

Asante Health System, OR
Avera Health, SD
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Erlanger Medical Center, TN
Forrest General Hospital, MS
Health First, Inc., FL
Lovelace Health System, NM
Mercy Medical Center, IA
Our Lady of the Lake Regional Medical Center, LA
Saint Joseph's Hospital, WI
St. Joseph's/Candler Health System, GA
Saint Mary's Hospital, MN
Sheltering Arms Rehabilitation Hospitals, VA
Sisters of Mercy Health System, MO
Twin Lakes Regional Medical Center, KY
University Health System, TX
Vanguard Health System, TN

August 31, 2008

Submitted electronically: <http://www.regulations.gov>

Re: CMS-1404-P

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers from around the country who gathered to provide comments on the 2009 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on July 18, 2008.

Introduction

The Provider Roundtable (PRT) is a group of providers representing 18 different health systems from around the country. The members of the PRT collaborated to provide substantive comments with an operational focus which CMS' staff should consider during the OPPS policymaking and recalibration process each year. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

We appreciate the opportunity to provide CMS with our comments, and recognize that providers must become involved in the comment process if OPPS is to improve with time. A full list of the current PRT members is provided in **Appendix A**.

Cost Report related items (Proposed calculation of CCR's, RTI report recommendations, New Cost Centers, etc)

I. Payment for Specified Covered Outpatient Drugs

The Provider Roundtable (PRT) strongly opposes CMS' proposal to reimburse separately payable drugs at the average sales price plus four percent (ASP + 4%). The PRT recommends that CMS freeze separately payable drug APC payment rates at ASP+6% until such time as the agency can determine the appropriate payment rate for both the acquisition and pharmacy handling/overhead cost associated with separately payable drugs. Providing reimbursement at ASP + 6% will at least streamline CMS' current drug payment policy between the physician office and hospital settings.

II. Changes to Cost Reporting

The PRT agrees, in principle, with making strategic decisions to refine the method of calculating both MS-DRG and APC weights for the integrity of both prospective payment systems. We also agree that accurate cost reporting is crucial to developing accurate payment rates that supports better hospital decision making regarding health care service lines. But, we strongly remind CMS that requiring providers to make changes to accounting, cost reporting, and billing practices to improve the accuracy of relative weights does *nothing* to add additional revenue into either payment system, and can cause enormous administrative and operational burden for providers.

Therefore, the PRT requests that CMS take the following seven points into consideration prior to proposing any operational changes that would impact the aforementioned hospital areas:

1. CMS should give significant preference to changes that it can make administratively through claims, cost reporting, and data analysis over changes that require provider action. This is critical in alleviating provider burden by ensuring that operational changes are made systematically rather than relying on providers to make changes. The PRT supports CMS making the following operational changes:

- Using text searches of provider's line descriptions to more appropriately classify non-standard cost centers in current hospital cost reports;
- Changing cost report preparation software to impose fixed descriptions on non-standard cost centers;
- Clarifying instructions to require hospitals to report all standard cost centers when they offer those services, but only if instructions regarding direct expense assignment, capital expense assignment, statistics for overhead allocation and matching gross revenue for both inpatients and outpatients are included;
- Revising the cost center aggregation table to eliminate duplicative or misplaced nonstandard cost centers and add nonstandard cost centers for common services without one;
- Using cost center 4300 (radioisotope) as the primary cost center for nuclear medicine revenue code(s) 034x;

- Using the RTI's revised revenue code to cost center crosswalk;
- Removing the primary cost-to-charge ratios (CCR) for revenue code 0275, and keeping only CCR for cost center 5500.

2. CMS should ensure that changes requiring provider action not add significant administrative burden or cost to those providers. Adding administrative cost to hospitals will take resources away from direct patient care and initiatives designed to drive or improve the quality of care. CMS and the hospital industry do not want to divert precious scarce resources away from beneficiaries, but this can unfortunately be the result when major operational changes are required as a result of CMS' proposed payment system changes.

3. CMS should be more deliberate and methodical in the process used to determine what changes to make, when, and how. CMS should announce a required change no less than one year prior to the effective date. The effective date should be at the beginning of a calendar quarter and the change should be effective for cost reporting periods beginning on or after that date. CMS must also coordinate cost report requirements with State Medicaid Programs. CMS should require Fiscal Intermediaries (FI) and Medicare Administrative Contractors (MAC) to meet with hospitals and agree on the methods used to implement the changes in the cost report because hospitals should not go through the effort of making these changes with the uncertainty of possible adjustments by FI and MAC audit staff at audit time.

4. CMS should *only* use cost-to-charge ratios derived from hospital cost reports that comply with CMS instructions for current relative weight calculation processes. If CMS continues to use suspect cost reporting data for relative weight development, the hospital industry and other stakeholders will continue to have concerns with the resulting payment policy decisions.

5. CMS must ensure that changes are designed to address cost reporting and cost accounting principles for both the outpatient and inpatient prospective payment systems. CMS should only require changes that are appropriate and applicable across both systems as good cost reporting principles require. The PRT asks CMS to be more explicit regarding charge practices that must be consistent between inpatient and outpatient services, particularly with regard to charge practices for non-routine services performed by nursing in routine cost centers.

6. CMS must be very prescriptive and detailed in its instructions for change in order to reduce providers' administrative burden and ensure consistency of implementation. CMS should explicitly define, for all hospitals, the components of the formula to derive CCRs from defining and grouping direct expense to a cost center, directly assigning capital to a cost center, allocating overhead to that cost center, matching revenue to that cost center, and then applying the CCR to the correct charges on claims.

7. CMS must have the ability to validate providers' implementation of the changes. Refinements to the relative weights as a result of these cost report and billing changes rely on hospitals as a collective whole to make the necessary changes. Otherwise, CMS will receive mixed data that will fail to achieve the desired results. CMS should also specify the compliance consequences to

hospitals that do not implement changes. Without this information, many hospitals may not implement the changes.

III. Cost Reporting Educational Efforts

CMS has stated that it supports the provider community in improving the accuracy of cost reporting and has issued Transmittals 321 and 362 as evidence of this support. The PRT is concerned that these transmittals merely restate cost reporting policy and principle, rather than instructing hospitals on how to improve their cost reporting practices. We seek specific guidance about what CMS expects hospitals to do because we believe that, unless specific action steps are detailed, hospitals will fail to change their current cost reporting practices. Therefore, the PRT urges CMS to be more specific in its educational efforts and to detail specific requirements and the consequences of non-compliance. The PRT asks CMS to provide the following information to all hospitals in transmittals and MedLearn Matter articles.

1. Cost Reporting Practices

CMS should publish simple singleton claim examples to illustrate to hospitals the importance of correctly pricing their procedures, supplies, and drugs; and of ensuring that the cost center reflecting the service’s expense is the same as that used by CMS in the revenue center crosswalk. Examples should be taken from revenue centers or cost areas that have generated a significant level of controversy, such as implants/devices and blood and blood products.

Rev Code	HCPCS	Charges	Primary Cost Center Line for CCR from Crosswalk	Secondary Cost Center Line for CCR from Crosswalk	Calculated Cost
250		\$134.15	5600 Drugs charged to patients = 0.34		\$45.61
258		\$174.22	5600 Drugs charged to patients = 0.34		\$59.23
275	C2619	\$8,200.00	3540 Prosthetic Devices = NA	5500 Supplies charged to patients = .23	\$1,886.00
320	71090	\$175.60	4100 Diagnostic Radiology = .51		\$89.56
361	33213	\$5,216.24	3700 Operating Room = .42		\$2,190.82
Total		\$13,900.21			\$4,271.22

This example would enable hospitals to clearly see that, if they defined cost center 3540 for prosthetic devices in their cost report, their pacemaker charges (required to be billed under revenue

code 275) would be reduced to cost using that CCR. It would be more appropriate to use CCR 5500 “Supplies charged to patients”. The reason that “NA” is listed under the primary cost center for revenue code 275 from above is that hospitals do not typically report pacemaker costs with prosthetic costs. This example also illustrates how CMS’ calculation results in an estimated pacemaker cost that is significantly lower than the true costs. Increased provider awareness of these issues will encourage them to apply proper mark-ups to their devices so that CMS’ payment calculations will result in a better approximation of actual costs which will help improve the APC median cost calculations over time.

We believe that CMS should publish specific steps that hospitals are recommended to follow in order to evaluate their cost report’s accuracy. For example, hospitals should evaluate each cost report line in the following manner (this is further illustrated in the table below):

- Map the cost report line to the department name;
- Assign the hospital general ledger expense account number;
- Assign the hospital general ledger revenue account number;
- Delineate PS&R revenue codes associated with the cost report line;
- Delineate actual billed revenue codes from the hospital charge master for each department.

Cost Report Line Number	Department Name	Expense GL No.	Revenue GL No.	PS&R Revenue Codes	Billed Revenue Codes
3230	CT Scanning	7680	4680	350 351 352 359	350 351 NA NA 361 340 272 255

The results of following these analytical steps demonstrate mis-matches between expenses and revenues for certain services. In the table above, minor procedures (revenue code 361), sterile supplies (revenue code 272), and drugs (revenue code 255) are all reported in the CT Scanning Cost Center.

This table also shows that charges billed under revenue code 0361 are for services provided by imaging departments like CT. FIs, MACs and non-Medicare payers require hospitals to bill the surgical component of interventional radiology procedures with non-imaging revenue codes, primarily revenue code 0361. CMS maps revenue code 0361 to the Operating Room cost center 3700. This is both an obvious and significant mis-match because a very large proportion of revenue and expense in imaging and cardiac departments is billed under revenue code 0361. The result is

highly distorted CCRs for imaging cost centers, which ultimately result in the development of inaccurate APC median costs and payment rates.

2. Hospital Charge Practices

The PRT asks CMS to be specific in answering questions about how hospitals charge and bill the same services for inpatients vs. outpatients, and emphasize the impact that charging practices have on expense apportionment in the cost report. CMS restated longstanding policy in the 2009 IPPS final rule with respect to what constitutes a routine service (sometimes called “room and board”), compared to an ancillary service. CMS did not, however, instruct hospitals about how to improve charging practices that impact cost apportionment. The result is that these providers lack specificity about what, exactly, CMS expects them to do. Unless CMS delineates specific action steps, hospitals will not change their current charge practices.

For example, the 2009 IPPS final rule discusses charging blood transfusion. Today, hospitals know that they must charge for this service under OPSS, but they are unsure if they should charge this service separately under IPPS. The PRT appreciated CMS’ discussion in the 2009 IPPS final rule of this subject. We believed that providers should separately charge blood transfusion services -- along with a several other non-“routine” nursing services such as drug administration, minor bed-side procedures, etc. -- when these are provided to inpatients. While we recognize that charging these services does not result in any additional DRG payment, we nevertheless feel that it is critical to charge inpatient and outpatients the same (as Medicare has stated before) for equitable cost apportionment. Yet, providers struggle with questions as simple as whether they can begin to bill a separate charge for blood transfusion services rendered by nursing in routine cost centers to inpatients, if they already charges the service to outpatients in those same routine cost centers.

Inequitable cost apportionment leads to incorrect CCRs for the blood cost center which is ultimately used to reduce billed charges to costs to create both DRG and APC payment rates. Issues surrounding these issues are likely to become more prevalent and we urge CMS to address them in a timely manner.

3. Overhead Allocation Statistics

The PRT requests that CMS define the statistics used to allocate overhead for each of the cost centers. Many of these cost centers use gross revenue or expenses to allocate indirect or overhead expense, but both of these cause distorted CCRs. The PRT presents a simple example below about the recently finalized new cost center for implants/devices, to illustrate how costs differ depending on the statistic used to allocate central service department overhead cost.

	Expense	Revenue	CCR
Medical Supplies - Line 55	\$100,000	\$200,000	0.5
Implants/Devices - New Line	\$50,000	\$60,000	0.833333333

Overhead to allocate	\$1,000,000

Using Revenue to Allocate Overhead			
Medical Supplies - Line 55	Revenue of \$200,000 is 80% of total revenue		
Implants/Devices - New Line	Revenue of \$60,000 is 20% of total revenue		
	Expense	Revenue	CCR
Medical Supplies - Line 55	\$900,000	\$200,000	4.5
Implants/Devices - New Line	\$250,000	\$60,000	4.166666667

Using Expense to Allocate Overhead	
Medical Supplies - Line 55	Expense of \$100,000 is 67% of total expense
Implants/Devices - New Line	Expense of \$50,000 is 33% of total expense

	Expense	Revenue	CCR
Medical Supplies - Line 55	\$770,000	\$200,000	3.85
Implants/Devices - New Line	\$380,000	\$60,000	6.333333333

In this example, the CCRs vary wildly, depending upon how the overhead is allocated. The real question is whether either of these statistical bases reflects fiscal reality in apportioning overhead cost to supplies versus implants. If a given implantable device costs 10 times more than another given supply item, it is not clear if the actual overhead is 10 times higher, as well. We believe that this is unlikely. Yet, this would be the result, when expenses are used to allocate overhead. Unless a study documents that “costed requisitions” (the basis required under current cost-reporting regulations) accurately assign overhead to the supply cost centers, providers will not be able to assess if the new cost center for implantable devices will result in more accurate data or not. The PRT believes that, without assurances that accuracy will be improved; there is no point in making such changes.

IV. Supply Cost Center Accounting Concerns

The PRT is concerned with the recent decision to split the current cost center for Medical Supplies Charged to Patients into one line for “Medical Supplies Charged to Patients” and another line for “Implantable Devices Charged to Patients” based on revenue codes. Most hospital systems do not tie the hospital materials or item master to the charge master. It will be difficult for hospitals to determine the exact items billed under those revenue codes and then change accounting of those items into a specific natural class in the General Ledger to allow them to be grouped into the new cost center.

Many high cost C-coded devices under OPPS are not billed under any of the revenue codes

finalized in the CMS requirement (0275, 0276, 0278, and 0624) for the new cost center. This finalized proposal does not address how providers should report non-implantable C-coded devices in terms of either the revenue code to be used, or the cost center to which to assign the expense. This is problematic, because a large number of device-dependent APCs have non-implantable C-coded devices associated with them. Unless CMS addresses the reporting of these, it will continue to apply distorted CCRs.

Given CMS’ decision to include non-implantable items in this cost center, the PRT requests that CMS change its description to: “Specially reported devices charged to patients.” This will clarify the situation and ameliorate the confusion that would be caused by the cost center title being “Implantable devices”, when CMS requires *non-implantable* items to be assigned to this new cost center.

V. Drug Cost Center Accounting Concerns

The PRT appreciates CMS’ recognition of charge compression regarding separately payable drugs. The PRT is, however, very concerned about the proposal to separate drugs into two cost centers. All four of CMS’ options to define what drugs are grouped to each of the two cost centers are flawed and will be difficult for hospitals to implement. None of the proposals address the crux of the issue, which is overhead. Dividing the direct cost of drugs into two cost centers does not correctly allocate the overhead and does not go far enough to result in good cost reporting data for weight calculations.

Instead, the PRT recommends that each drug category defined by CMS as having different handling/overhead expense should have its own revenue code for billing and its own cost center. We also suggest a fourth category for pre-packaged hydration solutions because the handling/overhead is very different.

CMS Category	Description	Revenue Code
Category 1	Oral/Topical/Rectal	new
Category 2	Non-chemotherapy parenteral drugs	new
Category 3	Chemotherapy/MAB parenteral drugs	new
Category 4	Prepackaged IV Hydration Solutions	258

For the overhead allocation statistic, the PRT recommends each category be assigned a relative weight that represents overhead expense. Since these categories are self-explanatory for providers, there would be no need for CMS to assign or categorize drugs by HCPCS codes into them. CMS would only need to define the relative weight statistic for each category. The relative weight would be multiplied by the drug units billed under corresponding revenue codes. The sum of the weights multiplied by units for each category would be the statistic used by each hospital to allocate pharmacy overhead into each of the four drug expense cost centers, applicable to inpatients and outpatients. This method would result in each hospital having four separate CCRs for the above categories to reflect both acquisition cost associated with drugs, and pharmacy handling/overhead. These CCRs could be used by CMS to calculate much more accurate drug APC payment rates.

VI. Comments on Other RTI Recommendations

The PRT is pleased to respond to the CMS request for comment on the items described in the RTI report. Specifically:

1. There are no cost reporting instructions to determine the expense associated with blood administration/transfusion services (revenue code 0391) performed in routine and ancillary cost centers to reclassify the expense to the 4700 cost center. This understates the expense associated with this cost center, and results in a lower CCR. Hospitals should bill blood administration/transfusion services for all patients including inpatients, observation patients, ancillary department inpatients, and outpatients. CMS should define some formula-driven expense reclassification method to that transfer expense from the various cost centers to the 4700 cost center where the correct expense can be matched to the appropriate revenue for a proper CCR calculation.
2. We agree that many hospitals lack distinct units for observation services, and deliver these services on routine nursing units. For these hospitals, therefore, CCRs from line 25 are more appropriate as the primary cost converter for observation.
3. The PRT strongly encourages CMS to create new standard cost centers for cardiac catheterization, CT, and MRI, but only if appropriate requirements regarding direct expense assignment, capital expense assignment, statistics for overhead allocation and matching gross revenue for both inpatients and outpatients are also promulgated.

Given the vast and complex issues concerning cost reporting, the PRT asks CMS for a separate rule-making decision specifically on these issues. The PRT likens this to CMS providing the hospital industry with a recipe for creating accurate cost reporting data so that all stakeholders can have confidence in the resulting payment rates for both the IPPS and OPSS.

Multiple Imaging Composite APCs

The PRT understands that CMS believes that its proposal to create new Multiple Imaging Composite APCs, described in the 2009 OPSS proposed rule, to be a “natural progression” of the development of Composite APCs, and a modification to its 2006 proposal to reduce APC payments by 50 percent for certain multiple imaging procedures provided in a single session. In the 2009 proposed rule, CMS stated: “...we determined that a proposal to revise our methodology for paying for multiple imaging procedures is warranted because the current OPSS policy of providing a full APC payment for each imaging service on a claim, regardless of how many procedures are performed during a single session using the same imaging modality, neither reflects nor promotes the efficiencies hospitals can achieve when they perform multiple imaging procedures during a single session, as seen in the claims data.”

For 2009, CMS proposes five new composite APCs (8004, 8005, 8006, 8007, and 8008) for multiple imaging modalities for Ultrasound, CT/CTA, and MRI/MRA services provided in a single session. The PRT understands the methodology CMS used to prepare the revised proposal, both from the claims processing perspective and the elimination of the concept of the “contiguous body area”. We do not believe, however, that CMS should implement the imaging composite APCs at this time; there are a number of other, long-term changes that the agency could implement instead which would lead to more accurate APC payments over time.

It is not clear why CMS thinks that efficiencies are not already being achieved or promoted. In fact, CMS has admitted that its own analysis did not disprove these efficiencies or provide “a definitive answer” related to existing efficiencies inherent in the current CCR methodology. We appreciated CMS’ finding on this issue, as it is consistent with the comment the PRT made in response to the 2006 OPPTS proposed rule, that: “*an arbitrary reduction to second and subsequent procedure APC payments ignores the fact that some of the purported economies to scale are already reflected in the cost-to-charge ratio used by CMS to arrive at the median cost data.*”

The PRT continues to believe that CMS’ current APC payment rate setting methodology already reflects an aggregation of resource costs related to both high-intensity and low-intensity encounters, and therefore captures the efficiencies CMS seeks. While the PRT recognizes that CMS believes there are further efficiencies to be gained, we think that all the inherent efficiencies may only be more readily discernable through the analysis of more accurate data.

The PRT is concerned with CMS’ findings in claims analyses that are related to the variations in providers’ reporting of imaging costs on the Medicare Cost Report under the Diagnostic Radiology Cost Center. Our concerns are further underscored by the findings of the RTI report related to Imaging Modalities. In its report, RTI recommended that CMS create new, separate standard cost centers, prompting CMS to solicit comments on the creation of standard cost centers for both CT and MRI. The PRT supports the RTI recommendation to create new separate standard cost centers and urges CMS to move forward with this action.

Our review of the RTI report outlined a number of concerns and issues associated with the use of existing diagnostic imaging cost-to-charge ratios (CCRs) when applied to CT and MRI services. The RTI report raised serious concerns about the CCRs related to CT and MRI when they are separated from the Diagnostic Radiology cost center. It is clear that there are large variations in the way that providers structure and report both their charges and costs. CMS should review these findings and consider RTI’s recommendations for implementation before it makes *any* changes in the existing payment methodology. The PRT believes CMS should standardize reporting costs for both advanced imaging technologies and other problematic cost centers before it makes any methodological changes to the payment system.

The PRT would also like to highlight how hospital practice patterns differ from physician office practice patterns due to the types of patients hospitals typically serve. For this reason, certain efficiencies are already reflected in hospitals’ cost data. Multiple imaging services that are provided in a physician’s office or freestanding imaging centers typically occur on a non-urgent basis. In

contrast, multiple imaging encounters that are provided in the hospital setting often are the direct result of an emergent presentation of clinical symptoms or occur in very complex, specialized types of patients.

For a hospital to perform a thorough assessment of such a patient's clinical symptoms, it may have to examine different body systems (which are separated by anatomic markers for physical assessment references). Multiple imaging services may be necessary to evaluate an entire body system, as illustrated by the following examples:

- If a patient presents emergently with abdominal pain, both a CT of the abdomen and the pelvis will be ordered in order to see the entire abdominal cavity.
- If the patient presents with a urological complaint, both an abdominal CT and a pelvic CT will be ordered since the kidneys anatomically are in the abdominal cavity, the bladder is in the pelvic cavity, and the ureters are seen in both. In order to scan the entire urinary system, therefore, *both* cavities must be scanned to assess where the problem lies.
- If the patient presents after an automobile accident and complains of head and neck pain, CT scans of the head, neck, and thoracic spine may be ordered.

The efficiencies that result from providing multiple scans in a single session may not currently be evident, given the current single diagnostic imaging cost center used to capture all of these data. If CMS implemented the RTI recommendation to create a separate cost center for CT and a separate cost center for MRI, however, it would provide much more accurate charge and cost data for these imaging modalities. It would also allow more appropriate rate setting of all other diagnostic imaging modalities, such as general radiology.

The PRT urges CMS to adopt the RTI recommendations related to creating new standard costs centers for CT and MRI rather than implement the proposed imaging composite APCs. CMS must recognize that moving forward with the former proposal will enhance the accuracy of cost reporting. The creation of new standard cost centers and adoption of the revised revenue code to cost center crosswalk proposed by RTI -- and supported by the PRT -- will result in significant shifts in the underlying CCRs for ALL APCs, thereby impacting all relative weights and payment rates across all services. Although we agree with CMS that, in the aggregate, overall OPSS system payments should remain stable, any substantive cost report changes will dramatically affect not only imaging APCs but also all other APCs as well, and will cause sweeping redistributions in the entire system.

Before making any payment system changes, the PRT urges CMS to examine the impact of the cost reporting changes to the costs generated from providers' billed charges reduced to costs from the claims data for at least a two- to three-year period. This has been CMS' traditional approach to making other coding or data changes before creating new APCs. These data should be examined in detail before CMS moves forward with the creation of imaging composite APCs.

Finally, the PRT urges CMS to abandon the implementation of both multiple imaging composite APCs for 2009 and the development of any further Composite APCs until decisions have been

finalized about creating standard cost report lines for CT/MRI and other clinical areas. We also encourage CMS to first provide clear instructions to providers on how to use the new cost centers, as well as explicit direction in the correct allocation of the service-specific costs to the new cost centers.

Proposed Changes to Packaged Services

(1) Packaged Services Addressed by APC Panel Recommendations

Recommendation 1 – The PRT has no comment on this recommendation.

Recommendation 2 – The PRT agrees with the placement of CPT 36592, and thanks CMS for reviewing and acting on our prior comment regarding the status of this code.

Recommendation 3 – The PRT has no comment on this recommendation.

Recommendation 4 – The PRT agrees with CMS’ response to this Panel recommendation.

Recommendation 5 – CMS has not accepted the APC Panel’s recommendation to unpackage IVUS/ICE services because they were selected for packaging as a result of their “always integral/dependent” nature. CMS further noted that resource cost was not a factor considered in packaging intraoperative services.

The PRT generally supported the concept of packaging intraoperative services for 2008; however, as stated last year, we remain concerned that CMS does not consider resource cost when making packaging decisions. We wish to reiterate our suggestion that CMS adopt volume and cost threshold criteria when making ancillary packaging decisions. This is not unprecedented in the OPPTS, since CMS uses a cost threshold for determining drug packaging.

We believe that volume and cost criteria are valid because CMS does not currently selectively package, and because low volume/high cost procedures that are performed infrequently with primary procedures are not adequately accounted for in the medians of the primary procedures. Hence, when infrequent, high-cost services are incorporated into the overall payment system, providers will never be appropriately paid for the primary procedure.

Recommendation 6 – The PRT has no comment on this recommendation.

Recommendation 7 – The PRT supports the continuation of the APC Panel’s Packaging Subcommittee and appreciates the work this committee does in concert with CMS staff. Since we do not have either the ability to purchase the Medicare claims data file or the resources to run different data analyses, PRT members truly rely on the Packaging Subcommittee’s requests for data and analyses from CMS staff.

(2) IVIG Preadministration-Related Services

For 2009, CMS proposes to assign status indicator “N” to HCPCS code G0332. CMS’ rationale for this change is based on a review of claims data, combined with the OIG’s April 2007 report on IVIG payment and availability. The PRT encourages CMS to reconsider this proposal, as the OIG report is over a year old, and was based on two-year-old data. The PRT knows that the conditions that led to the creation of this code (e.g., market instability, product availability, decreased manufacturing capacity, and increased usage) continue to exist and have not totally abated. Several of our member pharmacies continue to report difficulty in obtaining IVIG. The PRT recommends that CMS perform a more thorough new study to assess the true market conditions of IVIG availability before it proceeds with packaging this HCPCS code.

Additionally, CMS stated in the proposed rule that the median cost data are relatively low for this service. As we commented last year, the PRT believes that a number of factors contribute to this situation, including variation in CCRs pursuant to the various revenue centers used to report the service, and providers failing to accurately set charges to reflect the true cost of providing G0332. (In fact, some providers have arbitrarily chosen to bill the \$75 APC payment or an even lower amount, thereby artificially lowering the median cost). Based on this experience, we do not believe that “a relatively low median cost” is a valid argument for packaging this particular service.

If CMS proceeds with packaging G0332, the PRT recommends that CMS conditionally package the median costs along with CPT 90765 into the Level V Drug Administration Services (or, if the 2009 structure for Drug Administration is approved, into Level IV Drug Administration Services).

Proposed OPPS Payment for Hospital Outpatient Visits

New and Established Visits

In the CY 2009 proposed rule, CMS offers an updated definition for “New and established patient”: *“Specifically the meanings of “new” and “established” would pertain to whether or not the patient was registered as an inpatient or outpatient of the hospital within the past 3 years. Under this proposal, hospitals would not need to determine the specific clinic where the patient was previously treated because the proposed approach would not rely upon when the medical record was initially created but rather, would depend upon whether the individual has been registered as a hospital inpatient or outpatient within the previous 3 years....If a patient were registered as an outpatient in a hospital’s off-campus provider-based clinic or emergency department within the past 3 years, that patient would still be an “established” patient to the hospital for an on-campus or off-campus clinic visit even if the medical record was initially crated by the hospital prior to the past 3 years.”*

The Provider Roundtable (PRT) notes that since the advent of the OPPS, CMS has stated that the CPT definition for clinic visits does not reflect the hospital services and resources provided

-- a statement with which hospitals enthusiastically agree. The PRT believes the length of time between visits offers no better reflection of the services and resources provided. Whether a patient has been seen by a hospital outpatient department or been admitted as an inpatient within the past three years, there is no correlation between the time between visits and the resources required to evaluate, manage, and treat the patient's current condition.

Example 1 – “Patient A” is seen in a hospital ED for services related to a fall. An evaluation is completed and diagnostic tests are ordered and performed. Patient A is diagnosed with fractured ribs, receives a rib belt, a prescription for pain medication and is released. Three weeks later, Patient A is seen for the first time in the hospital's wound care clinic with a new, stage III ulcer of the right leg and a new, stage II ulcer of the right foot. The wounds are evaluated, debrided, treated, and dressed. Education is provided and a follow-up visit is scheduled. “Patient B”, who has never received services at this hospital, is seen in the wound care clinic with a stage I ulcer on the toe. The wound is evaluated, cleaned with an enzyme cleaner, and dressed. Patient B is scheduled for a follow-up visit.

In this example, under the proposed definition of “new and established patient”, Patient A would be reported as an “established” patient for the wound care clinic visit because he/she had been seen in the ED three weeks earlier. When seen in the wound care clinic, Patient B would be reported as a “new” patient because he/she had not previously been seen in this facility. Based on the proposed definition and the current reporting structure, the visits reported would show higher resources required for the “new” patient (Patient B), although that patient's care was actually less intensive than the “established” patient's (Patient A) care. If these visits were reported based solely on the resources expended by the hospital clinic, however, the “established” patient (Patient A) would be reported at a higher level than the “new” patient (Patient B) and would generate reimbursement based on the facility resources expended. These examples illustrate that the length of time since the patient was seen has no bearing on the resource consumption for care. The resources expended are based solely on the services provided to the individual patient at the individual visit.

Example 2 -- A patient (Patient C) presents to the hospital to have lab work drawn. The treating physician provides the order for the service; the patient's blood is drawn and the patient leaves. Two years later, the patient returns for outpatient services in the chemotherapy infusion department. Patient C has a new venous access device, which has been causing pain and is warm to the touch, which was not the case when he/she visited his/her physician earlier in the week. The hospital staff evaluates the venous access device, contacts the physician, and obtains orders for management of the device and delay of the chemotherapy treatment.

In this example, Patient C is considered a “new patient” for the initial encounter when the lab work was drawn. At the second visit, the resources expended are much more intense, but the visit would have to be reported as an “established” patient visit to be in compliance with CMS' proposed three-year delineation.

The PRT believes there are also significant operational issues involved in implementing the “three-year” definition. Whether the patient has had a visit at the hospital in the last three years is

not information that is necessarily at hand when the patient presents to an outpatient department. Because medical information is covered under HIPAA law and considered PMI, many facilities do not retain these data in easily accessible areas of their computer systems after a certain period of time. Hospital personnel have restricted access for viewing previous admission history due to HIPAA privacy concerns. Many facilities actually limit the time for viewing past visits within their systems. For example, one PRT facility limits viewing to those admissions that occurred within the previous 40 days. The clinical areas can access the previous medical information, upon request, when this is needed for the patient's care but, since the care of the patient does not change based on the "new or established" classification, hospitals are unlikely to feel compelled to make this information easily accessible within its systems.

Therefore, the proposed three-year time frame requirement will cause an increase in the "back end" work necessary to submit a clean claim. In order to be compliant, facilities will have to implement an additional audit process for the sole purpose of verifying whether the patient had been seen by the hospital within the past three years (and should, therefore, be reported as an "established" patient), or had no visits within the past three years (and should, therefore, be classified as a "new" patient). While this will increase operational costs, it will not result in a direct correlation to resources expended and produce absolutely no improvement in patient care.

The PRT notes that CMS has the discretion to establish HCPCS codes to meet specific needs. In the CY 2007 rule, CMS proposed the establishment of G-codes to reflect hospital resources expended in OP clinic and ED visits. These G-codes were proposed in cooperation with the development of national E/M guidelines, and were delayed in the interest of implementing both the national guidelines and the new visit codes simultaneously. At that time, the PRT comment expressed our agreement with establishing G-codes to reflect facility resources expended for the provision of services. We acknowledge that, in the CY 2007 final rule, CMS noted that many providers had expressed operational concerns about the need to train staff to use new G-codes and then, within two years, needing to retrain staff to use the new national guidelines. Today, national guidelines are still being developed; their implementation is not in the immediate future; and current CPT codes do not reflect hospital resources. In light of the fact that the "three-year" provision is difficult to operationalize for facilities, the PRT recommends that CMS establish the G-codes for outpatient facility visits. We also note that, when national guidelines are implemented, they can easily be mapped to the established G-codes.

The PRT recommends that CMS create a set of G-codes for "Hospital Outpatient Visit Levels 1 through 5", and merge the cost data for the new and established CPT codes into the appropriate level APC. Hospitals have already created individual internal guidelines to reflect the resources expended for an individual visit (and we can state definitely that these levels are not based on the amount of time since a patient's last visit). Hospitals can easily crosswalk their own guidelines to the new G-codes for hospital outpatient visits and with their corresponding APCs, since there would be the same number of levels as there are currently new/established CPT codes. Because resource consumption would not change – and only the codes for reporting would change – we would not expect there to be any impact on the stability that has been reflected in the claims data reported for the past two years.

The PRT recommends the following structure and descriptions:

HCPCS code	Suggested HCPCS short description	Suggested HCPCS long description
GXXX1	Hospital OP visit Level 1	Hospital OP visit Level 1 – report Level 1 service (non-ED) corresponding with individual facility’s guidelines based on CMS’ defined 11 criteria
GXXX2	Hospital OP visit Level 2	Hospital OP visit Level 2 – report Level 2 service (non-ED) corresponding with individual facility’s guidelines based on CMS’ defined 11 criteria
GXXX3	Hospital OP visit Level 3	Hospital OP visit Level 3 – report Level 3 service (non-ED) corresponding with individual facility’s guidelines based on CMS’ defined 11 criteria
GXXX4	Hospital OP visit Level 4	Hospital OP visit Level 4 – report Level 4 service (non-ED) corresponding with individual facility’s guidelines based on CMS’ defined 11 criteria
GXXX5	Hospital OP visit Level 5	Hospital OP visit Level 5 – report Level 5 service (non-ED) corresponding with individual facility’s guidelines based on CMS’ defined 11 criteria

The PRT submits the following crosswalk for CMS’ use in developing median costs to set payment rates for the proposed G-codes; this crosswalk is based on current E/M visit codes and APC assignment.

Suggested APC titles:	Crosswalk CPT codes	Merge Cost data and set payment based on CY 2008 assigned APCs
Hospital OP visit Level 1	99201, 99211	0604
Hospital OP visit Level 2	99202, 99212	0605
Hospital OP visit Level 3	99203, 99213	0605, 0606
Hospital OP visit Level 4	99204, 99214	0606, 0607
Hospital OP visit Level 5	99205, 99215	0607

The PRT notes that many of our facilities have trouble with Medicaid and non-Medicare payers alike recognizing that hospitals’ reporting of physician CPT codes is acceptable to show the outpatient level of services provided. It is also important to note that there are still instances in which payers require hospitals to report the same level of E/M codes as that reported by physicians. The existence of specific codes just for hospitals’ use should facilitate resolution of these issues with payers.

Several PRT members are concerned, however, that State Medicaid and other local payers may not recognize G-codes, although we believe that they should under HIPAA. We therefore urge CMS to stress the importance of this code set and its applicability to the hospital setting, and to instruct Medicaid contractors to accept these new G-codes, in order to minimize problems with claims that cross over to Medicaid. Medicaid programs owe legitimate co-payments when secondary to Medicare. CMS should act to ensure that these crossover claims that are related to beneficiaries who are eligible for both Medicare and Medicaid are reimbursed appropriately under Medicaid.

The PRT feels so strongly that the “three-year” provision is absolutely meaningless for facility purposes that we are recommending the establishment of G-codes. While we suspect that we will have difficulties with other payers accepting these codes, it would be less cumbersome for us to work through the problematic payer issues than try to meet CMS’ “three years since last visit” provision. Our experience has shown that, with some encouragement from CMS, other payers usually follow CMS’ lead. Just as they use the Inpatient-only list as a guide, we hope that they would also agree with “hospital only outpatient visit codes”.

The PRT proposes these G-codes as a temporary measure toward transition to facility CPT codes. The American Medical Association (AMA) set a precedent for this in CY 2008 by acknowledging differences with hospital resources and processes and establishing CPT code 90776 (*Therapeutic, prophylactic or diagnostic injection; each additional sequential intravenous push of the same substance/drug **provided in a facility***). We implore CMS to work with the AMA and make a formal proposal to convert the recommended G-codes for hospital outpatient visits into CPT codes for 2010. Doing so would ensure that hospitals report one code set to Medicare, Medicaid, and commercial payers. It will also guarantee that the codes reflect *actual* hospital resources for services provided, and ensure consistent charging in the same manner for the same services to both Medicare and non-Medicare payers. The PRT notes that these changes would help CMS to meet other goals and priorities that it has established, such as pricing transparency policies, and reflection of actual hospital resources utilized.

We also note that the eleven criteria for internal guidelines as published in the 2008 final rule will need to be revisited should CMS accept the PRT’s proposal and proceed with temporary G-codes as a bridge to CPT codes.

In summary, the PRT recommends that CMS not distinguish between “new” and “established” visits in the outpatient hospital setting; that CMS create a five level G-code series for reporting Hospital Outpatient Department visit services; that CMS instruct State Medicaid agencies to accept these G- codes; and that CMS work with the AMA to have these G-codes converted to CPT codes in 2010.

Type B Emergency Visits

The CY 2009 proposed rule notes: *"Based on these data, 342 hospitals billed at least one Type B emergency department visit code in CY 2007, with a total frequency of visits provided in Type B emergency department of approximately 200,000. All except 2 of the 342 hospitals reporting Type B emergency department visits in CY 2007 also reported Type A emergency department visits. Overall, many more hospitals (approximately 2,911 total hospitals) reported Type A emergency department visits than Type B emergency department visits."*

The PRT very much appreciates the analysis of the data regarding Type A and Type B Emergency Department visits that was performed on the 2007 claims, and CMS' explicit discussion about how this was reviewed and how the changes were explained in the proposed rule. Yet, the PRT cautions that it may still be too soon to see the full granularity within these data. We encourage CMS to continue looking at the data analysis, which is still evolving. CMS acknowledged in the CY 2009 proposed rule that hospitals are still becoming accustomed to reporting these codes for this level of service, stating: *"As more cost data become available and hospitals gain additional experience with reporting visits to Type B emergency departments, we would continue to regularly reevaluate patterns of Type A and Type B emergency visit reporting at varying levels of disaggregation below the national level to ensure that hospitals continue to bill appropriately and differentially for these services."*

In addition, after the publication of the CY 2008 OPPS Final Rule, there was much discussion and potentially delayed decision-making about whether some areas designed for "throughput" and process purposes should be carved out as Type B emergency departments. This continuing discussion and confusion is evidenced by the number of questions raised by providers on the Hospital Open Door Forum calls, and multiple inquiries to FIs about whether a set of rooms designed for quick processing of less serious cases truly met the definition for a Type B section of ED.

The PRT appreciates CMS' creation of the four Type B APCs, but suggests that CMS create one additional APC in this series to account for the highest level of the Type B ED visit as well. Five levels of APCs will allow CMS to mimic the Type A Emergency Department levels and the outpatient visit structure. We accept CMS' proposal to reimburse HCPCS code G0384 (Level 5 Type B) at a rate of \$187.10, which is the same payment rate CMS has proposed for CPT code 99285 (Level 5 Type A). We also agree with CMS' proposal to include HCPCS code G0384 (Type B Level 5 visit) in the criteria for determining eligibility for payment of composite APC 8003.

Secondly, the PRT recommends that CMS instruct hospitals to set charges that reflect resource use for Type B services, whether they are provided in a separate area of the hospital or in a "carve out" in the main Emergency Department. We note that there are existing methodologies and non-Medicare payers that require the same charge be reported for the same CPT code, and that hospitals must also comply with those requirements. While CMS has created G-codes to reflect the services in a Type B area, some payers may not recognize the difference in the areas or not accept the G-codes for establishing this difference. The PRT also strongly recommends that CMS rerun the

same data analysis in a year.

In the spirit of the cost report changes proposed both by RTI and CMS, the PRT proposes that the following questions should be considered for the future: should a separate cost center for Type B Emergency Department services be created? Should a separate revenue code be considered for these services? Would “Fast Track” areas that are truly carve out areas of a Type A Emergency Department, be reported with revenue code 450 or under a newly created revenue code specifically for Type B services?

Visit Reporting Guidelines

The PRT generally agrees that CMS should pursue establishment of National Evaluation and Management Guidelines to ensure consistency in regulatory auditing and beneficiary copays across facilities. The PRT strongly encourages CMS to work with (and encourage) the AMA to include a hospital-specific E/M section as part of CPT. Such an E/M section should incorporate CMS’ 11 principles for guidelines (as finalized in the CY 2008 OPPTS final rule) as well as specific CPT codes for reporting hospital services. Doing so would ensure easy access to the guidelines and promote consistency in reporting services among all providers. It would also enable other payers to accept that CMS’ use of the AMA CPT codes is different in the hospital versus the physician settings. While the principles should be the same across all guidelines, the PRT agrees that guidelines for the Emergency Department must be separate from other hospital outpatient areas, because of the uniqueness of the Emergency Department.

Until there are national visit guidelines, the PRT reiterates our previous request that CMS require FIs/MACS 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 FIs/MACs persist in imposing their own, unpublished E/M criteria rather than utilizing the provider’s internally developed E/M guidelines during facility audits. These FIs/MACs are determining services’ “reasonableness” as they relate to placement within various levels. When applied by the FI, these unpublished guidelines are detrimental to the hospital claims data, as they produce lower-level calculations than the hospital’s internal guidelines. More importantly, they are in direct conflict with CMS’ directive requiring providers to develop and use their own guidelines to report hospital outpatient department and Emergency Department E/M visit codes. Hospital internal guidelines must be recognized by the FIs/MACs. The PRT cannot express strongly enough its view that CMS *must* provide clear direction to its FIs/MACs requiring them to use the individual facility’s E/M internal guidelines when conducting a review or audit. CMS should explicitly state that no FI (or MAC) is allowed to impose its own criteria upon the provider. The PRT asks that CMS issue these explicit instructions to FIs and MACs as soon as possible.

This concern is exacerbated by the OIG’s audit activity, as well as CMS’ plans to expand the RAC audits nationally. Hospitals are concerned that these organizations will choose the guidelines that they believe are “better”, or make more sense to them, instead of using the hospital’s individual and internal guidelines. It would be detrimental to both hospitals and to CMS’ claims data if audit results change E/M levels based on unpublished criteria rather than continue to use the guidelines

established and utilized by the individual hospital.

Proposed Procedures That Will Be Paid Only as Inpatient Procedures

The PRT remains concerned about outpatient claims for inpatient-only procedures denied by Medicare in situations where the inpatient-only procedures are performed on an unscheduled basis intra-operatively and where the physician does not admit the patient as an inpatient. The fact that the intra-operative procedure is an inpatient-only procedure is not determined until after the surgeon dictates the operative report and the patient is discharged as an outpatient. Hospitals do not concurrently code surgical procedures immediately after surgery or during the post anesthesia stay. The PRT requests that CMS recognize the OPSS ancillary services in these cases like it has recognized the ancillary services for inpatient-only cases performed on expired ED patients. CMS can create a HCPCS modifier similar to modifier –CA for hospitals to bill unscheduled, intra-operative inpatient-only procedures when the patient is discharged as an outpatient.

Proposed Quality Measures for CY 2010 and Subsequent Calendar Years and Proposed Process to Update Measures

I. Reporting Quality Data for Annual Payment Rate Updates

The PRT endorses the concept to review the IPPS RHQDAPU for further selection for the HOP QDRP. Nonetheless, we believe that this should only occur after an analysis is completed by a national consensus building entity such as the National Quality Forum (NQF) and the analysis has been endorsed by the provider community. It is our firm view that providers should have the opportunity to review and comment on any analysis performed by such entities before measures are implemented. Only in this way will providers gain an understanding of how the proposed standards specifically measure quality, and how reporting that measure will affect the hospital's ability to capture the data element efficiently.

1. Proposed Imaging Measures for CY 2010

CMS has proposed adoption of four imaging measures to be calculated using claims data. CMS believes that these measures will capture high-quality and efficient use of services for the outpatient setting and the proposed rule indicates that the imaging measures have been submitted to the NQF for consideration. The proposed rule does not describe, however, the rationale for these measures nor delineate why CMS believes they will act as indicators of quality care for hospital providers. The proposed rule also lacks any statement of clinical evidence that would support the need for CMS to recommend adoption of these measures.

If the driver for these indicators is MedPAC's "concern about potential overuse of imaging services based upon the rapid growth in the volume of usage over the past 5 years", as mentioned in the proposed rule, the PRT wishes to note that *physicians* order these services based on their

assessment of the patient's clinical condition. Hospitals merely follow those physician orders and perform the ordered exams, which the physician's medical judgment has indicated are necessary for good patient care. The PRT believes that CMS has inappropriately assumed that hospitals fail to provide quality care due to the number of imaging services they perform, when in fact they are merely working with their physicians and following their orders to provide high quality healthcare to Medicare beneficiaries.

We believe that the provider community deserves to see the clinical evidence underlying these measures, as well as any future measures to assess quality of care. This information would help providers ascertain what CMS expects to derive from the claims data, as well as answer pending questions about these measures (e.g. how does the indicator OP-10 (*Abdomen CT with use of contrast material*) specifically reflect hospital quality?). Without knowing what CMS expects to measure using these newly proposed four indicators, it is virtually impossible for providers to comment on their appropriateness.

The PRT agrees with CMS' stated goal of ensuring high quality of care for all patients, regardless of where the care is provided. To this end, we strongly urge CMS to supply the provider community with an explanation of what it expects to learn by using the proposed imaging measures. We also ask that CMS supply detailed explanations presented by the professional societies (such as the NQF) to all providers in its official rules and other publications.

2. Proposed Process for Updating Measures

CMS proposes to establish a sub-regulatory process in order to update existing measures' technical specifications when the evidence warrants a change and when guidance is given through the NQF or other consensus-building entity. CMS also proposes to update the measures through notification on the QualityNet Web site, and in the CMS *Hospital Outpatient Quality Measures Specifications Manual*. The PRT is concerned with the proposed time period of "no less than three months before any changes become effective for purposes of reporting under the HOP QDRP". We recommend a notice of *at least* six months in order to allow providers the opportunity to field-test measures before the proposed changes become effective. This testing is necessary because changes in a measure's specifics are likely to affect the current trending pattern and decrease compliance. Providers need adequate time to educate physicians and other hospital staff to these new requirements.

The proposed rule cites an example of how the sub-regulatory process would modify a measure. For example, "A change in antibiotic selection and/or timing" is considered a modification to a measure. While it is simple to reword the measure, making the change requires additional actions on the part of providers. In addition to educating hospital staff and physicians, providers must also inform the clinical Pharmacy & Therapeutics (P&T) Committee. This committee has oversight for reviewing and approving changes to hospital formularies and protocols, drug efficacy, and the hospital's expense/cost compared to other available products. Completing this process is time-consuming. Moreover, various physician specialties have different practice patterns, which may require investment of additional time before they can finalize and enforce pharmacy formulary

changes. Three months is simply not enough time for providers to make the necessary internal process changes. Such a short time frame jeopardizes providers' compliance with a measure on which they may well have previously been compliant.

For these reasons, the PRT strongly encourages CMS to publish specific guidelines within which this sub-regulatory process would operate. We believe that CMS should specifically define "technical specification" and ensure that any change would go through the usual rule-making process. The PRT also strongly encourages CMS to publish these changes in a transmittal as well as on the NQF website.

3. Possible New Quality Measures for CY2011 and Subsequent Calendar Years (CY)

CMS is seeking comment on 18 possible new quality measures for CY 2011 and subsequent years, in addition to the four imaging measures described above. The PRT is concerned that, while the four proposed measures for 2009 will be abstracted through claims data, many of the proposed 18 measures for 2011 appear to resemble items collected in the physician office setting. We are concerned that additional abstracting requirements on hospital outpatient services may be very labor-intensive and present additional burdens to hospitals. For this reason, the PRT requests additional background information and rationale about how CMS intends quality to be specifically assessed by these 18 new measures.

The PRT additionally suggests that CMS establish criteria to select outpatient quality measures. We offer the following as examples of criteria for quality measures, and include specific comments on a few of the 18 CMS proposed measures.

1. Hospital measures should measure *hospital* services rather than *physician* services.

Indicators that measure quality in the inpatient or physician setting are often inapplicable to the hospital outpatient setting. CMS may be able to "harmonize" quality measures by choosing a set of monitors that provide a picture of care across all settings but measure different elements within each setting. The following proposed measures for 2011 are examples of indicators that measure physician practice but not hospital practice.

- Radiation therapy is administered within one year of diagnosis for women under age 70 receiving breast-conserving surgery for breast cancer: *The decision to undergo radiation treatment is one made by a woman and her doctor, after weighing all the alternatives. Hospitals have no involvement in either this decision or in the quality of care issues associated with either the decision-making process or the timing of when the treatment begins.*
- Adjuvant Hormonal Therapy for breast cancer patients: *Decisions about this treatment alternative are made by her doctor. The therapy is also usually an oral preparation with no hospital involvement in the course of treatment.*

2. Data collection should not increase hospital burden by requiring additional FTEs to either collect data or improve data collection systems. Claims or other resources (e.g., cancer

registries) should be the primary source of outpatient quality data. CMS must allow adequate time for system modifications. The following proposed measures provide examples:

- *Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection*: This measure may be appropriate within certain parameters. The biopsy may not always be performed at the same facility as the surgical resection. Therefore, if information concerning the biopsy is required, it will be burdensome to obtain this information from another source.
 - *Low-density lipoprotein control in Type I or Type II Diabetes Mellitus*: Hospitals may assess a patient's understanding of how to manage his or her diet and lifestyle to keep this disease under control, but there may be no other direct interaction between hospitals and the patient.
 - *High Blood Pressure Control in Type I or Type II Diabetes Mellitus*: Hospitals can educate patients on medications, necessary life style changes, and healthy living. However, it is not an appropriate quality measure for hospitals to "control" high blood pressure, as there is no direct interaction between hospitals and the patient on this issue.
3. Quality measures should be recognized and/or developed by national quality associations. Representative organizations such as the National Quality Forum (NQF), American Health Quality Association (AHQA) or the Institute for Healthcare Improvement (IHI) should be consulted before an outpatient measure is proposed to ensure that the measure is based on evidence-based practice and is meaningful for evaluating quality care.
 4. Quality measures should evaluate *quality* rather than *resource utilization*. CMS has other processes that are used to control over-utilization of services. Quality should be evidence-based and defined by patient outcomes. It is not appropriately assessed by measures of utilization, cost, or other such indicators.
 5. The measures must be clearly defined in the proposed rule. CMS must provide specific information in the federal register on proposed measures so that hospitals can understand the rationale of the proposed measure. Unless hospital providers understand the measure, they cannot provide meaningful feedback to CMS concerning the applicability of the measure, especially in the outpatient arena.
 6. The measure should apply to a unique patient population that is easily defined. Examples include a monitored cardiac rehab patient or a chemotherapy patient.

The PRT requests that CMS adopt the six criteria provided (or other appropriate criteria) for the purpose of evaluating quality measures for outpatient services. In addition we ask CMS for maximum transparency in published rules so that providers fully understand the measures proposed and/or implemented.

II. Health Care-Associated Conditions

The PRT agrees with CMS that only a small number of the proposed IPPS conditions are possible candidates for OPSS, and these conditions may only apply in limited service areas. The PRT does not support present on admission (POA) reporting of the hospital-acquired conditions for OPSS services. The PRT strongly believes that reporting a POA in the outpatient setting would be operationally burdensome for hospitals due to the tremendous volume and nature of outpatient services. For example, a patient may present for an ancillary service such as lab work or a radiology exam. Due to the limited nature of these encounters, it would be rare for a diagnosis not to be “present on admission” in the majority of outpatient visits.

In the limited service areas in which POA may be applicable, the PRT encourages CMS to delay the implementation of HAC for hospital outpatients until the adoption of ICD-10, at which time providers can submit more specific claims data through the assigned ICD-10 code set. In the proposed rule, CMS stated that ICD-10-CM and ICD-10-PCS will: “*provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes.*” The PRT agree with CMS’ assumption in this matter and are encouraged that a delay in implementation will allow hospitals to operationalize the process using the new code set.

Conclusion

The Provider Roundtable would sincerely like to thank 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 years’ 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 one of our spokespersons:

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A full list of the provider roundtable members is included below in Appendix A.

Sincerely yours,

Members of the Provider Roundtable

Appendix A: Current Members of the Provider Roundtable

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