs, then it should be sufficient for all hospitals.

Section 42 CFR 410.27 — Proposed Edits & Self-Administered Drugs

The PRT thanks CMS for proposing to change the language in this section by inserting the word “therapeutic.”

The PRT wishes to draw CMS’ attention to other wording in this section that causes confusion among the hospital industry. The language in 410.27(a) defines services paid under Part B that are provided incident to a physician services, and ends with the phrase “*including drugs and biologicals that cannot be self-administered.*” The PRT is aware of recent questions asked on the Open Door Forum about self-administered drugs (SADs) and related drug administration services. The PRT notes that there has been an increase in SADs since the inception of the Medicare Part A and Part B programs. The shift of more patients to the outpatient setting (including outpatient observation services) results in an increase of non-covered SADs. The PRT is concerned about what we see as an erosion of the Medicare benefit to beneficiaries and the increased financial burden for beneficiaries, which places hospitals in a compromising position with respect to our patients (e.g., the beneficiaries).

The PRT seeks clarification about whether CMS has conducted any analysis regarding this erosion of beneficiaries’ benefits. We recommend that CMS examine the change in total hospital charges billed under revenue code 0637 since OPSS’ inception. We also seek clarification about whether CMS has considered the increase in the incidence of co-morbid conditions for which SADs are integral to medically necessary medical management of the patient during outpatient encounters — particularly observation encounters. One example is provided by the increase in diabetes among the Medicare beneficiary population over the last decade. The PRT recommends that CMS consider the significant patient safety risks associated with patients bringing their own

medications to the hospitals, which has necessitated most hospitals to prohibit such a practice. We recommend that CMS educate Congress about this erosion of benefits.

The PRT is also concerned about CMS' development of outpatient experience of care measures when this is a significant issue for beneficiaries and their experience of outpatient hospital care. As CMS stated in the original 1998 rule (63 FR 47563):

This presents problems in the outpatient hospital setting because even a painkiller given to a groggy patient postoperatively would not be covered. The only way such drugs can be paid for is for the hospital to bill the beneficiary. In many cases, the hospital does not, both because keeping track of such small charges for billing purposes is burdensome and because beneficiaries would not understand why they are being asked to pay for, for example, pain medication that was clearly related to the procedure they had undergone.

CMS has made OPPS payment policy changes to cover self-administered drugs that are “so integral to a treatment or procedure that the treatment or procedure could not be performed without them” and “packaged payment for such drugs into the APC payment for the procedure or treatment of which they are an integral part.” This policy does not, however, help cover most SADs that are dispensed to manage co-morbid conditions for outpatient beneficiaries. We ask that, as CMS considers developing outpatient experience of care measures, it also reexamine its policy regarding SADs. We recognize that Congress may need to amend the Social Security Act, but we encourage CMS to use its considerable influence with Congress to bring attention to this increasingly troublesome and unreasonable benefit issue.

Conclusion

The Provider Roundtable thanks CMS and its staff for reviewing and considering our comments. The PRT members are very encouraged by the policy-making process and appreciate how our input can have an impact on future year's rules and policies. We are very grateful to CMS for considering our comments in past years as well as again this year. We hope the operational issues we have outlined will be helpful to CMS in considering future system changes.

If you have any questions or require additional information, please contact our chairperson, John Settlemyer, MBA, MHA; Assistant Vice President, Revenue Cycle, (704) 512-6483.

Sincerely,

Members of the Provider Roundtable