



## Provider Roundtable

August 31, 2010

*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)*

*Saint Joseph's Hospital (WI)*

*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)*

The Honorable Donald Berwick, MD  
Administrator, Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1504-P  
PO Box 8013  
Baltimore, MD 21244-1850

**CMS-1504-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2011 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Proposed Changes to Payments to Hospitals for Certain Inpatient Hospital Services and for Graduate Medical Education Costs; and Proposed Changes to Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations**

Dear Dr. Berwick,

The following comments are submitted by the Provider Roundtable (PRT), which gathered to generate comments on the 2011 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on August 3, 2010.

The Provider Roundtable (PRT) includes representatives from 16 different hospitals and health systems from around the country. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services under OPPS, but do not have any specific financial relationship with vendors.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual 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.

If you have any questions, please feel free to contact me at (704) 512-6483 or via email at: [John.Settlemyer@carolinashealthcare.org](mailto:John.Settlemyer@carolinashealthcare.org).

Sincerely,

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## **Hospital Outpatient Department Quality Measures**

The PRT understands — and supports — the need to report quality indicators for Medicare outpatients. These patients are typically in our hospitals for 24 hours or less. In that time, 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 visit. We present our comments for each proposed year's payment determination below, and make general recommendations at the end of this section.

The PRT endorses the concept of further selection of measures for the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), but believes it is important that CMS provide information concerning how reporting a specific measure will affect the measurement of hospital quality, and how facilities can ensure that the data are captured efficiently. Furthermore, the PRT recommends that any quality measure selected should have an easily identifiable correlation to clinical outcomes.

### ***HOP QDRP Quality Measures for 2011***

The PRT is particularly concerned by the disparity between the HOP QDRP and the Physician's Quality Reporting Initiative (PQRI). The PQRI program does not require submission on all existing measures; further, physician requirements are met with success in only three measures. In contrast, HOP QDRP requires hospital participation in *all* quality measure submission to successfully meet the requirements. The PRT appreciates CMS' sensitivity to the administrative burden that chart abstraction imposes on providers and the fact that both time and labor costs increase using this method of data retrieval.

### ***Publication of HOP QDRP Data***

The PRT agrees that using the website is a beneficial way to notify the hospital community that new information is available for review. PRT members note that the information provided on the Hospital Compare website is somewhat vague. If the data are confusing to providers experienced in this area, we are concerned that they will be inaccessible and even more confusing to Medicare beneficiaries. For example, the website does not provide a clear explanation of what "not applicable" or a blank entry means. Beneficiaries have no way to assess if these notes indicate that a hospital is non-participating for some reason, or has better or worse quality outcomes than others listed. We also fear that this information may be misleading due to the age of the data presented and the timeframe in which the data were collected. More specific information is needed in these areas so that data can be clear, useful, and informative to users.

### ***Proposal of Measures for More than One Payment Determination***

The PRT supports CMS' proposal to introduce proposed measures for more than one payment determination in a single rule-making cycle. Providing the information proactively allows facilities to collect data, make revisions, and plan for forthcoming requirements. We suggest, however, that each specific year's measures should be open for comment in the annual proposed rule but only be *finalized* in the final rule pertaining to the year in which the measures are to be implemented. (In other words, measures for 2014 would be finalized in the Final Rule for 2014, not in any prior year's final rule.)

### ***Data Sources***

The PRT supports the use of registries to collect data for future quality measures as an alternative to chart abstraction, and we appreciate CMS defining the term "registry". We recommend that CMS define the criteria for participating registries in order to ensure both quality and consistent data submission formats. The PRT believes that any and all registries should be required to obtain CMS' approval and/or sponsorship in order to be considered for gathering data. Further, if registry participation becomes a requirement, hospitals *must* be given adequate time to implement processes and registrations for registry participation.

The proposed rule indicates that data for several proposed quality measures could be obtained by CMS via the facility's electronic health records (EHR). The PRT appreciates CMS' response to the concerns we raised in last year's comments, and applaud CMS' collaboration with the Office of the National Coordinator for Health Information Technology (ONC) on matters affecting electronic health data transmission. While we encourage CMS to continue to work with ONC, we also recommend that CMS allow hospitals to participate in developing electronic standards for data submission. We encourage CMS to work with hospitals to create a one-way interface (provider to CMS) for electronic data submission. We continue to oppose CMS having direct access to a facility's EHR for data abstraction, and we believe the general public would voice similar oppositions, and would likely view such access as government intrusion into private medical information. The PRT believes that specific data submission from the EHR could be developed in order to provide necessary information electronically without increasing hospital burdens or alarming the public.

### ***Proposed Measures for 2012 Payment Determination***

The PRT believes that the provider community must be allowed to see the clinical evidence underlying these measures and learn what CMS expects to derive from these data before we can make any comment. The PRT reiterates our previous comment that CMS should use additional criteria for quality measures, specifically: (1) Hospital measures should measure services provided in the *hospital outpatient setting* rather than measuring physician services or services controlled by the physician (e.g., prescribing or ordering services); and (2) Data collection should not increase hospitals' operational burden by increasing FTEs to either collect data or improve data collection systems.

### *Structural Measures*

The PRT is concerned about the introduction of a new structural measure that will assess the ability for providers with health information technology (HIT) to receive laboratory data electronically directly into the EHR. Although we agree that timely availability of laboratory results leads to improved quality of care, we seek clarification on the type of laboratories to which this measure applies. We ask CMS to clarify if it is applicable to both our external/reference lab interfaces and our internal facility laboratories. The PRT is also concerned about the high volume of these data and the provider burden involved in capturing them for submission to CMS. It is unclear if the provider community knows whether hospitals' internal electronic health record systems have the functionality to capture the data needed to comply with this measure.

### *New Claim-Based Measures*

Four new claims based measures are proposed for 2012: Pre-Operative Evaluation for Low-Risk Non-Cardiac Surgical Risk Assessment; Stress Echo SPECT MPI, Cardiac Stress MRI Post CABG; Brain CT & Sinus CT Simultaneously; and Brain CT for Atraumatic Headache.

The PRT has comments on two specific measures:

- 1) *Pre-Operative Evaluation for Low-Risk Non-Cardiac Surgical Risk Assessment*: The PRT asks that CMS further define the term "low-risk" in future OPPS rulemaking, and describe what sources are used to make the determination.
- 2) *Stress Echo SPECT MPI, Cardiac Stress MRI Post CABG*: The PRT questions the validity of data CMS will obtain from this measure. In our experience, physicians do not often indicate a diagnosis of "post-CABG" on orders for these diagnostic services. As a result, per coding guidelines, V45.81 will not be submitted as an additional diagnosis on the outpatient claim, thereby hampering CMS' efforts to identify these cases through claims submission.

While the PRT appreciates CMS' recognition that there are valid uses for these combinations of tests and its provision of exclusions, we are concerned about the high-volume nature of these procedures and the completeness of the data CMS will receive for these measures. As noted, when following official coding guidelines, coders do not typically code signs and symptoms associated with a conclusive diagnosis, so the codes for associated symptoms that qualify as exclusions may not be available on these claims.

### *New Chart-Abstracted Measures*

The PRT believes that *Troponin Results for Emergency Department AMI Patients or Chest Pain Patients Received within 60 Minutes of Arrival* is a reasonable quality measure. We are concerned, however, by how the 60-minute timeframe will be measured. This could be the time frame from when the laboratory result is available in the electronic health record, or alternatively when the physician providing care acknowledges receipt of the results in the medical record. The time frame will vary, which will affect the quality measure outcome, depending on the answer. The PRT asks CMS to clarify this measure in future rulemaking for the benefit of providers at large and include a common data element in use by hospitals to accurately report the measure.

### ***Proposed Measures for 2013 Payment Determination***

The PRT is concerned by the apparent trend for increased number of chart abstraction measures with each successive year. While individual measures might be appropriate, in the aggregate, the sheer number of extractions required by CMS is overwhelming and problematic for providers. The abstractions require increased staff effort, time, and training, which create administrative burden. Specifically, all of the 2013 proposed quality measures require either chart abstraction or data entry for submission, both of which increase provider burden. We ask CMS to be mindful of the effect on providers and limit the number of measures implemented each year.

### ***Structural Measures***

The PRT agrees that data for *Tracking Clinical Results Between Visits* should be easily captured. We are concerned, however, that not all referrals are completed electronically; some exist only in paper format in the patient's medical record and will require increased staff effort to report them.

### ***Chart Abstracted Measures***

Six new measures are proposed for 2013: Median Time from ED Arrival to ED Departure for Discharged ED Patients; Transition Record with Specified Elements Received by Discharged patients; Door to Diagnostic Evaluation by a Qualified Medical Professional; ED Median Time to Pain Management for Long Bone Fractures; Patients Left Without Being Seen; and ED Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Who Received Head CT Scan Interpretation within 45 Minutes of Arrival.

The PRT objects to the first five measures, which are through-put measures unrelated to improved quality of care or clinical outcomes. The resulting data will provide *no* information on quality of care provided by hospitals. In fact, the need to demonstrate efficiency in these measures might lead hospitals to work more quickly with ill effect for beneficiaries. Faster is not always better, particularly with respect to these proposed measures. The PRT urges CMS to publically release the clinical evidence underlying these measures in future rulemaking so that providers at large can understand what CMS expects to derive from these data and comment on them more specifically.

CMS must recognize that, in the Emergency Department, wait times from arrival to departure may be significant for patients with less emergent clinical presentations. A patient who arrives in an ambulance after a car accident takes precedence over a patient presenting with a sore throat, for example. The latter's longer wait time does not indicate in any way that he or she received lower-quality care than the former, just that the need was less dire. The ED's purpose is to care for emergent and critical patients based on the clinical scenario, rather than to ensure a short waiting time for all patients. It should also be noted that longer wait times are associated with higher-level trauma centers and do not measure quality provided by hospitals.

In addition, we have questions about certain specific measures. With respect to *Transition Record with Specified Elements Received by Discharged Patients*, we understand that CMS is

concerned about continuity of patient care and agree that this measure's specific data elements could be built into the discharge instruction process for outpatient and ER services. The PRT is concerned, however, about the volume associated with this proposed measure and note that implementing it will require abstracting of data from *all* emergency room visits, thereby creating a huge impact on provider resources.

For *ED Median Time to Pain Management for Long Bone Fractures*, the PRT request CMS to provide clearer guidelines about when the time measurement begins. It is not clear if this commences when the patient arrives at the facility or when the diagnosis of a long bone fracture is made. For *Patients Left Without Being Seen*, we are concerned both about the vagueness of the term "being seen" and the impact of providers' varying record-keeping. At many facilities, no medical record is created when a patient leaves prior to registration. We request that CMS define "being seen" and specify the point at which a patient would be considered to have "left without being seen" (e.g. before or after triage).

Further, CMS notes that these new measures coincide with the expansion in the RHQDAPU program and that it believes these particular measures will eventually be submitted via EHR and thereby eliminate chart abstraction burdens. The PRT proposes that CMS delay implementation of these measures until the data are, in fact, retrievable by EHR. We also strongly recommend that CMS work with hospitals and ONC to validate that the required performance measures are based on standard, clinical data that are captured in the electronic health records.

For the sixth measure, *ED Head CT Scan results for Acute Ischemic Stroke or Hemorrhagic Stroke who received Head CT Scan Interpretation within 45 Minutes of Arrival*, the PRT agrees that the timeliness of healthcare provided to a stroke victim plays a vital role in outcomes. For this measure, however, we encourage CMS to clarify whether it requires the actual CT scan report to be present in the medical record within 45 minutes of arrival, or if verbal communication between caregivers that is documented in the medical record will suffice for this measure.

### ***Proposed Measures for 2014 Payment Determination***

#### *Chart Abstracted Measures*

Five chart-abstracted measures are proposed for diabetes for 2014: Hemoglobin A1c Poor Control in Diabetic patients; Low Density Lipoprotein (LDL-C) Control in Diabetic Patients; High Blood Pressure Control in Diabetic Patients; Dilated Eye Exam in Diabetic Patients; and Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.

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. These measures are not applicable to the outpatient setting and the PRT submitted this view in our comments on the 2008 OPSS rule. CMS agreed with our comments, highlighted the patient challenges associated with the measure, and declined to implement these measures. We ask that CMS consider these issues again and remove these measures from the implementation list for 2014.

## *Imaging*

The measure on *Exposure Time Reported for Procedures using Fluoroscopy* assesses the percentage of final reports for procedures using fluoroscopy that document radiation exposure or radiation time. The PRT notes that exposure to fluoroscopy time is impossible to measure, since the service is bundled into the primary procedure; the time-based fluoroscopy CPT codes 76000 and 76001 are infrequently used. Other fluoroscopy guidance CPT codes are not time based, and thus are unable to capture fluoroscopy time. Radiologists and other physicians using fluoroscopy with a procedure do not document the time and the code descriptors do not include a time; thus, even chart abstraction will not identify this information. To meet this measure, hospitals will have to “train” radiology staff and/or radiologists to include this new information in the patient record, which will create an added administrative and staffing burden.

Further, while the PRT recognizes that there is a patient safety issue connected with exposure to fluoroscopy, hospital quality measures must be something that can be accessed by *hospitals*. If CMS wants to require physicians to document data elements so hospitals can conduct chart abstraction, then the agency must require *physicians* to document this information and include this requirement in physicians’ regulations. The PRT is also concerned that CMS appears to be moving towards future requirements that hospitals record time for other contrast agents (e.g., PET scans) and seeks clarification on the desired outcome. It is not clear why tracking this information will help ensure quality on a hospital level.

### ***Administrative Requirements***

The PRT questions the time-frame for submission of participation applications, which CMS presents as 180 days. The 180-day period may not allow facilities enough time to make a decision, educate staff, and obtain the resources needed to participate. We also question the requirement of a participation form for hospitals that do not bill under OPPS and seek clarification on the consequence to those hospitals for their failure to submit this form.

### ***Sampling and Case Threshold***

The PRT agrees that hospitals with five or fewer claims for a specific measure should not be required to submit patient-level data for the entire measure topic for that quarter, but should be allowed to report their data voluntarily. The PRT believes that this stipulation should apply to hospitals with less than six *Medicare* claims, not less than six claims across *all* payers.

### ***Validation Requirements***

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, MAC). While these programs were developed by CMS to serve specific purposes, the end result is that

facilities will receive multiple requests from each contracted entity. It is highly likely that these requests will be made concurrently and that meeting them will significantly increase hospital providers' labor investment and costs. The PRT encourages CMS to review the validation process with respect to other data requirements rather than seeing it as a single request, and to consider the operational impact that receiving multiple audit entity requests will have on any single provider.

### ***Reporting ASC Quality Data***

As CMS notes in the proposed rule, Ambulatory Surgical Centers (ASCs) are not currently required to submit data for *any* quality measures. CMS proposes to continue this deferment for CY 2011 and to address it in future rule-making. The PRT is concerned that CMS is applying two different sets of criteria to hospitals and ASCs. This is especially troublesome, given the agency's increasing emphasis on collecting data from submitted claims.

The PRT understands the burden that ASCs may experience from abstracting measures from medical records, but we cannot understand why implementing claims-based measures (such as imaging measures) would be burdensome to these facilities. The PRT also suggests the following hospital measures that would be highly applicable in the ASC setting: Timing of Antibiotic Prophylaxis; Selection of Antibiotic Prophylaxis; Appropriate Surgical Site Hair Removal. Other applicable topics that would be relevant in the ASC setting are: Patient Fall in an ASC; Burns; and Presence of Physician During Entire Recovery Period. We strongly believe that physician supervision rules that apply to hospitals should also apply to the ASC.

The PRT has commented previously on this issue, and we continue to encourage CMS to develop consistent quality indicators for hospitals and ASCs. The PRT strongly believes that Medicare beneficiaries should receive the same high quality of care regardless of the site of service. While CMS has indicated its intent to level the playing field, having two sets of reporting criteria does not further this goal.

### ***Summary***

As noted, the PRT supports the need to report quality indicators for Medicare outpatients. We believe, however, that it is vital for these measures to accurately capture *quality* rather than other, less meaningful, information. To this end, the PRT suggests that CMS establish criteria to guide the selection of outpatient quality measures for HOP QDRP. First and foremost, hospital measures should measure *hospital outpatient services* rather than inpatient or physician services. We note that quality indicators in the inpatient or physician settings are often inapplicable and inappropriate to the outpatient setting. CMS may be able to "harmonize" quality measures by choosing a set of monitors that assess care across all settings yet measure different *elements* within each setting. Moreover, quality measures must be evidence-based and correlate with patient outcomes, rather than merely describing resource utilization or speed in which care is provided — otherwise, the data provided indicate nothing about quality.

Further, these measures must be clearly defined in the proposed rule. It is essential for CMS to provide specific information in the *Federal Register* on proposed measures so hospitals can

understand the rationale underlying them. CMS must provide information about how reporting a specific measure will affect measurement of hospital quality, and how facilities can ensure that the data are captured efficiently. Any time-based measures must be specifically described in terms of the time-frame and when the clock starts. Only if hospital providers understand the measure (and its use) can we provide meaningful feedback to CMS about its applicability in the outpatient arena. Measures must apply to a *unique* and clearly defined patient population, such as a monitored cardiac rehab patient or a chemotherapy patient. We further suggest that each specific year's measures only be finalized in the final rule pertaining to the year in which the measures will be implemented.

We also strongly believe that ASCs must be required to submit data on quality measures as well. Medicare beneficiaries should receive high-quality care regardless of where they are being served. In addition, physician supervision rules that apply to hospitals should also apply to ASCs.

With respect to registries, we encourage CMS to define the criteria for participating registries and give hospitals adequate time to implement their registries. We urge CMS to continue working with ONC and engage hospitals to develop electronic standards for data submission, and particularly to generate a one-way interface for submitting data to CMS. We also ask CMS to specify that the validation requirements will be the *only* Federal data submission requirement and will replace (rather than supplement) those already established as part of the Federal integrity audit processes (e.g., RAC, Medicaid Integrity, ZPIC, MAC).

To be useful to beneficiaries, more information must be provided on the Hospital Compare website. CMS should ensure that it is clear what entries such as “not applicable” or “blank” say about individual hospitals, or beneficiaries will risk comparing apples to oranges and fail to gain any benefit from the effort to publicize performance measures.

Finally, while the PRT supports efforts to improve the quality of care provided to beneficiaries, we request CMS to continue to be sensitive to the administrative burden that these measures are likely to impose on hospitals and to mitigate that burden whenever possible. Individually, these measures may be feasible to implement, but their sheer volume risks overburdening providers that seek to comply. We encourage CMS to limit the number of measures imposed on hospitals until it has collected and analyzed more data. We recommend that CMS collect data on a smaller number of measures for a period of time (such as two years) before adding additional measures. Better, CMS could substitute new measures for previous ones, and keep the absolute number performance measures stable, thereby reducing provider burden. This would be particularly helpful over the next few years, as EHRs ramp up and become more widely implemented.

### **Proposed OPPS 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 OPPS, the costs incurred by Cancer Hospitals under APCs exceed other hospitals' costs. The ACA also authorized the Secretary to provide for an appropriate adjustment to the Cancer Hospitals to reflect any identified higher costs.

In the 2011 Proposed OPSS Rule, CMS suggests making a positive adjustment to Cancer Hospitals by redistributing “enough payments from other OPSS hospitals to give Cancer Hospitals a PCR that is comparable to the average PCR for other hospitals.” In aggregate, based on Table 55, this results in an impact of -0.7% in total payments to “all other hospitals.”

The PRT opposes redistributing money from other hospitals to make this positive adjustment for Cancer Hospitals, particularly since Cancer Hospitals already receive TOPS payments that are not required to be factored in to budget neutrality. We oppose the movement of money within the system to create this cost adjustment due to the fact that it will penalize all other providers. CMS should identify another mechanism for making this adjustment; the PRT offers alternate suggestions such as fixing the cost report and/or updating the payment-to-cost ratios outside of the OPSS update process.

### **Proposed OPSS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals**

#### ***Reimbursement for Separately Payable Drugs (Average Sales Price)***

The PRT has consistently asked CMS to provide reimbursement for separately payable drugs using at least the average sales price (ASP) plus six percent (ASP+6%). We believe this to be the *minimum* acceptable payment level to cover drug acquisition and pharmacy handling costs, and to allow CMS to create parity for drug reimbursement between the physician’s office and hospital settings. For this reason, the PRT was pleased by CMS’ proposal of ASP+6% for separately payable drug reimbursement for CY 2011 and support this as the minimum amount CMS reimburses for separately payable drugs.

The PRT understands CMS arrived at the ASP+6% reimbursement level by using the same reallocation methodology as was contained in the CY 2010 OPSS/ASC Final Rule: a portion of drug costs associated with coded packaged drug and uncoded packaged drugs were moved to the pool of separately payable drugs before CMS computed the ASP-plus percentage. The PRT appreciates CMS’ willingness to engage in a reallocation process that recognizes and legitimately moves the disproportionate amount of pharmacy handling/overhead costs associated with packaged drugs as a result of charge compression over to separately payable drugs. As CMS knows, charge compression leads to an underestimation of the cost pool associated with separately payable drugs that results in an ASP-plus percentage that is unacceptably low unless CMS conducts a reallocation or another methodological change. We are pleased CMS recognized this disproportion in both the 2010 OPSS proposed and final rules.

The PRT views CMS’ reallocation methodology as a step in the right direction to creating a more appropriate payment level for separately payable drugs. It is unnecessary, however. CMS can achieve a stable payment methodology for payment of separately payable drugs simply by adopting ASP+6% as a minimum payment level for *all* separately payable drugs. Such a policy would be far less cumbersome than CMS’ reallocation methodology, and would create a more stable reimbursement environment for hospitals. Therefore, the PRT asks CMS to pay no less than ASP+6% for all separately payable drugs in CY 2011 and to consider adopting this minimum payment level for future years (with updates for inflation, etc.).

In addition, for CY 2011 the PRT understands CMS proposes to increase the drug packaging threshold to \$70. The PRT is very concerned by this proposal, due to the apparent relationship between the drug packaging threshold level and CMS' calculation of the payment level for separately payable drug APC reimbursement. Therefore, the PRT urges CMS to maintain the current drug packaging threshold at \$65 rather than raising it to \$70 for CY 2011. We believe this is necessary as CMS finalizes a stable separately payable drug APC calculation methodology, since the drug packaging threshold level influences the final payment rates for separately payable drugs.

Finally, if CMS continues with the reallocation process, the PRT believes that CMS would receive more complete and accurate data from hospitals if it simply *required* providers to report HCPCS codes for all drugs under OPDS that have HCPCS codes. It is generally 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 believes that, by stating this requirement clearly, CMS would see an increase in the number of HCPCS-coded packaged drugs hospitals report, particularly if hospitals understand that CMS is using these data to set future rates for separately payable drug reimbursement.

Consequently, due the NDC/HCPCS requirement most providers have had to meet for state Medicaid drug rebate program purposes, we believe many providers are using J3490 for all drugs that do not have a specific HCPCS. We also believe that CMS should require hospitals to report J3490 for *all* drugs that do not have a HCPCS. CMS should also leave revenue code reporting to the discretion of hospitals and mandate that contractors accept detail on 25X revenue lines if utilized. The PRT acknowledges that hospitals and the American Hospital Association (AHA) have been concerned about additional requirements that increase hospitals' operational burden. With the advent of Medicaid NDC reporting requirements, however, the PRT believes that this is no longer a prevalent issue. Hospitals are now required to have a HCPCS code in order to report NDCs to Medicaid programs (including using J3490 as miscellaneous). For this reason, we believe that a requirement to report J3490 for all drugs without a HCPCS code would present a minimal additional burden to providers.

### ***Data Used for the Separately Payable Drug Methodology***

As noted, the PRT is pleased that CMS has proposed ASP+6 for CY 2011, as we have long believed that this is an appropriate minimum payment rate. We are concerned by the inputs used in the methodology, however. If CMS continues to use data for its methodology to set the ASP rate, we suggest a change in the time frame for the data used. The PRT understands that, for CY 2011 proposed payment rates, CMS used data from the April 2010 ASP file and that the final rule will use data from the July 2010 ASP file. Concurrently, CMS will use charge and cost data from 2009 claims data, and cost reports from 2008 and 2009 in the rate-setting methodology.

It is inappropriate to use 2010 ASP information that reflects sales reported to CMS in the first quarter of 2010, which is a completely different time frame than the other data used. More critically, it is illogical for CMS to use ASP file, cost report, and claims data from different years, when it is not only feasible but also more accurate to use data from the *same* year. Therefore, the PRT requests CMS use an ASP file that is better aligned with its claims and cost

report data to determine the “plus” percentage in the ASP-plus calculation used to determine the CY 2011 APC reimbursement rates for separately payable drug.

### ***Therapeutic Radiopharmaceuticals Payment Rate***

The PRT understands that, for CY 2011, CMS proposes to compute APC payment rates for therapeutic radiopharmaceuticals either by using voluntarily reported manufacturer ASP data, if available, or by following its usual charges-reduced-to-cost methodology. The PRT commented on this issue in response to the CY 2010 OPPTS/ASC Proposed Rule and reiterates our views again this year, since we remain concerned about two issues.

First, the PRT notes that manufacturers only have access to their own cost information on radiopharmaceuticals, and do not know about any costs that might be added by the radiopharmacy for its part of this process, or any costs stemming from hospital overhead or handling. For this reason, CMS must be cautious in its use of manufacturers’ ASP data alone. We encourage CMS to require these ASP data from all therapeutic radiopharmaceutical manufacturers and for all therapeutic radiopharmaceuticals (not just a few).

Second, the PRT believes that CMS should allow cost-based reimbursement for therapeutic radiopharmaceuticals in cases where manufacturer-submitted ASP data are not available, rather than relying on its standard claims based rate-setting methodology. If CMS lacks these data from manufacturers, it should continue to pay at cost (i.e., cost-based reimbursement), rather than use an APC rate that is based on claims data.

### ***Clinic Visits – New vs. Established Patients***

The PRT has submitted comments on this area 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 in 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 present visit.

CMS stated in the 2008 Proposed OPPTS Rule: “*The AMA defines an established patient as ‘one who has received professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the past 3 years.’ To apply this definition to hospital visits, we stated in the April 7, 2000 final rule with comment period (65 FR 18451) that the meanings of ‘new’ and ‘established’ pertain to whether or not the patient already has a hospital medical record number. If the patient has a hospital medical record that was created within the past 3 years, that patient is considered an established patient to the hospital. That same patient could be ‘new’ to the physician but an ‘established’ patient to the hospital.*”

The PRT notes, once again, that the original definition in 2000 did *not* specify the three-year time frame; this was added in the 2006 OPPTS final rule. In addition, this time frame is operationally difficult for hospital providers to apply. A hospital medical record number is

created for the individual patient the first time services are provided, which could be at birth, or the first time the patient seeks services from a specific hospital provider. This unique number is utilized each time the patient presents for services and is never assigned to any other patient. A multi-hospital system can choose to use the same medical record number at all of their facilities regardless of which campus the patient presents to. To the extent that hospitals expend additional resources evaluating and managing a new patient, these resources can be accounted for in each hospital's internal visit guidelines, as is the case with consultation codes.

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, the "new patient" visit codes may simply be reported as a matter of course, rather than through some 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 CMS observes. Simply put, the PRT does not trust the data reported by providers to CMS, given our own experiences, the extreme challenges in using the "new patient" codes, and our knowledge that we do not report them very often. 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, rather than having to adhere to CMS' required definition of "new patient".

We once again reiterate our view that CMS should change its policy and require hospitals only to report the five established visit codes, and should continue to map these to five separate APC payment rates. We propose that CMS blend the median cost data for new and established visit codes and create five distinct levels of APC payment for these visit codes. We sincerely believe that CMS will receive much more accurate and complete cost data after two years, at which time we expect APC payment rates for visits will stabilize and be more reflective of our resource consumption.

If CMS chooses to continue reporting 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" and return to the original definition published in 2000: *"If the patient has a hospital medical record, that patient is considered an established patient to the hospital."*

### **E/M Guidelines**

The PRT notes that hospitals are required to both develop and use evaluation and management (E/M) visit guidelines. We believe, for consistency, that CMS should require contracted program auditors (i.e., FI, MACS, RAC) to also use these guidelines when conducting a hospital audit. As we noted last year, until there are national visit guidelines, CMS should **require** auditors to request the individual hospital's E/M guidelines before performing any review or denial of E/M levels. The PRT has learned that some contracted program auditors persist in imposing their own, unpublished E/M criteria rather than using the provider's internally developed E/M guidelines during facility audits. These auditors are determining services' "reasonableness" related to placement within various levels. When applied by these auditors, these unpublished

guidelines are detrimental to the hospital claims data and produce lower-level calculations than the hospital's internal guidelines.

More importantly, this practice conflicts with CMS' directive requiring providers to develop and use their own guidelines to report hospital outpatient department and Emergency Department E/M visit codes. Our concern is heightened by the Office of the Inspector General's (OIG) audit activity and national expansion of RAC audits. We fear that these organizations will choose guidelines they believe to be "better" or more understandable, rather than using the hospitals own, internal guidelines. It harms both hospitals and to CMS' claims data if audit results change E/M levels based on unpublished criteria rather than using guidelines established and utilized by the individual hospital.

Simply put, hospital internal guidelines must be recognized by contracted program and Federal auditors. Moreover, CMS must provide clear direction to all auditors that they are *required* to use the individual facility's E/M internal guidelines when conducting a review or audit. CMS should explicitly state that no contracted program auditors (FI, MAC, RAC, etc.) may impose their own criteria upon the provider. We encourage CMS to issue these explicit instructions as soon as possible.

### **Drug Administration**

*In the proposed rule, CMS responded to the APC Advisory Panel's 2<sup>nd</sup> recommendation by noting: For example, CPT code 96376 would be billed with CPT code 96374 (Therapeutic, prophylactic, or diagnostic injection; intravenous push, single or initial substance/drug), which describes an initial intravenous push code and, as a result, the cost for CPT code 96376 would be reflected in the total cost for CPT code 96374. Moreover, payment for these services has always been packaged into payment for the drug administration services without which they cannot be correctly reported. These two codes each describe services that, by definition, are always provided in conjunction with an initial drug administration code. These services have been packaged since the inception of the OPSS, and we continue to believe they are appropriately packaged into the payment for the separately payable services without which, under CPT guidelines and definitions, they cannot be appropriately reported. Therefore, for CY 2011, we are proposing to make packaged payment for CPT code 96368 and CPT code 96376 and assign them a status indicator of "N."*

The PRT notes that this statement contains several inaccuracies. It is not the case that payment for these services has "always been packaged into payment for the drug administration services...since the inception of the OPSS." In reality, hospitals formerly used a single CPT code for reporting IV push administrations, CPT 90784. This code was reported and paid separately for each and every IV push of either the same or different medications. When the CPT coding system changed, payment for the "initial" successor CPT code (90774 [now 96374]) remained virtually identical to the rate for the previous code. Similarly, services now reported with 96368 were historically reported under CPT codes 90780 and 09781 and received separate payment.

Last year, the PRT requested that CMS provide separate payment for two additional drug administration CPT codes; CPT code 96376 and 96368. We noted that hospitals have been

reporting these codes without receiving any separate reimbursement for the last several years. We believe that CMS has sufficient data with which to make a separate payment determination for these services. The PRT has previously submitted comments on the resources required to provide multiple IV push injections of the same substance or drug being similar to the initial, or even the subsequent, IV push injection code. We once again ask CMS to assign CPT code 96376 to the same APC as 96374. We note the AMA's intent that this unique code only be used by facilities. We continue to believe CMS should recognize the additional nursing time and resources required during both an IV Push for the same medication as well as a concurrent infusion and provide separate reimbursement for both CPT codes 96376 and 96368. We urge CMS to provide a discussion of the median costs for both of these services in the final rule and to begin providing separate reimbursement in 2011.

### **Physician Supervision**

#### ***Direct Supervision of Therapeutic Services***

In the OPSS proposed rule, CMS reiterates its “*continuing commitment to require direct physician supervision of the services in a Hospital Outpatient Department as requirement for payment.*” In addition, CMS notes that: “*if there were problems with outpatient care in a hospital or in an on-campus PBD [provider-based department] where direct supervision was not in place (that is, the expectation of direct supervision was not met), we would consider that to be a quality concern.*” The PRT appreciates CMS’ interest, stated in the CY 2011 OPSS/ASC Proposed Rule, in having a “robust discussion” on this very important issue that is of concern to hospitals, including critical access hospitals (CAHs) and rural hospitals. The PRT is pleased to engage in this robust discussion and wishes to provide the following comments.

In the proposed rule, CMS discusses details about the difference in the Conditions of Participation (CoPs) and payment requirements and we understand CMS’ discussion of CoP versus payment policy. We fundamentally disagree with the premise, however, as well as the statement that CoPs are: “*established as minimum standards for patient health and safety, focusing on creating a foundation to insure quality and safe care for beneficiaries.*” This concept creates discord on a practical level. In a recently communicated transmittal (Transmittal 60 Pub 100-07, dated 7/16/2010), CMS itself stated that an individual is protected by the hospital’s Conditions of Participation, which protect patient’s health and safety and ensure high-quality care is furnished to all patients in Medicare-participating hospitals.

If an entity meets the requirements of the CoPs and therefore is deemed to be in existence as a facility, but cannot receive reimbursement for services because the payment requirements are onerous, the facility will be required to close operations and will cease to exist. This creates especially large payment issues for facilities with very high Medicare and Medicaid populations. If a facility is incapable of meeting the CoP requirements, then clearly it will not be recognized as a facility and will not be eligible to receive payment under the Medicare program. CMS’ CY 2011 OPSS/ASC proposed rule places stricter guidelines on facilities to receive payment — and the PRT fundamentally disagrees with this. Congress created the exemption related to supervision of therapeutic services for CAHs to allow beneficiaries to have access to services and quality care. If a hospital meets the CoPs, but cannot meet the more onerous payment

requirements, the opposite will occur: beneficiaries will *lose* access to care, which, in our opinion, is the equivalent of CMS disregarding Congress' intent in providing the CAH exemption.

CMS suggests in the proposed rule that, because CAHs are reimbursed based on cost, they are better able to hire staff to meet the supervision requirements, stating: “...we also believe that both small rural hospitals paid under the OPPIs through section 1833(t) of the Act and CAHs paid at reasonable cost under section 1834(g) of the Act have similar staffing and resource constraints. In fact, given that CAHs are reimbursed based on their reasonable costs, we reasoned that CAHs might be better able to hire staff to provide direct supervision.”

The PRT appreciates CMS allowing non-physician practitioners (NPP) to provide direct supervision and believes this will create a positive situation for all hospitals, including CAHs. However, one of the obstacles for CAH facilities is the difficulty in recruiting and sustaining practitioners who understand the culture of a rural community, the limitations of the healthcare offerings, and usually frequent “on call” obligations resulting from the limited number of practitioners in the community. There are huge challenges to convince providers to practice in rural areas, regardless of the salaries offered or paid, which is one of the main reasons that Congress granted the supervision exemption to CAHs. Being forced to meet these supervision requirements will produce one of two results: either costs to the program will increase due to difficulties in obtaining and/or retaining practitioners, or the CAH will cease to exist due to lack of practitioners to fulfill the stringent supervision requirements.

CMS should deliberate this point further, while it engages in this robust discussion. If the agency feels compelled to do something for CAHs, the minimum it should consider is to allow CAHs to continue to operate using the baseline established by the CoPs and extend the existing moratorium on the 2010 physician supervision rules for two years while continuing to gather data. This issue is critical and all avenues should be considered before a permanent policy is established.

The PRT submits that supervision has long been established for all services provided to a beneficiary. The *Medicare Benefit Policy Manual* (Pub 100-02), chapter 6, section 20.5.1 requires that: “services and supplies must be furnished on a physician’s order and delivered under supervision” and “during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often enough to assess the course of treatment and the patient’s progress and, where necessary, to change the treatment regimen.” Outpatient services are initiated with a physician’s order that shows the service is “incident to” the physician’s professional service. The service is based on the individual patient’s diagnosis and clinical situation. Continuing services have a plan of care driven by the attending physician and detailing the type, frequency, and duration of the service, along with physician-documented monitoring. The attending/treating physician has had to be continually involved in the care of the patient, as evidenced by the physician ordering a therapeutic service for his/her patient. The physician personally sees and evaluates the patient; creates a treatment plan; monitors the patient’s response within the treatment plan; and makes any needed changes and/or adjustments to the plan for the individual patient.

This ownership belongs to the treating physician and he/she is already supervising the treatment of the patient via communication with the treating department/facility as well as on-going evaluations of the patient. It is the physician's responsibility to know the facility and staff and the services provided by the facility, and to justify the medical necessity of the ordered service. This is the physician's on-going role in managing the patient; the expectation has already been laid out for the ordering/treating physician and treating facility to ensure that medical management occurs.

In the past, guidance language was neither so specific nor restrictive and allowed hospitals to create the most appropriate structure to meet the "incident to" requirement. More recently, however, CMS has begun to more specifically define what the structure should be — which complicates operational processes. Because hospitals knew supervision was required, they both needed and wanted to ensure safe provision of services to patients. Each hospital's governing body established an appropriate structure to provide supervision of hospital services based on the individual premises. These structures are in place today, but CMS' recent, detailed discussions have complicated the concept of physician supervision. It now appears that the rules have changed overnight, making it more costly to implement and administer the concept without any added value to the hospital, beneficiaries, or the Medicare program.

CMS believes that the additional layer of requirements for hospitals will improve the quality of services rendered. These requirements include having a physician or non-physician practitioner "immediately available" who is credentialed to provide supervision for the specific service being provided, who possesses the ability to take over the performance of the procedure, and who can change a procedure or course of treatment if necessary. The PRT disagrees wholeheartedly with CMS' belief. The prescribed requirements do *nothing* to promote quality care or add value to the services provided. They serve only to delay treatments and services and to add layers of cost and complexity to facilities' operations, resulting in increased cost to the Medicare program. CMS' requirement for direct supervision means a physician cannot be involved in anything that may not be interrupted. This requirement creates a situation in which hospitals have to purchase physician and non-physician practitioner supervision services, resulting in increased Part A physician administrative costs. A physician cannot render Part B payable patient care during his/her responsible period of supervision; therefore, the hospital must absorb this cost as Part A administrative costs and include it as part of the overhead resources expended to provide services. This further increases costs to the Medicare program without adding value.

CMS reiterates that it is a "value-based purchaser" as originally defined in the CY 2007 OPPTS proposed rule: "*Value-based purchasing*" may use a range of incentives to achieve identified quality and efficiency goals, as a means of promoting better quality of care and more effective resource use in the Medicare payment systems." The PRT understands the principles underlying value-based purchasing and supports the use of incentives to motivate providers to improve the quality of health care services. We fail to see, however, how the proposed requirements add value or promote quality when they simply serve to increase inefficiencies and costs. This proposed requirement does not advance CMS' stated goal. Nor does the PRT believe that quality of care, appropriate risk mitigation, and supervision are the responsibility of the facility and treating physician who has ordered the services — rather, these requirements are met through compliance with the CoPs.

Physician supervision is a CoP issue for facilities, but should not be a payment issue. CMS acknowledges that hospitals are providing quality care currently as there have been few incidents reported nationally of any significant adverse events for HOPD services. Ensuring such quality is one reason that CMS requires Hospital Quality data reporting, and reduces a hospital's payment if it fails to report quality data. The above is in direct harmony with CMS' statement in the CY 2007 proposed rule: *"We believe that the collection and submission of performance data and the public reporting of comparative information about hospital performance can provide a strong incentive to encourage hospital accountability in general and quality improvement in particular. Measurement and reporting can focus the attention of hospitals and consumers on specific goals and on hospitals' performance relative to those goals. Development and implementation of performance measurement and reporting by hospitals can thus produce quality improvement in actual health care delivery."*

Direct Supervision does not apply if there is a specific benefit category, such as Radiation Oncology, Therapy Rehab services, Medical Nutrition Therapy, or Diabetes Education. Payment under a separate benefit category does not eliminate any concerns related to quality of care and access to services. Because of requirements that are already in place, hospitals have implemented consistent processes to monitor provision of *all* services to ensure a quality environment for all beneficiaries. CMS has acknowledged that these benefit categories are fine and do not appear to suffer diminished quality as provided under the overall CoP quality oversight by facilities. It is unclear why non-specific benefit services should be uniquely identified for additional physician supervision.

In the proposed rule, CMS cites four criteria to be utilized in the selection process for services that will be classified as "nonsurgical extended duration therapeutic services" (NSEDTS). The PRT is vehemently opposed to the establishment of this list. It is incomplete and will have to be reviewed, updated, and maintained annually —just as the Inpatient-Only list has been since OPPTS' advent. This is burdensome to both the provider community and CMS' policy staff. While CMS believes it is feasible to provide a "blended" level of supervision, in reality, this is anything but feasible for providers.

CMS should remember that not all patients have infusion therapy ordered at the same time. Patients requiring these services arrive at all hours of the day and night. To provide an initial period of direct supervision for each patient would necessitate having a physician in-house *at all times*. This is the case because as soon as one patient can safely move to a general level of supervision, a second patient will arrive and the direct supervision period will begin for the initiation period of that patient's infusion service.

For example, consider a patient who has infusion therapy for two hours, at which point the physician deems the initiation period to have been completed, and the patient to be stable. The physician leaves the hospital and goes home. Three hours later, that patient requires the *next* scheduled infusion (infusion services are often provided to patients in this manner over the course of their observation stay). This next infusion is on the list of services requiring direct supervision for initiation on a patient who is already stable. In this case, the physician would be required to return to the hospital for the next scheduled infusion and would have to return to the

hospital several times during the night. Yet, this service can be safely administered by the clinical staff on the basis of being “incident to” a physician order.

Another example is provided by the patient who comes to the hospital three times a day, five days a week, for a course of antibiotic therapy for a condition such as cellulitis. Under the proposed rule, the physician would be required to attend *each* initiation of *each* session of the antibiotic treatment. For rural and CAH hospitals, these examples present especially troubling scenarios, as these facilities operate in provider-shortage areas, as noted previously. The PRT appreciates CMS’ attempt to help hospitals, but this proposal does nothing of the sort.

In addition, the proposed list fails to include other therapeutic services that require less direct supervision, such as clinic visits for blood pressure checks or ostomy care and treatment. These services exclude an invasive procedure and their risk classification is very low; nonetheless, based on CMS’ current proposal, these services will require direct supervision as a therapeutic service. These scenarios are not specified in the NSEDTS table, but the PRT understands CMS’ proposal to mean that any service not specifically listed in the CY 2011 OPPI/APC proposed rule’s Table 37 that meets the definition of a “therapeutic service” will require direct physician supervision. It is unclear how a facility will be able to convince a physician to provide direct supervision for this type of service, and how this level of supervision contributes positively to the quality of care and service that CMS states it is purchasing.

The PRT believes that CMS intended the proposed exception for the NSEDST to provide increased flexibility for hospitals, but notes that the result (if this proposal is finalized) will be increased complexity; increased administrative burden; and greater levels of frustration on the part of hospitals, physicians, and NPPs — with *no* added value or measurable improvements in quality of care.

In the proposed rule, CMS acknowledged that consideration was given to the possibility of allowing the hospital’s Quality Committee to review services rendered and plan for the appropriate level of supervision. CMS states: *“We considered proposing minimum requirement for these internal supervision guidelines, including annual review and approval by a governing committee, periodic internal evaluation of implementation, and the ability to make these guidelines available to Medicare program auditors if requested. Further, these guidelines would be reviewed thoroughly by CMS should a quality issue arise. Given the complexity of services such as chemotherapy and blood transfusions, and the probability that the physician’s or nonphysician’s physical presence will be required during the service, we decided to propose a policy to ensure greater safety for these higher acuity services. We also chose not to pursue this internal guidelines option because we believed that hospitals would find these requirements onerous and that the policy would not necessarily provide the flexibility that CAHs and rural hospitals desire.”*

The PRT believes that this language describes an option that is far superior to the NSEDTS proposal. Given CMS’ expectation that supervision will be provided, and that there should be flexibility incorporated into the process, the PRT contends that an internal governing committee process is much less onerous for all facilities than the CMS’ CY 2011 proposal. In general, we agree that the supervision level needs to be appropriate for the type of service and risk involved,

and that the creation and monitoring of this level should be controlled by the local community, the individual state's practice acts, and governing body of the individual hospital.

Each licensed discipline has a scope of practice, which specifies the limitations of practice for the individual discipline. For example, the Nurse Practice Act contains the scope for practicing as a Registered Nurse. Nurses who seek a higher level of practice are required to obtain additional education and licensure at a higher level. Continuing education is also required to maintain credentialing and continued proof of competency to practice at the higher level of competency/licensure. Each Practice Act is designed to ensure that the highest level and quality of care is provided to each patient. Each facility already has a Quality Committee in place, which is the appropriate environment for discussions and decisions concerning the provision and level of supervision for hospital services. These committees already investigate adverse outcomes, since it is a hospital's responsibility to protect their patients. CMS and its approved accrediting agencies require that facilities have these checks and balances in place to create a framework to avoid quality of care problems. It would require minimal operational burden to alter the current infrastructure and incorporate a more formal focus on outpatient services into the committee's oversight and monitoring activities. CMS' proposal included the capacity for "*periodic internal evaluation of implementation*", which is already a responsibility of the Quality Committee. This existing structure would allow the appropriate level of supervision for therapeutic services commensurate with high-quality care as well as increased access to services.

We believe this is feasible, given regulations CMS has implemented in the past and hospitals' demonstrated compliance with these regulations. CMS outlines 11 guidelines that hospitals must follow in creating their own internally developed guidelines for outpatient Evaluation and Management (E/M) visits. CMS allows facilities flexibility in determining what sort of guidelines to create (i.e. time-based, intervention based, etc.) and how best to incorporate them so quality, compliance, and safety standards are met. Hospitals already have processes in place for handling emergencies and intervening when an unexpected occurrence happens (e.g. a patient has a reaction during a blood transfusion). In such instances, the hospital staff is immediately on the phone with the attending/ordering physician regarding the patient and the intervention process is activated before the supervising physician arrives. Just as CMS trusts these mechanisms, it should trust its CoP requirements — along with all other safety and quality guidelines already in existence — with respect to hospitals providing outpatient services incident to a physician's service. Should a quality issue arise, or a hospital show a lack of commitment to quality care and outcomes, then CMS should be involved in discussions with that facility and take action as needed.

Facilities currently have operational processes in place to prevent adverse incidents to the extent possible. For example, when a new drug arrives, the Pharmacy and Therapeutics (P&T) Committee issues guidelines that often specify the credentials required for each physician, to insure that the medication is ordered only by qualified practitioners. These guidelines also outline specific criteria regarding diagnoses for which the medication can be ordered and administered, as well as specification of appropriate dosage(s) for specific scenarios. Hospitals created this internal mechanism not only to meet the requirement for drug usage review but also to be proactive and mitigate the potential for adverse situations/occurrences.

Likewise, the Food and Drug Administration (FDA) recently announced a new requirement for all healthcare professionals who prescribe and administer drugs known as Erythropoiesis Stimulating Agents (ESA). An education program is required for all hospital staff and other healthcare professionals who administer these drugs; in addition, specific documentation is required to support the patient's understanding of any risk related to receiving the drug. The FDA's requirement supports the already established internal hospital structure of an internal mechanism to assure appropriate quality of care.

In summary, the PRT urges CMS not to implement the "nonsurgical extended duration therapeutic services" (NSEDTS) list. Alternatively CMS should allow hospitals' Quality Committees to review services rendered and plan for the appropriate level of supervision, whether it be general or direct supervision, for outpatient therapeutic services.

### ***Supervision of Diagnostic Services***

The PRT understands that currently, under section 1834(g) of the Act, CAHs are exempt from supervision level of diagnostic services as noted in the MPFS. CMS stated the following: "*We note that the current requirement in §§410.28(e)(1) and (e)(2) that physician supervision of diagnostic services provided in the hospital or in any provider-based department follow the levels for diagnostic services established under the MPFS explicitly applies to hospitals that are paid pursuant to section 1833(t) of the Act, which is the statutory authority for the OPFS. Because Medicare makes payments to CAHs pursuant to section 1834(g) of the Act, at this time, CAHs are not subject to this supervision requirement.*"

The proposed rule's discussion intimates that CMS is considering removing this exemption for CAHs. The PRT wholeheartedly opposes this consideration, as it totally negates the CoPs that were created to allow services to be provided to beneficiaries living in rural and outlying areas. Extension of this requirement inflicts additional payment requirements onto hospitals that already face a shortage of practitioners. Therefore, the PRT requests CMS to fully and clearly clarify in the 2011 OPFS/ASC final rule what it intends with respect to the supervision of diagnostic services in CAHs.

### ***Supervision Requirements for ASCs***

The PRT is concerned that, once again, CMS appears not to describe a direct physician supervision requirement for ambulatory surgery centers (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 there is no requirement for a physician to be on-site or immediately available. This policy creates significant inequalities and variations in the requirements for physician supervision between hospital outpatient departments and ASC facilities, which provide many identical services.

The PRT believes that CMS may be allowing existing CoPs to guide ASC practices without adding any separate requirements related to physician supervision, and asks 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.

### *Summary*

- The PRT does **not** support creation of a list of “nonsurgical extended duration therapeutic services”.
- The PRT submits that the Hospital Conditions of Participation should suffice for assuring quality care and supervision of services not only for CAHs but also for all facilities participating in the Medicare program.
- The PRT recommends that CMS exercise flexibility and trust hospitals to create the governance to ensure that quality of care is met, and notes that hospitals have proven this can be successful. Formalized guidelines can be created by the individual hospital to work within the facility’s operational processes.
- The PRT encourages CMS to continue to deliberate the challenges facing CAHs. If the agency feels compelled to do something in the short-term, the minimum action it should consider is to allow CAHs to continue to operate using the baseline established by the CoPs and to extend the moratorium for two years while this robust discussion continues.
- If CMS is determined to create this list, however, the PRT suggests that a more palatable alternative is to create a list of services that require *only* general supervision, not direct and/or some hybrid approach. Further, if this list must be created, CMS should consult with the American Medical Association about which services require direct versus general supervision.

### *Inpatient-Only Procedures*

The PRT has asked CMS to eliminate the list of procedures paid only in the inpatient setting on more than one occasion in our comments on previous OPSS rules. We reiterate this request, since we believe that the inpatient-only list is unnecessary. The list also increases Medicare expenses by maintaining procedures in the inpatient setting long after technology and medical advances have made them safe to be performed in the outpatient setting. CMS has stated that the inpatient-only list is maintained as a safety mechanism to protect the older Medicare beneficiaries. We note, however, that age alone should *not* be used to determine whether a procedure is appropriately provided in the inpatient and/or outpatient setting. Medicare beneficiaries may be, and often are, healthier and hardier than younger patients covered by other types of insurance. The appropriate surgical setting should be decided by the physician’s assessment of the patient’s clinical picture, in conjunction with the desires of the patient and his or her family.

If CMS insists on maintaining the inpatient-only list, the PRT asks that the following codes be removed from it and that reimbursement be allowed when these procedures are performed in the outpatient setting.

*28800 — Amputation, foot; midtarsal (e.g., Chopart type procedure)*

The PRT recommends removal of CPT code 28800 from the inpatient-only list. We believe that, due to advances in wound healing, tissue oxygenation evaluation, antibiotic therapy, and vascular and amputation surgery techniques, this is appropriate. We note that CPT code 28805 (amputation, foot; transmetatarsal) is a similar procedure and was removed from the inpatient-only list in 2010. The following paragraphs, from *Coder's Desk Reference*, describe these procedures, which are similar other than in the level of the amputation (i.e., midtarsal versus transmetatarsal).

28800: The physician amputates the foot across the midtarsal region. The physician makes the incision so that skin flaps are made dorsally and plantarly. The skin is refracted and the dissection is carried down through the soft tissue. The tendons are severed and allowed to retract. The dorsal and plantar ligaments of the calcaneocuboid and talonavicular joints are released so that the foot can be removed. The physician may also perform a percutaneous Achilles tenotomy (reported separately) to prevent flexion contracture. Skin flaps are closed and a soft compression dressing is applied.

28805: The physician amputates the foot across the transmetatarsal region. The physician makes the incision so that skin flaps are made dorsally and plantarly. The skin is refracted and the dissection is carried down through the soft tissue. The tendons are severed and allowed to retract. The dorsal and plantar ligaments are released so that the foot can be removed. The physician may also perform a percutaneous Achilles tenotomy (reported separately) to prevent flexion contracture. Skin flaps are closed and a soft compression dressing is applied.

The PRT believes that, if CPT code 28805 is appropriately provided and reimbursed in the outpatient setting, it is consistent to remove the restriction on outpatient reimbursement for CPT code 28800 as well.

*43770 — Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components):*

The PRT requests that CPT code 43770 be removed from the inpatient-only list. Both *Milliman Care Guidelines* and InterQual criteria indicate that CPT code 43770 is appropriately performed in the outpatient setting. A review of the *Bariatric Accreditation Manual* from the American College of Surgery (ACoS) Bariatric Surgery Center Network Accreditation Program also provides information supporting Laparoscopic Banding in the outpatient setting (see <http://acsbscn.org/docs/Program%20Manual%20V2.11-1-08.pdf>).

*60270 — Thyroidectomy, including substernal thyroid; sternal split of transthoracic approach:*

The *Milliman Care Guidelines* recommend that CPT code 60270 be performed in the ambulatory setting. In addition, an Internet review provides many examples in recent literature to support outpatient thyroidectomy as safe and cost effective. A good example is: Snyder, S.K., Hamid K.S. Roberson, C.R., et al., "Outpatient Thyroidectomy is Safe and Reasonable: Experience With More Than 1000 Planned Outpatient Procedures", *Journal of the American College of Surgery*

2010; 210:575-584. The PRT requests CPT code 60270 be removed from the inpatient-only list for 2011.

*63267 — Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar:*

CPT 63267 can be used for any non-neoplasm lesion, from a small synovial cyst to a large benign tumor. The size and type of the lesion determines the length of the surgery and the degree of invasiveness. It is worth noting that, in the last five years, discectomies (CPT 63075) have been removed from the inpatient-only list, and that other laminectomies are also absent from the inpatient-only list. *Milliman Care Guidelines* recognize that limited or minimally invasive laminectomies can safely be performed as an outpatient procedure. Rather than require an inpatient stay for a minimally invasive removal of a synovial cyst, the PRT request that CPT code 63267 be removed from the inpatient-only list entirely.

In summary, the PRT encourages CMS to remove CPT codes 28800, 43770, 60270, and 63267 from the inpatient-only list for calendar year 2011.

#### **Proposed Payment for Partial Hospitalization APCs**

The PRT recognizes and applauds the fact that CMS supports the creation of separate APCs to differentiate between the cost of services provided in the hospital-based PHP setting and the Community Mental Health Center (CMHC) setting. We believe that it is appropriate to distinguish between these types of providers, as the CMHC is a distinct provider type that should not have been included in the hospital cost data from the inception of OPSS.

#### **Proposed OPSS APC-Specific Policy: Skin Repair (APCs 0134 and 0135)**

The PRT does not support the creation of two new HCPCS G-codes for reporting the application of Apligraf and Dermagraft for the lower extremities at this time. We believe that the American Medical Association (AMA) and the CPT Editorial Panel have been reviewing issues related to Apligraf and Dermagraft application, CPT codes 15340 and 15341, and CPT codes 15365 and 15366. Reporting HCPCS codes to Medicare and CPT codes to non-Medicare payers requires providers to maintain two coding structures in order to report the same service, a process that is operationally difficult. Therefore, the PRT recommends that CMS work directly with the AMA to expedite the creation and release of permanent CPT codes for the application of Apligraf and Dermagraft to the lower extremities. This will yield a viable, long-term solution. Conversely, any proposed G-codes released by CMS now will have to be replaced with permanent CPT codes in the near future. Changing codes in this manner merely creates confusion and is burdensome for coding staff.

The PRT has previously commented both in support of — and in opposition to — CMS' development and use of HCPCS Level II codes for reporting services. The PRT reviews the merits of each proposal on a case-by-case basis; we recognize that sometimes it is both important and operationally acceptable to have HCPCS codes. This is not one of those cases, however,

since CPT codes are imminent and creating HCPCS will not only complicate the situation but also necessitate additional changes in the near future.

**Conclusion**

The Provider Roundtable sincerely 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 at (704) 512-6483*. A full list of the provider roundtable members is included below in Appendix A.

Sincerely yours,

***Members of the Provider Roundtable***