59

Asante Health System, OR
Avera Health, SD
Baptist Healthcare System, KY
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Forrest General Hospital, MS
Health First, Inc., FL
Mercy Medical Center, IA
Our Lady of Lourdes Regional Medical Center, LA
Saint Joseph's Hospital, WI
Saint Mary's Hospital, MN
Sisters of Mercy Health System, MO
Southwestern Vermont Medical Center, VT
University of Colorado Hospital, CO
University Health System, TX
White River Medical Center, AR

September 28, 2006

Submitted electronically: http://www.cms.hhs.gov/regulations/ecomments and in hard copy
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS-1506-P

Dear CMS:

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 2007 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on August 23, 2006. It should be noted that our comments below were also submitted electronically by Valerie Rinkle, MPA, Asante Health System on behalf of the PRT throughout the month of September in order to give CMS staff as much time as possible to review them. The PRT members listed above appreciate the opportunity to submit these comments for consideration by CMS. A full list of the current PRT members is provided in **Appendix A**.

Introduction

The Provider Roundtable (PRT) is a group of 17 different hospitals and health systems representing over 50 hospitals from around the country. Like many others, our hospitals, and the departments within our institutions, continue to struggle with OPPS and its many coding and billing complexities. Providers are often too busy, or unaware of the overall process, to submit comments to CMS on their own. Therefore, 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.

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.

1. Relative Weights

Cost to Charge Ratios

CMS is " ... *specifically inviting comments on ways that hospitals can uniformly and consistently report charges and costs related to all cost centers, not just radiology, that also acknowledge the ubiquitous tradeoff between greater precision in developing CCRs and administrative burden associated with reduced flexibility in hospital accounting practices.*"

The PRT believes that one of the best means for CMS to provide guidance to hospitals to consistently report charges and costs related to all cost centers is to provide specific examples in the OPPS final rule preamble and in transmittals that explain how provider line item charges on claims and hospital CCRs are used to develop APC payment rates.

Using simple singleton claim examples will help illustrate two things to hospitals: (1) the importance of correctly pricing their procedures and supplies and drugs and (2) ensuring that the cost center where the cost of the service is reflected in the cost report is the same cost center used by CMS in the revenue center crosswalk. Providing such examples may also encourage hospitals to provide comments back to CMS on its crosswalk. If the cost center or CCR is not the correct CCR, then CMS should encourage hospitals to reclassify expense and revenue whenever appropriate or provide comment to CMS as to why the cost center is not appropriate to use in the crosswalk. In this manner, CMS is not mandating changes in hospital accounting practices, but encouraging hospitals to self-adjust those practices based on the knowledge of how the claims and cost report data is used. Finally, CMS must also instruct Fiscal Intermediary staff to allow hospitals to reclassify expense and revenue whenever appropriate. Examples should be taken from revenue centers or cost areas where there has been a lot of controversy such as blood and blood products and implants/devices.

CMS could use a pacemaker example such as the one below.

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		$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**

In this example, hospitals would be able to clearly see that if they defined cost center 3540 for prosthetic devices in their cost report, then their pacemaker charges are being reduced to cost using that CCR rather than the more appropriate CCR which is likely to be 5500 Supplies charged to patients. Hospitals do not typically report pacemaker costs with prosthetic costs. Pacemakers are implants that must be reported under revenue code 275 for pacemaker, not prosthetics. CMS uses the CCR for 5500 for revenue code 278 charges for other implants like stents, therefore, it is a better cost center for pacemaker 275 than prosthetics.

By providing such an example, hospitals would be able to clearly see that all expense and revenue related to items billed under revenue code 275 should either be reclassified on hospital cost reports into cost center 3540 or 5500. Hospitals would also be able to understand why their pacemaker cost that is significantly more than $1,886 (in the example) is calculated as such. This will encourage hospitals to apply proper mark ups to their devices so that CMS payment calculations result in a close approximation of actual costs which will help improve the APC median cost calculations over time.

The PRT notes that it is crucial that if CMS provides these examples and hospitals respond by trying to correctly classify revenue and expense, that the Fiscal Intermediary (FI) audit staff allow reclassifications to take place and do not reverse them in audit adjustments.

CMS could use another example for blood products and blood administration.

Rev Code	HCPCS	Charges	Primary Cost Center Line for CCR from Crosswalk	Secondary Cost Center Line for CCR from Crosswalk	Calculated Cost
258		$76.25	5600 Drugs charged to patients = 0.34		$25.93
272		$53.64	5500 Supplies charged to patients = .23		$12.34
390	P9040	$280.00	4700 Blood Storage, Processing = .54		$151.20
391	36430	$662.22	4700 Blood Storage, Processing = .54		$357.60
Total		**$1,072.11**			**$547.06**

From this example, hospitals would be able to understand the impact of not marking up their blood product processing costs from Red Cross. Furthermore, hospitals would likely comment that using cost center 4700 with revenue code 391 is not appropriate. From the Revenue Crosswalk published on CMS' web site, CMS uses hospital's charges under revenue code 391 for blood product administration services and reduces those charges to cost using the cost-to-charge ratio from cost report line 4700 for blood products. This is not a logical choice for charges reported in revenue code 391. Blood administration services billed using revenue code 391 is for nursing services. The primary CPT code billed under revenue code 391 is 36430 for transfusion of blood or blood components. Transfusions are performed by nursing personnel on clinic outpatients or on observation outpatients. The expense of nursing personnel should not reside in the blood bank cost center and it would not make sense to reclassify those revenue and expenses to the blood bank cost center. The blood bank cost center retains the cost of blood and blood product processing and the supplies, staff and equipment to track and keep these blood products safe, but NOT the actual administration expense. It is inappropriate to map revenue code 391 to 4700. A better mapping would be to 6200 or 6201 for observation and to 6000 for clinic.

Another suggestion is for CMS to conduct a survey of its FI auditing staff and the validity of revenue code to cost center crosswalk. For example, CMS can survey FIs to find out what cost centers hospitals typically report pacemakers (275), defibrillators and other implants (278), isotopes (343 and 344) and other items for which the APC payment rates have been controversial. CMS would learn from such a survey where adjustments in the crosswalk should be made over time.

Finally, the PRT has reviewed the revenue code to cost center crosswalk and provided line-by-line comments where appropriate. This was submitted as a separate Excel attachment via our electronic comments and is available in hard copy upon request. We hope that CMS makes adjustments in the crosswalk as indicated by these comments.

Packaged Revenue Codes

The PRT reviewed the list of packaged revenue codes and became concerned when non-OPPS service revenue codes were listed. We compared the 2006 list of packaged revenue codes to the list of revenue codes from the OCE that allow charges with no HCPCS code present. We then compared to the list of packaged revenue codes from the 2007 proposed rule.

We believe some changes need to be made in the list of packaged revenue codes that are more consistent with OPPS payment policy and also with appropriate billing of OPPS services. Continuing to package costs from some claims with suspect revenue codes may result in poor median cost calculations.

The following table provides these comparisons and our comments.

Comparison of Packaged Revenue Code Lists				
2007 proposed rule	**Description**	**2006 final rule**	**Oct 2006 OCE list blank HCPCS OK- meaning allow as a packaged revenue code**	**PRT Comments**
250	PHARMACY	250	250	
251	GENERIC	251	251	
252	NONGENERIC	252	252	
254	PHARMACY INCIDENT TO OTHER DIAGNOSTIC	254	254	
255	PHARMACY INCIDENT TO RADIOLOGY	255	255	
257	NONPRESCRIPTION DRUGS	257	257	
258	IV SOLUTIONS	258	258	
259	OTHER PHARMACY	259	259	
260	IV THERAPY, GENERAL CLASS	260	260	
262	IV THERAPY PHARMACY SERVICES	262	262	
263	SUPPLY/DELIVERY	263	263	
264	IV THERAPY/SUPPLIES	264	264	
269	OTHER IV THERAPY	269	269	
270	M&S SUPPLIES	270	270	
271	NONSTERILE SUPPLIES	271	271	
272	STERILE SUPPLIES	272	272	
			273	These are non-covered charges.

274	PROSTHETIC/ORTHOTIC DEVICES	274		This Revenue Code is for non-implanted prosthetic/orthotic devices which require a HCPCS code and are paid under the MPFS and have a SI "A" under OPPS. Costs under this revenue code should not be packaged under OPPS. Furthermore, the OCE will not allow charges under this revenue code to be reported without a HCPCS code. Therefore, the PRT requests CMS remove revenue code 274 from the packaged revenue code list.
275	PACEMAKER DRUG	275	275	
276	INTRAOCULAR LENS SOURCE DRUG	276	276	
278	OTHER IMPLANTS	278	278	
279	OTHER M&S SUPPLIES	279	279	
280	ONCOLOGY	280	280	The PRT is unable to identify any oncology service that would not be characterized by a CPT/HCPCS code. Therefore, the OCE should require CPT/HCPCS codes for line items billed with revenue code 28X and should not consider these services packaged. Hospitals billing charges under revenue code 28X without a CPT/HCPCS would be suspect and should not be included as packaged costs.
289	OTHER ONCOLOGY	289	289	See above comments for revenue code 280.
290	DURABLE MEDICAL EQUIPMENT	290		By definition, DME is for use in the home, not in the outpatient hospital setting. Furthermore, the OCE requires a HCPCS code when this revenue code is billed and DME is not billable by hospitals to Intermediaries. The hospital must obtain a DMERC provider number and separately bill DME to the DMERC. Therefore, packaged costs billed by hospitals for outpatients under this revenue code are suspect and should not be used in the rate setting process.
343	DIAGNOSTIC RADIOPHARMS	343	343	Radiopharmaceuticals are required to be billed with HCPCS codes. While CMS may ultimately determine that radiopharmaceuticals are packaged HCPCS, this determination is made individually for each radiopharmaceutical HCPCS code, therefore, charges billed under 343 or 344 without the appropriate HCPCS codes should be suspect. The PRT recommends the OCE edit for HCPCS codes on these revenue codes and that these revenue codes be removed from the list of packaged revenue codes.
344	THERAPEUTIC RADIOPHARMS	344	344	See the above comment for revenue code 343.
370	ANESTHESIA	370	370	
371	ANESTHESIA INCIDENT TO RADIOLOGY	371	371	
372	ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC	372	372	
379	OTHER ANESTHESIA	379	379	
390	BLOOD STORAGE AND PROCESSING	390	390	

399	OTHER BLOOD STORAGE AND PROCESSING	399	399	
560	MEDICAL SOCIAL SERVICES	560	560	Services characterized by revenue codes in the 56X series are separately billable only by Home Health Agencies. Hospitals billing charges under the 56X revenue code series are billing for suspect services and therefore, the revenue codes in the 56X series should not be on the packaged revenue code list and charges submitted with these revenue codes should not be used in the rate setting process.
569	OTHER MEDICAL SOCIAL SERVICES	569	569	See the above comments for revenue code 560.
621	SUPPLIES INCIDENT TO RADIOLOGY	621	621	
622	SUPPLIES INCIDENT TO OTHER DIAGNOSTIC	622	622	
624	INVESTIGATIONAL DEVICE (IDE)	624	624	
630	DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS	630	630	
631	SINGLE SOURCE	631	631	
632	MULTIPLE	632	632	
633	RESTRICTIVE PRESCRIPTION	633	633	
			637	These are non-covered charges.
681	TRAUMA RESPONSE, LEVEL I	681	681	
682	TRAUMA RESPONSE, LEVEL II	682	682	
683	TRAUMA RESPONSE, LEVEL III	683	683	
684	TRAUMA RESPONSE, LEVEL IV	684	684	
689	TRAUMA RESPONSE, OTHER	689	689	
700	CAST ROOM	700	700	
709	OTHER CAST ROOM	709	709	
710	RECOVERY ROOM	710	710	
719	OTHER RECOVERY ROOM	719	719	
720	LABOR ROOM	720	720	
721	LABOR	721	721	
			732	
762	OBSERVATION ROOM	762	762	
			801	
			802	
			803	
			804	
			809	
810	ORGAN ACQUISITION	810	810	

819	OTHER ORGAN ACQUISITION	819	819	
			821	
			822	
			823	
			824	
			825	
			829	
942	EDUCATION/TRAINING	942	942	

Packaged Services

The PRT would like to thank CMS for designating specific CPT codes as "special packaged codes" and for allowing separate payment for them when billed on a date of service without any other OPPS payable service. Many of the codes given this status are ones that the PRT has submitted to the APC Advisory Panel's Packaging Subcommittee. We support and appreciate the work of this subcommittee and urge that it continue to work on this and other data issues.

The PRT understands that CMS is clarifying for future claim submission that if a packaged service (status indicator "N") is the sole service performed at a visit and there are no other separately identifiable services to justify a hospital visit code, that the hospital cannot bill a visit code in lieu of the packaged service procedure, even when it is the sole service rendered and there are no other services on the claim, OPPS services or otherwise. Note that packaged OPPS services are packaged only to other OPPS services, not to other fee schedule service such as lab or rehabilitation. The PRT has a data concern with respect to this instruction. While we agree that the situation should be very rare, CMS is now preventing a hospital from even submitting the claim to CMS at all. How will CMS ever obtain the data to determine whether the service may need to be reclassified to a "special packaged code?" The PRT believes that it is important for hospitals to be able to report these situations even if they result in no separate OPPS payment at the time. Is it possible for a claim with a single "N" status line item that is "returned to provider" (RTP) to be read into the claims database so that CMS is able to evaluate these claims? If not, isn't it a concern to CMS that a valid outpatient hospital encounter is not reported to CMS, particularly when CMS is concerned about quality of outpatient care? There is a mandatory Part B claim submission requirement – in this case, the hospital is unable to report a claim to CMS. The PRT believes that the claims should be able to be resubmitted to CMS with a remark in the remarks field so that CMS can obtain the claims data for future analysis.

2. APC Specific Policies/APC Reconfiguration

Medication Therapy Management Services

The PRT presented a proposal to the APC Advisory Panel at the March 2006 meeting to recognize and provide separate APC payment for Category III CPT Codes related to MTM. CMS did not adopt the Panel's final recommendation on this issue. The PRT is pleased to see that CMS did not move forward as the Panel's recommendations did not reflect the original intent of our proposal. We agree, in principal, that CMS has no need to distinguish MTM services provided specifically by a pharmacist, as this would mean providers would have to keep up with differing methods of reporting incident-to services depending on the staff providing the service.

We appreciate that CMS has validated the fact that these services are already accounted for within the OPPS system. We seek clarification from CMS regarding the term "component of", as it relates to clinic visits, however. While we agree that MTM might be performed as a component of emergency visits, procedures, and diagnostic tests, we also know that MTM is often performed as a stand-alone service in the clinic setting meeting all of the incident-to and coverage requirements. To that end, we ask CMS to specifically state, as it did in July 2003 (see the embedded FAQ below from the CMS web-site though no longer visible online), that a clinic visit may be reported to identify these services, if they are separately identifiable from other OPPS services on the same date.

Answer ID 2101
Topic Payment/Billing
Category Prospective Payment System (PPS) Outpatient Hospital
Date Created 07/22/2003 06:40 AM
Date Updated 10/06/2003 06:44 AM

If a patient receives medication management services on the same date that their medication level is tested, may a hospital bill a low-level clinic visit (CPT code 99211) in addition to the CPT code for the laboratory test?

Question

When medication management services (such as anticoagulation therapy management services) are furnished to an outpatient in a hospital outpatient clinic on the same date that the patient's medication level is tested, may a hospital bill a low-level clinic visit (CPT code 99211) in addition to the CPT code for the laboratory test?

Answer

When face-to-face medication management is provided by qualified hospital staff on the same date of the laboratory test to an outpatient in a hospital outpatient clinic, a hospital may bill CPT 99211 if the services are medically necessary and constitute a distinct, separately identifiable E/M service that is consistent with the hospital's criteria for a low-level clinic visit.

Example: A registered outpatient who is being treated with coumadin for deep venous thrombosis (DVT) receives face-to-face counseling from qualified hospital staff, such as interpretation of the test, discussion of dietary concerns, evaluation of the patient, and modification of the treatment regimen, on the same date that prothrombin time is tested. The hospital could bill CPT 99211 for the medication management services in addition to CPT 85610 for the laboratory test. The interpretation of frequently recurring laboratory tests such as PT or INR and the communication of normal test results to a patient or patient's care giver is not by itself sufficient for the 99211 code. Factors which may support the 99211 code could include the need to adjust medication dose based on the test result or patient's clinical status.

Other APCs

The PRT would like to take this opportunity to thank CMS for making changes to the APCs involving fractures, as we believe the change from one to three APCs for these services better recognizes the differences in hospital resource utilization. Additionally, we appreciate the movement of CPT code 57267 from APC 0154 to 0195, as this better reflects clinical and resource homogeneity. Lastly, we applaud CMS for continuing to support the appropriate reimbursement of HBOT through the use of overall hospital CCR, as opposed to the respiratory therapy cost center.

3. Radiology Procedures

The PRT agrees with CMS' position to NOT apply a 50% discount percentage when two or more diagnostic imaging procedures from the same family of codes are provided during one session. We are aware this was CMS' proposal last year and understand based on its own analysis that certain economies of scale are already captured in the cost report when multiple diagnostic imaging procedures are provided. Therefore, we agree with CMS' position not to apply discounting to multiple diagnostic imaging procedures when provided during the same visit.

4. Device Dependent APCs

The PRT would like to comment on several issues related to device dependent APCs. First, we understand the logic behind the device offset and its application when a device-dependent APC procedure is performed and there is no device cost or the cost is minimal due to a recall or warranty replacement situation. However, we are unclear how the offset will be applied to device-dependent APCs with a status indicator of "T", which are subject to multiple procedure discounting. Is CMS proposing to first apply the device offset and then reduce the residual APC amount by another 50 percent? This would effectively pay a nominal amount for the actual procedure. The PRT is concerned that this would not be appropriate to cover the cost of the procedure, packaged drugs, or supplies, even in cases where there is no cost associated with the device.

The second issue the PRT is concerned about relates to devices under warranty reported with condition code 50. CMS proposes to implement an adjustment for device replacements through the use of an appropriate modifier that would be specific to a device replacement without cost or crediting of the cost of the device by the manufacturer. Hospitals would be required to report the modifier with the specific procedure when two conditions are met. The first condition occurs when the procedure is assigned to one of the APCs in Table 21 of the proposed Rule. The second condition occurs when the device for which the manufacturer furnished a replacement device (or provided credit for the device being replaced) is included in Table 22 of the proposed Rule. (The adjustment would only apply to devices included in Table 22 so that the adjustment is not triggered by the replacement of an inexpensive device whose cost does not constitute a significant proportion of the total payment rate for an APC.) The presence of the modifier would trigger the payment adjustment for the APCs in Table 21 of the proposed rule. CMS recognizes that the current FB modifier may not be

appropriate for cases in which the replacement device is more expensive than the device that is being removed. CMS also recognizes that the modifier's use may need to be expanded to encompass all potential APC payment scenarios.

On occasion, devices that have been recalled or deemed defective are replaced with an upgraded device and the cost to the hospital for the upgraded device is greater than the cost of the replaced device. The device manufacturer may give the hospital a credit for the sales price of the device being replaced, and the hospital may than have to pay the manufacturer the difference in the prices of the two devices. Hospitals have asked CMS how to bill Medicare for these differences and in Transmittal R903CP, CMS instructed hospitals to report the HCPCS code for the upgraded device and condition code 50, denoting "Product Replacement for Known Recall of a Product – Manufacturer or the Food and Drug Administration has identified the product for recall and therefore replacement"; and the charge for the upgraded replacement device equaling the difference between the replaced device's usual charge and the upgraded device's usual charge. The Transmittal instructs providers not to report the FB modifier because the device is not being furnished without cost by the manufacturer.

The PRT agrees with this proposal, providing that CMS gives assurance that device costs with condition code 50 will be included with the modifier requirement or excluded from the claims data when determining median cost calculations in instances when there is a difference in the device cost billed to Medicare. If this does not occur, device costs will be underestimated. The PRT seeks confirmation that such devices reported with condition code 50 only will not be used in the median cost calculation and asks for clarification of this issue in the final Rule.

Finally, the PRT supports CMS' suggestion of expanding the current device edits in the OCE to include additional edits. We understand CMS is in the process of creating device HCPCS C-code to procedure edits and support this effort. We also encourage CMS to create similar edits for other procedures and services where natural linkages are expected. For example, we believe CMS can link certain radiology procedures requiring contrast agents with codes for the contrast agents. In addition, CMS could create also edits for nuclear medicine procedures and radiopharmaceuticals. We understand creating such edits is no easy task and that they must be carefully constructed. Therefore, we encourage CMS to continue researching expansion of edits in order to generate even more correctly coded claims to use in the APC rate setting process.

5. Drug Administration Coding and Payment

Coding Issues

The PRT understands CMS is proposing to continue requiring a combination of HCPCS C-codes and CPT codes for use in 2007. The majority of the 17 PRT member hospitals and health systems, representing over 50 hospitals in 21 states, have been fortunate enough to have their non-Medicare payers follow Medicare's reporting requirements for reporting drug administration services using a combination of CPT and HCPCS C-codes. However, several member hospitals have not been so fortunate and hence have encountered many difficulties this year as is often the case when different reporting requirements are in place for Medicare vs. non-Medicare payers. In addition,

many have encountered problems with their state Medicaid plans not accepting the Medicare HCPCS C-codes and have thus not been paid allowable co-payments and deductibles for these services by Medicaid plans when secondary to Medicare.

One of the main problems with the dual coding for drug administration services is that there are more CPT codes than HCPCS C-codes so a one-to-one code crosswalk cannot be created to automate the charging process to Medicare vs. non-Medicare payers. Because many payers adopted the full set of CPT drug administration codes and do not recognize the Medicare C-codes, hospitals are unable to automate charging process to charge all patients the same. We have to employ extra staff and rely on manual review of many claims to ensure accurate billing to all our payers. All PRT members agree that the current CPT codes for drug administration are not intuitive or easily applicable in the hospital setting. Physicians using definitions and logic to treat the patients they see in their private practice settings created the codes. The patient population receiving drug administration in a physician office is quite different than in a hospital setting. Hospitals treat more complex cases, emergent cases, and patients who require multiple hours of infusion such as those admitted for observation. Because of the different patient population, the logic and definitions that are applicable in the physician office setting are not applicable in the hospital setting. Nevertheless, those PRT members who have payers that require the CPT codes have had to learn to work with the codes and in essence use them to charge all patients the same and have found ways to manually convert the CPT codes to HCPCS C-codes for Medicare reporting on the back-end of the billing process. For these PRT members, it would be much easier if CMS moved to the full use of the drug administration CPT codes for 2007 while simultaneously working with the CPT Editorial Panel and the AHA to redefine the CPT code definitions so they are applicable for both physician and hospital use.

Having said that, the majority of PRT members have payers who follow Medicare's requirement of reporting HCPCS C-codes and CPT codes for drug administration services. These hospitals have not had to train staff or update systems to use the full set of CPT codes. Therefore, many of the PRT members do not support CMS moving to the full use of CPT codes until the code definitions are applicable for hospital use.

While many hospitals around the country are already experienced with the full set of drug administration CPT codes as a result of non-Medicare payer requirements for 2006, most will not be able to easily convert to the full use of CPT without facing huge administrative and operational burden – the same type of burden faced by many providers this year. The large part of the problem comes from the concept of reporting only one "initial" service code, which is inappropriate in the hospital setting since our patients are often seen in multiple departments. This was included in our comments to CMS last year. In addition, the concepts of subsequent, sequential, and concurrent are not well-defined and again difficult to employ across multiple nursing units and hospital departments. For most hospitals, moving to the full use of CPT will necessitate hiring additional staff to handle the increased coding requirement of reviewing medical records for drug administration. We know this to be the case as some hospitals have *already* incurred this burden and cost simply to report accurately to Medicare and non-Medicare payers this year. Smaller hospitals may be forced to abandon providing and/or reporting these services altogether due to the complexity of charging initial/subsequent drug

administration at the point of service, or because they are unable to expend funds for additional coders.

With one code set that is intuitive and applicable to the hospital setting, all hospitals will be able to charge and code for drug administration services at the departmental level, meaning the point of care, through the Charge Description Master-- a much simpler and more efficient method than having Health Information Management (HIM) professionals code these services or training nursing staff to learn all of the coding rules and keeping track of services provided in their department vs. other departments. Hospitals would much prefer to have their scarce and valuable nursing resource spend time caring for patients rather than tracking services across departments and coding rules.

We noted above that many hospitals currently have to bill non-Medicare payers using CPT codes only, because the HCPCS C codes are not recognized by many commercial payers nor are they recognized by some state Medicaid programs. Even though some hospital billing systems can handle billing different codes to different payers, this is only possible with one-to-one code crosswalks. The drug administration codes do not have a one-to-one relationship, so hospitals are unable to automate this process, thereby requiring manual intervention by staff to adjust the coding to meet the individual payer's coding requirements. This intervention is very burdensome, substantially increases administrative costs and slows down claims processing.

Given the different experiences of PRT members this year with respect to reporting CPT codes and HCPCS C-codes to both Medicare and non-Medicare payers, it was difficult for us to come to an agreement on our final recommendation to CMS for 2007. Our members have several different opinions on what CMS should do, but we are all in total agreement that CMS must work with the CPT Editorial Panel and the AHA to create a set of drug administration codes and descriptions that are intuitive and applicable for physician and hospital reporting. Some of our more specific recommendations are below:

- CMS should consider changing the drug administration HCPCS C-codes to G-codes, which in theory should be accepted by all payers though there are still some payers that are not readily accepting G-codes, though we believe they should due to HIPAA transaction set rules
- CMS should continue with HCPCS C-codes and CPT codes as implemented in 2006 until such time that a full set of CPT codes is applicable in the hospital setting
- CMS should move to the full use of CPT drug administration codes as long as it also agrees to work with the AMA to improve these code definitions so they are applicable in the hospital setting
- CMS should mandate state Medicaid plans to accept HCPCS C-codes when they are present on Medicare/Medicaid cross over claims if C codes are retained for 2006

If CMS decides to retain some combination of HCPCS/CPT reporting, CMS weakens its current position that the HCPCS language must reflect the full language of CPT. A prime example is that of IV Push Administration (currently C8952). The previous CPT code (90784) did not include any language limiting use "by the drug", and hospitals were able to bill for each and every separately identifiable IV Push. Under this mechanism from the inception of OPPS, hospitals were legitimately paid for each IV push of a packaged drug (i.e., the packaged drug was paid through the payment of the IV push administration code), but this ability to be paid was stripped away during 2006. We continue to believe the CMS erred when mandating that C8952 must follow the logic of 90774 (IV injection, initial drug), which allows billing only once per each different medication. It is not clear why CMS would allow hospitals to bill for each and every IM/SQ Administration (90772), yet not allow the same methodology for IV Push Administration (C8952). If CMS retains some form of HCPCS, the PRT asks that the codes reflect hospitals drug administration practices, which are more complex and costly than that experienced in the physician office setting.

The PRT urges CMS to review current Drug Administration policies to address the ongoing inconsistencies outlined above.

Payments and APC Groupings

The PRT is very pleased to see that CMS has proposed six different APC payment groups for drug administration services. We concur with the placement of most of the codes into the APC groups with the exception of the following: 96440 (chemo, pleural cavity), 96445 (chemo, peritoneal cavity), and 96450 (chemotherapy into CNS). Because these procedures are much more invasive than the other drug administration services (e.g., they require catheters inserted into body cavities), and because they are performed by the physician (as opposed to nurses performing all other drug administrations), the PRT recommends that CMS remove these procedures from the six APC groups, and pay for them under a separate APC with a higher payment amount.

It should be noted that the current payment for thoracentesis (32000), peritoneocentesis (49080), and lumbar puncture (62270) are paid at a higher rate than the same procedures when performed as part of a chemotherapy administration service per the code definitions listed. The exception is CPT code 62270, in which the chemotherapy APC payment for CPT code 96450 is higher than the payment for CPT code 62270 – but only slightly higher ($16.43, which is insufficient to cover the extra costs associated with providing chemotherapy).

Thoracentesis	32000	APC 0070	$224.20
Peritoneocentesis	49080	APC 0070	$224.20
Lumbar Puncture	62270	APC 0204	$138.43
Chemo inclu thoracentesis	96440	APC 0439	$97.84
Chemo inclu peritoneocentesis	96445	APC 0439	$97.84
Chemo inclu lumbar punc	96450	APC 0441	$154.86

The PRT requests these three chemotherapy codes be paid under a separate APC, and at a higher rate than the surgical procedures when provided alone as this does not meet a reasonableness test. It makes intuitive sense that the procedure + a chemotherapy administration service should result in a higher APC payment than either service alone, yet that is not what the APC payment rates reflect. In addition, these chemotherapy administration procedures are significantly more invasive and hence resource intensive than the other drug administration services and should be paid through a different APC.

One alternative to our above recommendation would be for CMS to remove the CCI edits that currently do not allow us to report the both the surgical procedure and the chemotherapy service separately on the same date of service. If the edits were removed and appropriate guidance provided, then we would bill for each part of the overall service separately and receive appropriate payment. We strongly urge CMS to examine this issue further.

In addition, we are very pleased to see that CMS has proposed to pay for the first hour of an infusion separately from each additional hour. While we believe the APC payment rates for the each additional hour service codes is low, we understand this is due to CMS using provider claims data from 2005 – the first year in which hospitals were allowed to report each additional hour of infusion therapy (chemotherapy as well as non-chemotherapy) separately under OPPS. Therefore, while the 2005 claims data is poor, we expect it to be improved over time.

We also understand that CMS is moving away from the per-visit payment concept for drug administration services and towards a per-service concept and this is reflected in the proposal to pay separately for each hour of infusion therapy. However, it is not clear what this means for chemotherapy injection services given that in the past we were only paid for one unit of Q0083 or one unit of C8953 even if multiple injections were provided to the patient. With the per-service payment concept, we believe CMS will pay separately for each chemotherapy injection provided and ask that CMS address this in its final rule.

Finally, the PRT is concerned about the median cost calculation methodology CMS used to set the APC payment rate for the non-chemotherapy IV push injection service. In 2005, providers reported CPT code 90784 with multiple units when multiple IV push injections were provided along with a dollar charge reflecting each injection. It is not clear to us whether CMS has factored this into its payment rate calculation since these claims may have been considered multiple procedure claims and hence discarded from the rate setting process. We urge CMS to review its payment rate calculation and adjust it accordingly so that at least on average the APC payment rate for IV push injection reflects multiple injections of the same substance or drug. This is critical particularly if CMS continues to disallow providers to report and hence FIs to pay for multiple IV push injections of the same substance or drug – though we are hopeful that CMS will follow the APC Advisory Panel's recommendation on this issue and change its policy for 2007.

Additional Drug Administration Issues

Modifier -59

CMS states that it no longer needs to give specific drug administration instructions related to the use of modifier -59, and that hospitals should use modifier -59 consistently with coding principles generally used for other OPPS services. CMS needs to clarify the intent of this statement because it is unclear if CMS simply means that the OCE parameters will be changed to allow multiple APC payments for multiple codes and units even if they are reported without modifier -59 (see 100-4, 230.2 D. – Table 1) due to changes in per-service vs. per-visit logic. Alternatively, CMS might mean that it is going to remove the entire discussion regarding use modifier -59 (see 100-4, 230.2 C.) from its manual instructions/transmittals.

The PRT believes that CMS must issue a Transmittal to discuss the myriad drug administration issues that will continue to arise from a coding standpoint about whether or not modifier -59 will be needed, depending on the final 2007 coding methodology chosen. For example, if CMS continues with HCPCS C-codes then:

- How will providers report a second, non-concurrent, non-chemo infusion so that it processes for payment? For example, if a patient receives medically necessary hydration for an hour followed by an infusion of antibiotics for one hour, hospitals will need to report two units of the only available code for both of the situations above (C8950) and it is not clear if this code will need modifier -59 or if CMS will allow the OCE to generate two APC payments.
- Will providers be allowed to report a single line item with multiple units of the first hour infusion code and the each additional hours infusion code respectively and be paid appropriately even without the use of modifier -59 if the hours of infusion span two separate visits on a single date of service. In theory, this should process for payment through the OCE, but it is not clear if CMS plans on removing the per-visit units of service limits that are currently in place or expects to rely on the use of modifier -59.

Further, we believe that continuing to apply the Physician CCI edits for drug administration services under OPPS is inappropriate as this forces providers to report modifier -59 far too often and unnecessarily resulting in CMS' data being "flooded" with modifier -59, rendering it meaningless with respect to understanding what is happening with the provision of drug administration services. CMS recognized this to some extent earlier this year and "turned off" some of the CCI edits related to drug administration services, but many inappropriate edits continue to be in place resulting in hospitals being forced to report this modifier on virtually every multiple procedure claim that crosses service departments. For instance, virtually every radiology service in the CCI edit tables that includes a related injection (whether inherent in the CPT or reported by another distinct code) ends up looking like an "error" even when the injection is truly legitimate, separate and distinct from the radiology procedure, and most often provided in other departments, such as the Emergency Department or Observation. The PRT encourages CMS to take one service area (e.g. CT) and run data to look at the use of drug administration codes in the physician office setting along with the CT scan, versus the

use of drug administration codes on 2006 hospital claims along with the same CT scan. We believe the data will clearly show a tremendous volume difference between the two settings, illustrating that hospitals provide multiple different services through multiple departments on the same date of service which physicians in their office settings do not and hence the same set of edits are not applicable. They simply result in increased administrative burden for hospitals which we believe can easily be alleviated by CMS by "turning off" the physician drug administration CCI edits.

6. Drugs, Biologicals, and Radiopharmaceuticals

The PRT understands CMS will use a variety of payment methodologies to pay for drugs, depending on whether the drug is a pass-through, packaged, or separately payable and depending on whether average sales price (ASP) data or other data is available. The PRT continues to believe CMS is incorrect in its assumption that using a percentage increase over the ASP to set payment rates for most separately payable and pass through drugs is sufficient to cover both our cost acquisition and pharmacy handling costs. We, like others, commented on this issue last year and urged CMS to find an administratively simple way to capture pharmacy handling data. We were disappointed that no progress has been made and urge CMS to continue exploring methods to capture this information so that future drug payment rates are more appropriate.

The PRT does not support CMS' proposal to pay for drugs at ASP + 5%. This 1% decrease over how we are paid today is not appropriate and furthermore, results in another site of service differential between the physician and hospital setting given that physicians are still being reimbursed at ASP+6%. The PRT cannot understand how or why CMS would allow such a differential to exist, particularly since physicians are paid for each and every drug, while hospitals are not due to the existence of the drug packaging threshold. Finally, given that CMS does not allow for multiple APC payments for multiple injections of the same drug/substance, we lose out on the administration payment and also on the drug reimbursement if the drug being injected is packaged. Therefore, the PRT urges CMS at a minimum to continue reimbursing separately payable drugs using ASP + 6% as is done today.

Finally, and related to the previous comment about packaged drugs, the PRT strongly believes CMS should eliminate the drug packaging threshold and allow separate payment for all HCPCS coded drugs, biologicals, and radiopharmaceuticals regardless of their median cost. While we understand that this methodology goes against OPPS packaging principles, we believe that there are inherent advantages to adopting this payment methodology, including the items mentioned above. Beyond that, we believe CMS' own statement that it will serve to speed the creation of procedural APC medians through the use of more single procedure bills is another reason to accept this recommendation. Making such a change will not result in any sort of burden to providers given that providers should already be reporting each and every HCPCS code reflecting the services rendered to a patient regardless of whether the item, service, drug, etc. results in separate payment. Therefore, there would be no additional coding or billing burden for providers. Last year CMS stated that it wanted providers to report all HCPCS codes, regardless of payment status, to encourage data collection for claims analysis. We agree with this and have diligently worked to report complete and accurate claims data even if

certain line items have generated no additional payment to date. In addition, by paying for all HCPCS coded drugs separately, CMS will move closer to aligning payment policy across the physician and hospital settings. We believe this level of payment consistency is important across care settings, particularly to ward off any sort of "physician cherry-picking" that might come into play.

Finally, with respect to Brachytherapy and Radiopharmaceuticals, the PRT believes it is important for CMS to continue basing payments on cost due to the fact that the claims data may be incomplete and incorrect given the frequent code and descriptor changes. CMS has not had the advantage of claims data from 2006 where payment was based on charges reduced to cost and the revised codes were used for billing. Therefore, relying on median cost data as the basis of setting APC payment rates for these services could impact beneficiary access to care as we suspect the calculated payment rates will be severely understated due to the known data issues

IVIG

For CY 2006, CMS created a new HCPCS G-code,G0332 for *pre-administration related services for IV infusion of immunoglobulin (IVIG), per infusion encounter* to offset hospital expenses associated with the extra work related to the problems experienced due to the unavailability of the IVIG product. In the 2007 OPPS Proposed Rule, CMS states that its review of the IVIG marketplace indicates that a separate IVIG pre-administration payment is no longer necessary in CY 2007.

Our own pharmacy directors continue to experience a significant shortage of IVIG as each hospital is allotted a specific (limited) quantity of IVIG based on our past purchase history. After each hospital has exhausted its allotment, the hospital has to scramble to obtain more of the product, often from the "gray" market, as there is a known shortage. Not only are we forced to purchase from the "gray" market, but, in fact, we also face paying an approximately 25-40 percent higher rate and must accept whatever form of the drug we are able to locate. Because different forms of IVIG require different levels preparation, obtaining "extra" IVIG often results in increased costs due to the extensive preparation resources our facilities have to expend to mix the drug.

The PRT realizes that CMS will begin, in CY2007, paying for additional hours of infusion. According to the Proposed Rule, this reimbursement is intended to cover the additional nursing resources ("significant clinical staff time to monitor and adjust infusion based on patients' evolving condition") incurred during additional hours of infusion and not for obtaining IVIG. We urge CMS to not confuse appropriate payment for IVIG as a product with its proposal for paying for additional hours of infusion therapy. These are two different things.

Due to the continued difficulty in the acquisition of IVIG, the PRT recommends allowing payment for code G0332 for as long as the shortage of IVIG continues.

7. Hospital Coding and Payment for Visits

New HCPCS G-codes

The PRT supports the creation of HCPCS G-codes specific to hospitals for reporting facility levels of care for the emergency room and clinic visits. Many of us have trouble with Medicaid and non-Medicare payers recognizing that hospital reporting of the physician CPT codes is acceptable to show the clinic level services we provide. Having specific codes just for hospital use should facilitate resolution of this issue with these payers. However, several PRT members are concerned that state Medicaid and other local payers may not recognize the new G-codes if made final for 2007, even though we believe they should under HIPAA. We urge CMS to stress the importance of this code set and its applicability to the hospital setting so we can avoid problems with state Medicaid programs and other local payers if these HCPCS G-codes are made final for 2007.

We also urge Medicare to make sure that Medicaid accepts these new G-codes if made final so that we do not have problems with claims that crossover to Medicaid. Medicaid programs owe legitimate co-payments when secondary to Medicare. CMS must make sure that these crossover claims, related to Beneficiaries that are eligible for Medicare and Medicaid, are reimbursed appropriately under Medicaid programs.

Finally, we urge CMS to work with the AMA to make a formal proposal to convert the G codes for hospital visits to full-fledged CPT codes for 2008. This will ensure that hospitals report one code set to Medicare, Medicaid and commercial payers which ensures consistent charging in the same manner for the same services to both Medicare and non-Medicare payers. Note that consistent code sets among all payers for the same services best supports the development of price transparency policies.

We also support the movement towards five levels of payment for these services. We are pleased to see that CMS elected to remove the distinction between new versus established versus consult patient types, as we believe any differences among these types of patients are best addressed by the actual visit levels assigned, assuming the level guidelines are constructed in a manner to capture escalating hospital resource intensity. Moreover, we support the concept of having separate HCPCS G-codes to distinguish between true emergency departments per the CPT definition and other clinic/emergency settings treating urgent care patients. Therefore, we support the concept of the Type A & B HCPCS G-codes, but urge CMS to provide additional guidance on the use of Type A versus Type B emergency department HCPCS G-codes so all providers are clear on what codes to report. For example, full-fledged hospital emergency departments that clearly qualify for Type A HCPCS G-codes often operate sub-units or locations within the emergency department that are open or closed based on morning, afternoon or evening fluctuations in patient loads and in the types of patients treated. Often such sub-units are called "Fast Track areas". It is clear to PRT members, that all visits within this full-fledged ED of the hospital should report the Type A ED visit G-codes since the hospital ED itself is open 24/7 even though the sub-unit area may not be. We believe that urgent care clinics that are wholly physically separate departments of the hospital or that are

hospital-based but off campus would report the Type B ED codes because these clinics are physically separate from the 24/7 emergency department and no portion of these clinics are open 24/7. We believe it is important for CMS to clarify when to report the Type A vs. Type B HCPCS G-codes, sooner rather than later so that providers are not confused in reporting these codes if made final for OPPS 2007 and so that different types of providers or non-Medicare payers do not challenge hospitals on the correct codes for reporting visits. This will ensure that CMS receives accurate and complete data from the outset to use for future years' APC rate setting calculations.

Finally, we are concerned with CMS' use of time in the description of the new HCPCS G-codes proposed for critical care. CMS issued coding and billing instructions concerning critical care at the outset of the OPPS. On page 17 of Chapter II for Claims Processing System Modification for OPPS (the FI training manual) there is no indication that a time threshold of 30 minutes or more was required before reporting CPT code 99291. In addition, on page 18452 of the April 7, 2000 rule CMS states, *"we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore, we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."* Given the above information, we cannot understand why CMS is now proposing a time threshold for reporting the newly proposed critical care codes. The 30-minute time threshold for CPT 99291 applies to physician billing for their professional services, but not to hospitals under OPPS. The APC payment covers the hospital staff and facility resources expended when critical care is reported -- these resources are expended immediately, not after 30 minutes. In addition, CMS should continue to recognize what it recognized previously - that it will be burdensome for hospitals to keep track of the number of minutes spent caring for a critical care patient in the Emergency Department.

If new HCPCS G-codes for critical care are finalized for OPPS 2007, CMS should eliminate the reference to time in the definition of HCPCS codes Gccc1 and Gccc2. The PRT believes the inclusion of this new time requirement in the description for the proposed G-codes as stated in the 2007 OPPS proposed rule is inadvertent. Therefore, the PRT urges CMS to eliminate the time requirement and to continue with its long-standing OPPS policy concerning billing for critical care services.

In addition, the PRT recommends CMS consider a different structure for the newly proposed critical care codes. First, we recommend using the CPT guideline to define a critical care patient as one with a critical illness or injury that acutely impairs one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition. Critical care involves high complexity decision making to assess, manipulate and support vital system function(s) to treat single or multiple vital organ system failure and/or to prevent further life threatening deterioration of the patient's condition. Second, we believe it is appropriate to distinguish between critical care with and without trauma activation.

Hospitals deploy extensive resources to care for a critically ill or injured patient in the hospital, yet there are two levels of critical care for a hospital. The first level involves a patient who is critically ill or injured and extensive staff and facility resources are expended to evaluate and treat the patient. The second level involves activation of a trauma response team. This level entails even more staff and facility resources to be

expended. Because there are specific packaged revenue codes for field-activated trauma response, we believe that it is appropriate to recognize these two levels of critical care with separate APCs. APC 0617 should encompass the first level and the second, higher level that includes the trauma response team should be assigned to a separate new APC 0xxx. Both of these critical care levels include services and resources that are radically different from a high level ED visit 99215 proposed to be reported with HCPCS G-code Gyyy5 in 2007. The PRT proposes the following definitions for critical care G-codes for use under OPPS 2007:

> Gccc1 – Hospital Critical Care without Trauma Activation – APC 0617. (The patient must meet the CPT definition of a critically ill or injured patient, but there is neither a time threshold nor trauma response team activation.)
>
> Gccc2 – Hospital Critical Care with Trauma Activation – new APC. (The patient must meet the CPT definition of a critically ill or injured patient and there is a trauma activation called and billed on this account. Revenue codes in the 68x series have been established for reporting trauma response/activation. For this new APC, Critical Care with Trauma Activation, CMS could also consider an edit requiring the presence of the 68x revenue codes and the new Gccc2 code be reported on the claim.

The PRT believes the primary outcome of changing the current policy will result in providers more accurately reporting the actual service(s) provided – in this case critical care. Furthermore, by packaging trauma activation charges with the specific critical care visits for which they occur, the acuity and resource use of these visits will be better quantified. In addition, CMS will be able to collect data on the type of critical care visits with and without trauma activation and make future payment policy decisions based on more accurate data. The consequence of making no change is that providers will have to implement burdensome documentation requirements to track critical care visits and time. It is unclear what time is to be counted for a hospital critical care visit. Restructuring new critical care APCs will align OPPS payment with actual practice and resource utilization.

Payment Levels and Payment Rates

As expressed in our comments above, the PRT supports the use of proposed HCPCS G codes for hospital ED and clinic visits and the proposed 5 APC payment levels for each respective group of visits. We understand that the payment rates for these levels result from 2005 claims data reflecting hospitals use of their own facility guidelines for ED and clinic visit reporting.

With the introduction of new codes, five APC payment levels, and the upcoming release of national hospital ED and clinic visit level guidelines, the PRT is concerned with the resulting payments from application of the proposed guidelines and how the payments would not, on their face, reflect relative hospital resource utilization between the two major types of visits – type A ED visits versus hospital clinic visits. Furthermore, we are concerned that the application of the proposed guidelines with the 2007 payment rates also results in beneficiaries paying more in co-payment for the same service in a clinic versus an ED. This does not create appropriate incentives for use of

scarce healthcare resources. Beneficiaries should pay less in co-payments when having services rendered in organized clinics versus showing up in a hospital emergency department on an unscheduled basis. Furthermore, co-payments should be a factor to encourage beneficiaries to choose the most appropriate setting for health care services. Under the 2006 payment levels a Level I clinic visit co-payment was almost 50% less than a Level I ED clinic co-payment ($10.47 versus $18.71). With the 5 proposed APC visit payment levels for 2007, the Level I clinic visit co-payment is almost equivalent to a Level I ED visit co-payment ($9.95 versus $10.25).

2006 APC	2006 Pmt	2006 Co-Pmt	2007 HCPCS	2007 HCPCS Description	2007 APC	APC Description	2007 Pmt	2007 Co-Pmt
0600	52.37	10.47	Gxxx1	Level I Hospital Clinic Visit	0604	Level 1 Clinic Visits	49.75	9.95
0600	52.37	10.47	Gxxx2	Level 2 Hospital Clinic Visit	0605	Level 2 Clinic Visits	61.90	12.38
0601	60.25	12.05	Gxxx3	Level 3 Hospital Clinic Visit	0606	Level 3 Clinic Visits	83.38	16.68
0602	87.67	17.53	Gxxx4	Level 4 Hospital Clinic Visit	0607	Level 4 Clinic Visits	105.13	21.03
0602	87.67	17.53	Gxxx5	Level 5 Hospital Clinic Visit	0608	Level 5 Clinic Visits	130.65	26.13
0610	73.79	18.71	Gyyy1	Level I Hospital Type A ED Visit	0609	Level 1 Type A Emergency Visits	51.23	10.25
0610	73.79	18.71	Gyyy2	Level 2 Hospital Type A ED Visit	0613	Level 2 Type A Emergency Visits	84.50	16.90
0611	129.18	34.26	Gyyy3	Level 3 Hospital Type A ED Visit	0614	Level 3 Type A Emergency Visits	133.52	26.70
0612	224.78	51.89	Gyyy4	Level 4 Hospital Type A ED Visit	0615	Level 4 Type A Emergency Visits	214.14	42.83
0612	224.78	51.89	Gyyy5	Level 5 Hospital Type A ED Visit	0616	Level 5 Type A Emergency Visits	330.98	66.20
0620	477.73	131.61	Gccc1	Hospital Critical Care 30-74 Min	0617	Critical Care	493.44	98.69
Pkgd			Gccc2	Hospital Critical Care @ Addl 30 Min	Pkgd			

It is best to illustrate these concerns with examples. The draft visit guidelines released by CMS on its website essentially copy Level I ED interventions and define them as Level III Clinic interventions. This has the unfortunate result of paying a hospital less for the same service when performed on an unscheduled basis in the ED versus payment in a clinic setting where the service is likely scheduled and pre-planned with appropriate staff, supplies and equipment. Clinic settings should be more efficient and cost-effective, in general, than 24/7 hospital emergency departments. The 24/7 Type-A ED is the most resource intensive setting for health care services to be rendered and therefore should reflect appropriate payment and co-payment rates.

Under the draft guidelines released by CMS on its website, if the sole service rendered is a first aid procedure, this qualifies as a Level I ED intervention paying $49.75 of which $9.95 is the beneficiary co-payment whereas the same first aid procedure in a Clinic setting qualifies as a Level III Clinic intervention paying $83.38 of which $16.68 is the beneficiary co-payment. This means that performing the same service in the ED supposedly costs less than in a hospital clinic. On the surface this payment structure does not make sense to us. Furthermore, beneficiaries will be financially rewarded to come with minor healthcare problems to an ED setting rather to a more appropriate clinic setting.

As a whole, Type-A ED visit APC payments should be a significant order of magnitude greater than hospital Clinic visit APC payments as this reflects actual hospital expense. CMS should be able to evaluate this from the hospital cost report data, even if provider claims data does not reflect this due to each hospital using its own internally developed guidelines. A reasonableness test should be applied to the APC visit payment levels as it is more expensive and resource intensive to operate hospital 24/7 emergency departments than hospital clinics. For example, the Level 1 through 5 ED visits may have higher payment rates by the same order of magnitude compared to Level 1 through 5 Clinic visits. The visit levels should reflect relative resource intensity of interventions and services provided in each setting. Often, it is not the specific intervention that is resource intensive in and of itself, but the setting and circumstances that make it resource intensive (unscheduled, urgent, multiple staff involved to deliver the service in an ED setting vs. the same intervention delivered as a scheduled service in a clinic setting).

Another example from the draft guidelines released by CMS on its website is when the sole service provided is hospital staff assisting the physician with a patient examination such as a pelvic or prostate exam. Under the draft guidelines, if the exam is the sole service, this qualifies as a Level 1 ED intervention paying $49.75 of which $9.95 is beneficiary co-payment whereas the same examination in a Clinic setting qualifies as a Level 3 Clinic intervention paying $83.38 of which $16.68 is the beneficiary co-payment. Again, this implies that performing the same service in the ED supposedly costs less than when the service is provided in a hospital clinic. The circumstances under which a physician would perform such examinations in the ED usually entail many more resources than in a clinic. The exam room usually has to be set up for the specific examination with staff going to various locations both within the ED and to other hospital departments to obtain the appropriate equipment and supplies for the examination. In the clinic setting however (excluding Type-B ED visits) the clinic is specifically set up for such examinations and the patient is typically scheduled. The result of applying the draft guidelines and the interventions/services listed and comparing APC payment rates across the ED and clinic setting does not make intuitive sense to us.

Therefore, we urge CMS to look at the ED and clinic payment levels and proposed guidelines as a whole and make reasonable policy decisions regarding APC payment rates for services and beneficiary co-payments across the ED and the clinic settings especially since consistent provider data is currently lacking due to each provider having developed and used its own guidelines. Once CMS implements national visit coding guidelines for facility use we believe provider claims data will be more consistent and reflect the higher resource use in an ED setting.

Commercial insurances have addressed this issue by developing flat patient co-payment amounts for ED versus clinic visits regardless of the level of visit. CMS should evaluate whether it makes sense for the beneficiary co-payment to be the same regardless of the level of visit, for example, a $15.00 co-payment for clinic visits and a $50.00 co-payment for ED visits are common amounts imposed by commercial insurances. It is important that beneficiary co-payments do not encourage inappropriate ED visits thereby straining hospitals limited resources even further. It is also just as important that the APC payment rates for visits in the two settings appropriately reflect relative resource use.

National Guidelines Development Process

The PRT offers its comments concerning the eight areas that CMS has requested input about, regarding the development of national hospital visit coding guidelines. In concert with establishing the national guidelines, the PRT requests that CMS publish a more specific definition of "separately identifiable" for the hospital outpatient setting. We expand on this request in the discussion below.

A. Three versus Five Levels of Codes

The PRT agrees with CMS' decision to have five levels of codes and agrees that it would be difficult to pay five levels using current guidelines, which assign to only three APCs. We believe that significant variation exists within the levels that would correspond to the five proposed G codes, and that five payment levels are justified for both clinic and Type A and B emergency visits.

B. Lack of Clarity for Some Interventions

The PRT believes that – with well-defined guidelines for each intervention that include relevant clinical examples -- the majority of coders and staff assigning levels will be clear as to how to apply the guidelines. CMS has stated that it is committed to provide a minimum of 6-12 months notice to hospitals prior to implementation of national guidelines in order to give providers sufficient time to make the necessary system changes and educate their staff. We believe 6—12 months is a sufficient amount of time, and should not be problematic for the majority of the provider community. Once CMS revises and releases the guidelines, providers will become more proficient at "documenting for the guidelines" and in the assignment of levels based on the guidelines, which will result in more accurate visit claims data. It may be advantageous for CMS to communicate to providers the areas that were found to be unclear when the AHA/AHIMA model was tested, and use these areas as examples to train providers on the proper documentation and assignment of the levels.

C. **Treatment of Separately Payable Services**

The PRT agrees that separately payable interventions should be used as a proxy for increased resource utilization by allowing the inclusion of the interventions into the national visit guidelines. The PRT believes this should not be construed as double dipping. The guidelines should reflect "coordination of care" including getting patients ready for the procedures that need to be performed. We believe that the resource utilization of multiple separately payable services helps define the resource level of the separate visit itself.

We do not believe this would result in attributing the same hospital resources to both the visit and the separately payable services. Many of the separately payable services are interventions that occur in separate hospital departments and that require separate department resources to perform the service on the patient. The coordination of care leading up to the separately payable service in the performing department involves separate resource utilization within the clinic and ED. So, the number and type of separately payable services can help define the true hospital resources expended for the

patient in the visit itself. By including the interventions in the level guidelines, the national visit guidelines will become a true characterization of the hospital resources involved in a visit rather than an itemization or an all-inclusive list. The PRT agrees that -- if interventions become packaged or unpackaged -- the guidelines will be difficult to stabilize and it will, therefore, be difficult to obtain consistent data for future rate-setting purposes. The PRT urges CMS to use the American College of Emergency Room Physician (ACEP) model to identify examples of interventions that can serve as useful proxies.

The PRT further urges CMS to create guidelines that will be usable for clinical staff and have the potential to allow seamless conversion to an electronic medical record (whereby the level can be assigned based on standard documentation practices for interventions and nursing services). This means that the specific documentation requirements to support the guidelines should be widely recognized as common standard of practice that are likely to be built as discrete data elements/fields into electronic documentation systems. An example of resource utilization for separately payable services which require the coordination of care from the emergency room staff follows -- A patient who is going for an angiogram requires consent, education, and mental preparations in the emergency room prior to being transported to the department to have the angiogram. These resources are integral to the coordination of care for the patient, but not related to the actual resources involved in the performance of the angiogram procedure in the Radiology department. Another example is presented by a patient who requires an MRI and must be transported physically to the Radiology department by the emergency room staff. The transport requires resource consumption and coordination of care by ED personnel because the patient may have monitors and other medical conditions that require close observation prior, during and after the procedure.

The PRT reminds CMS to ensure that NCCI edits do not include the new G codes (or CPT codes if established) for hospital ED and outpatient visits.

D. Some Interventions Appear Overvalued

The PRT believes that the majority of the interventions are placed appropriately and do not appear to be overvalued. In the Proposed Rule, CMS noted that, "in field testing the AHA/AHIMA guidelines, a vast majority of the clinic and emergency visits reviewed were assigned to Level 1 during the review." Even with modifications to the guidelines, we do not believe interventions will be overvalued. Some interventions may be undervalued or not accounted for in the leveling system at all. For example, in the draft ED guidelines, if a nurse performs a complete body system assessment (above the triage), which may include a coma scale or neurological evaluation, but there are no other interventions listed under Level One, the visit would not even assign to a Level One ED visit. Yet, the nurse may have spent considerable time above the initial triage time interviewing the patient. It is noted that the Clinic Visit Guidelines has a Level 1 Intervention of "clinical staff assessment (excluding physician) or single specialized clinical measurement or assessment." This is not present in the ED guidelines. We believe that this intervention should be added to the ED guidelines. Every effort should be made to ensure that no disparities exist between the value of an intervention in the ED versus the Clinic.

"Oxygen administration – initiation and/or adjustment from baseline oxygen regimen" is listed on the proposed guidelines as a Level 1 intervention. The PRT disagrees with this low level assignment. The administration and adjustment of oxygen is a resource-intensive treatment that requires multiple assessments of the patient's respiratory rate, level of consciousness, skin color (including monitoring for the appearance of or the resolution of cyanosis), oxygenation of nail beds, pulse oximetry readings (which are not separately payable under APCs), chest auscultation for lung status, and communication with the physician. These factors, along with any other parts of the patient's treatment that may affect his/her respiratory status, must be constantly reassessed before and after any change in the oxygen administration level. This process is much more involved than just increasing or decreasing the oxygen flow.

Specimen collection requires varying degrees of resources, depending on the patient's level of comprehension of instructions and ability to follow those instructions. The examples cited in the guidelines are usually types of specimens that the patient can obtain after instruction from hospital staff. What appears superficially to be a "simple low resource" function is not so simply defined in an Emergency Department situation, however. By virtue of being in an Emergency Department setting, a patient's level of stress and anxiety can cause distraction and lack of concentration which may result in multiple explanations of what is needed. Depending on the situation, direct assistance from hospital staff may be required in order to collect the specimen. Specimen collection as a Level 1 intervention is appropriate in a clinic or other outpatient situation, but not in the Emergency Department.

E. Concerns of Specialty Clinics

The PRT believes that one set of guidelines can be used for all clinics and outpatient areas other than the Emergency Department. Outpatient clinics have many services in common, such as dressings, infusions, injections, etc. The biggest differences revolve around the intensity of resources involved in coordination of care and counseling, which vary depending on the patient's problem list, level of education/understanding, family resources, etc. These differences can best be addressed by a time factor. Time is the single biggest resource that varies between outpatient clinics. The guidelines should reference all resources provided by "qualified hospital staff" and not be limited to nursing. In most instances, multiple professional disciplines are involved in providing the best care for the beneficiary. Coordinating care for beneficiaries often involves a team effort within a single department and/or across multiple hospital departments with several staff working sequentially with the patient to achieve the best outcome possible.

The PRT believes it is CMS' intention to use the "clinic guidelines" section for any outpatient area that is not classified as an Emergency Department. Many hospitals have outpatient departments that perform the same services as a clinic, but are not classified as a true clinic. Therefore, the PRT recommends that this section of the guidelines be titled "Outpatient Visit Guidelines". The draft guidelines on the CMS website contain the wording "ED" in this section also and the guidelines appear to be an exact copy of the ED section. While many of the same procedures can be conducted in an outpatient department and an Emergency Department, there will be differences in resource levels.

The guidelines should reference all resources provided by "qualified hospital staff" rather than being limited to nursing staff. In most instances, multiple professional disciplines are involved to provide the best care for the beneficiary. For example, a patient may present with symptoms that may be related to the interactions between medications. The patient brings all of his/her medications to the visit. A nurse or hospital pharmacist reviews each medication with the patient. The interview provides insight into whether the patient understands what each medication is for, the dosage he/she is supposed to take, concerns about taking any of the medications, compliance with taking the medication as prescribed. There may be recommendations made by the pharmacist for alterations in the regime (such as not taking two medications at the same time but staggering them to prevent side effects) and/or education for the patient by the pharmacist and/or nurse concerning the importance of compliance with the medication regime based on the clinical picture and patient's symptoms.

A patient with multiple wounds that necessitate different methods of caring for the various wounds requires much more time for teaching and education on wound care between clinic visits, when compared to a patient with a superficial wound. A diabetic patient with limited eyesight requires more time resources to ensure that he/she can check glucose levels and administer the appropriate dosage of insulin than does a patient with good eyesight. A patient with a limited school education requires more time to ensure his/her understanding of a complex treatment plan. These are all valid use of resources for the best care of the beneficiary. Time is the biggest single factor in resource involvement for these areas. The guidelines must have a mechanism for including this factor in the determination of visit levels.

The PRT recommends that the outpatient visit guidelines include a mechanism for increasing the visit level if more than 50% of the visit is spent on counseling and coordination of care. It is important for CMS to recognize that patient-specific education is an important component in the patient's quality of care. The patient must understand the procedure to consent to treatment, understand what will happen during a procedure, and understand what the plan of care is upon discharge. Specialty clinics/outpatient areas must go a step further to ensure that a patient can follow his/her treatment plan between clinic visits. This may require much coordination of assisting resources. Each patient's situation is different and, while the medical treatment may not be complex, the time spent coordinating the care for these patients can be very resource-intensive. The PRT believes it is imperative that CMS recognize that, in the outpatient setting, this as a resource that must be recognized as separately "countable" in the outpatient visit/clinic setting. In other words, it is a contributory factor for outpatient visits. These types of resources are difficult to include in a traditional "E&M" structure or as an intervention, as it can be hard to quantify these resources other than by using the time expended. Therefore, the PRT encourages CMS to define these time periods within the level guidelines. Similar to the E&M codes in the physician setting, the Outpatient Visit Guidelines should define time levels such that a higher level can be chosen when more than 50% of the visit is counseling and coordination of care. For non-Emergency Department outpatient settings, the PRT believes it is appropriate for staff to document the services provided and the face-to-face time spent with the patient.

The following table illustrates how a time-based proposal for outpatient visits would be affected by the coordination of care and counseling time:

HCPCS code	Descriptor	Total documented visit time	Coordination of care and counseling
Gxxx1	Level 1 hosp outpatient visit	30 minutes	15 minutes or more increases level to level 2
Gxxx2	Level 2 hosp outpatient visit	45 minutes	23 minutes or more increases level to level 3
Gxxx3	Level 3 hosp outpatient visit	60 minutes	30 minutes or more increases level to level 4
Gxxx4	Level 4 hosp outpatient visit	75 minutes	37 minutes or more increases level to level 5
Gxxx5	Level 5 hosp outpatient visit		

Under this proposal, if the services provided to the patient meet the guidelines for a Level 2 hospital visit which took 40 minutes and, based on the hospital staff documentation, 22 minutes is documented as "coordination of care" (such as education), the hospital would bill for a Level 3 outpatient visit.

Coordinating care for beneficiaries often involves a team effort across multiple hospital departments to provide the best outcome possible. For example, a patient may have a scheduled appointment with several different staff disciplines during one "outpatient visit". The patient begins in the oncology area and receives lab work and a chemotherapy treatment. The lab results reveal that the patient's blood counts are too low for this chemotherapy treatment. This patient is also diabetic and the medications administered before the chemotherapy treatments are beginning to cause his/her blood sugar levels to fluctuate. The patient has a scheduled visit with the Diabetes Nurse to discuss dietary changes and insulin dosage adjustments possibly needed during this time frame. This visit includes an assessment of the patient's current dietary habits; alteration in taste due to the chemotherapy treatments; and nausea and decreased appetite due to the chemotherapy treatments. The patient has noticed a sore on his/her foot and also has an appointment with the wound care nurse. The wound care nurse performs an assessment and discusses the wound with the patient's physician and a treatment plan is formulated. The patient is educated on the care of the wound. Each of these evaluations (oncology, diabetes, and wound care) addresses a unique issue for this patient and represents a distinct and separate visit in a distinct and separate outpatient department of the hospital with three separate sets of resources utilized. As is currently the practice under OPPS, the PRT recommends that each of these visits continue to be reported separately under the new guidelines.

Hospitals have concerns regarding how these three distinct visits might be required to be reported as one visit under revised guidelines. The guidelines should be structured to allow a separate visit code for each of the physically separate departments that expended resources. Because the services cross department lines and are separately provided, it will be a difficult task to combine the services into one level.

Therefore, the guidelines should be very specific regarding how to bill these multiple visits on the same date of service. Under current CMS billing guidelines, modifier -27 and condition code G0 are reported to indicate physically separate visits that occur in different departments on the same date of service. The PRT proposes that this structure be utilized in the scenario described above.

The PRT also recommends that CMS publish a specific definition of "separately identifiable" visit for the hospital setting (i.e. visit code qualifying for modifier -25). Clinical staff will need more specific guidelines for when to report a level code on the same date of service as a procedure. For example, if a patient presents to the wound clinic for a scheduled visit for debridement and reports a new lesion to the nurse, a separate assessment of this new wound must be provided. In this case, it is easy to identify that the visit resources are related to a new problem, not related to the reason for the scheduled visit, and therefore can be reported separately.

Although some kind of evaluation/assessment is usually required for any visit to assess the patient's progress since the last visit, there are no clear guidelines for when this assessment/evaluation is considered to be "more than the usual." CMS should define whether a new problem must exist in order to qualify for "separately identifiable". CMS should clarify the appropriate action in situations where a particular reaction is expected, but the individual patient's reaction is worse than expected. For example, nausea and vomiting is expected with some chemotherapy regimes. Hospitals need guidance on the procedure for instances in which the patients vomiting continues beyond the expected period of time, and/or is much more severe than expected, both of which require significant hospital staff resources be expended in monitoring, assessing, and coordinating further treatments with the physician. At times, a patient's non-compliance with the plan of treatment creates a new situation for managing the patient's care that takes significant resources. However, it is not easy for hospitals to determine whether CMS would consider this a valid circumstance for reporting a separate outpatient visit code along with the procedure code.

For any outpatient visit, hospitals receive physician's orders for the services needed for the individual patient. There are times when the physician may write an order for a service that is not "typical" and could be provided at the physician's office rather than by a hospital outpatient department. The CMS guidelines must be structured in a way that prevents limiting the reporting of legitimate hospital services and allows them to be applied to any and every visit. For example, a patient may present to a hospital outpatient area with orders from the physician for adjustment of the gastric band component. This is usually considered to be a component of the physician's post-op care but, in this instance, the physician sent his or her patient to the hospital for this service. The guidelines must allow this service to be reported by the hospital.

Another example is an instance in which a PICC line was inserted in the physician's office and the patient referred to the hospital outpatient area for removal of the PICC line. There is no separately reportable CPT code for this procedure, and it would usually be expected to be performed in the physician's office. However, the guidelines must allow reporting of this service by hospitals using a visit code.

Finally, the PRT offers some specific examples of the different types of services provided in specialty clinics below.

Clinical Examples from Specialty Clinics

To assist CMS in development of hospital visit guidelines that will function well for hospital specialty clinics, the PRT provides some examples of specialty clinic visits and notes where the current proposed CMS guidelines do not address important clinical services provided in these clinics.

Geriatric
Reason for Visit: Poor Circulation in ankles and feet
Nursing Documentation: Vitals, Height, Weight, Temperature
Pain Assessment: 4/10; Location: toes; Severity: pin prick sensation
Fall Assessment performed by the RN as a result of the questions answered by the hospital internal monitoring tool (get up and go). Nurse documented a low score of 3 and contacted the physician with the results.
Allergies reviewed: NKA all drugs/herbs OTC's foods and environmentals reviewed
Ankle and Foot Assessment: Foot and ankle assessment notes that the foot and ankle were cold to the touch, foot and ankle not pink in color notified physician who ordered a manual Ankle Brachial Index. An Ankle Brachial Index (not separately billable since manual exam) was performed and result documented per physician's order.
Finger stick glucose is performed.
Time: 1.5 hours

- Under the purposed CMS guidelines: Low level visit
- Under current hospital guidelines: High level visit

Oncology
Reason for Visit: Follow-up post op mastectomy
Nursing Documentation: Vitals, Height, Weight, Temperature
Pain Assessment: 6/10; Location: Breast suture area; Severity: aching, pain is sharp intermittently
Wound Assessment: suture are intact, no redness no drainage noted. Patient following discharge guidelines
Review allergies: NKA
Physician examines the patient, decides to increase the size of the tissue expanders placed during surgery. 2 tissue expanders are filled with 20cc of saline.
Time: 1 hour

- Under the proposed CMS guidelines: Low level visit. Filling of tissue expanders (which does not have an assigned CPT code) is not addressed under the proposed CMS guidelines. The procedure requires hospital time and resources and should be considered in the hospital visit level assigned.
- Under current hospital guidelines: Mid level visit raised to a high level visit due to the procedure to fill the tissue expanders.

Chronic Pain
Reason for Visit: Back pain and to check pain pump
Nursing Documentation: Vitals, Height, Weight, Temperature
Pain Assessment: 4/10; Location: low back going down the legs; Severity: pin prick sensation in leg and sharp pain to the lower back
Pain Management: documented medication treatment and its results, coping strategies, effect of pain on quality of life.
Allergies reviewed: NKA all drugs/herbs OTC's foods and environmentals reviewed.
Documented RN site assessment: clean, dry, no redness or infection noted,
RN assessed the pain pump and provided 30 minutes of teaching for taking care of the pump at home per physician order. Teaching was documented on the hospital teaching sheet. Pump refill was not necessary. Documented that the pump was working properly.
Time: 1.5 hours

- Under the purposed CMS guidelines: Low level visit. The proposed CMS guidelines do not take into consideration 2 factors: 1. Maintenance of a pain pump without refill. Under current guidelines, CPT code 95990 (Refilling and Maintenance of implantable pump) must included both components before using that CPT code. Patient did not require refilling of the pump for this visit but nursing staff did provide maintenance and assessment of the pump. 2. The 30 minutes of patient teaching provided by the RN and directly related to a current medical condition.
- Under current hospital guidelines: High level visit.

Infectious Disease
Reason for Visit: Ear pain and difficulty breathing
Nursing Documentation: Vitals, Height, Weight, Temperature
Pain Assessment: 7/10; Location: bilateral ear pain; Severity: sharp throbbing pain to both ears
Allergies reviewed: NKA all drugs/herbs OTC's foods and environmentals reviewed
Assessment of respiratory: SOB started 3 days ago, dry cough, auditory wheezing heard
Physician ordered a resting pulse ox and a walking 5 minute pulse ox. Staff documented the results of both.
Physician ordered the RN to flush both ears as the assessment indicated the pain was caused by impacted cerumen.
Physician requested the RN to remove the PICC line as it is not longer needed. RN documented and removed the PICC line
Time: 1.25 hours

- Under the purposed CMS guidelines: Mid level visit. The proposed CMS guidelines do not take into consideration several factors. 1. Ear irrigation is not is not addressed and does not have an assigned CPT code. 2. Removal of a PICC line does not have an established CPT code, again training and competency is require by our staff in order to provide this type of service.
- Under current hospital policy: High level visit

Cancer genetic counseling clinic
The client is referred to the clinic by MD order. Usually a family member has cancer and the patient's MD, RN or social worker recommends possible cancer genetic counseling for the family. The client presents to the clinic nurses for the following services (approximately 1 ½ hours of time):
Obtain familial history related to cancer,
Discuss hereditary and sporadic cancer risk
Client views a 25 min video related to the process
Available and appropriate genetic testing options are reviewed, including benefits and limitations of genetic testing as well as associated management and cancer surveillance; health care coverage, privacy, and genetic non-discrimination.
Blood work is drawn if appropriate and submitted to outside testing facility.
Consult notes are documented
Follow up to discuss testing results or as needed.
Time: 1.5 hours

Coumadin Clinic visit procedures
The patients present to the Coumadin Clinic based on a physician order.
Patients receive in-depth consultation, both verbal and written, concerning warfarin administration;
Patients receive both verbal and written materials concerning clinic procedures, other drug information, diet interactions, drug interactions, frequency of lab tests, signs and symptoms of bleeding, and the importance of compliance with medication and clinic procedures.
The Nurse obtains an in-depth history from the patient including current and past medical history. A complete list of current medications is also obtained from the patient.
Finger stick PT and INR is performed. Resulted are documented and adjustments made in the Coumadin dosage as needed.
Follow up visits are scheduled according to lab values, typically from 1 – 4 weeks.
A clinical summary note is faxed to the referring MD which details the changes in patient's dosage and lab values that were obtained during the visit as well as all other information regarding changes in Vitamin K, diet, missed doses, upcoming medical/surgical procedures, etc.
Time (length of visit): varies between 10 and 30 minutes.

Ostomy Care
Reason for visit: Physician order to prepare patient for stoma.
Nurse assessment: Assess the patient's muscle parameters by having the patient sit, stand, and lie (if they can). Look for creases, old scars, umbilicus, and the general contour of the abdomen, and make sure the patient will be able to see the stoma. Methyl Blue dye is injected under the skin to mark the spot where the surgeon will create the stoma.
Education: Patient and family are educated about the stoma and what to expect. Patients often exhibit anxiety and nurses spend time to build rapport with patient and family. Fear and anxiety are particularly significant with cancer patients and the elderly..
Referral to Social Worker: Counsel patient on ostomy products, cost, vendor indigency programs.
Time: 2 hours

F. Americans with Disability Act

The PRT is aware that there may be state case law that could result in visit guideline statements such as "Special needs requiring additional specialized facility resources" from the AHA/AHIMA model as a violation of the 'Americans with Disabilities Act". Regardless of the stated factor or criteria in the visit guidelines, patients with special needs often require more time and effort. The current E&M criteria for physician visits and most hospital guidelines today result in higher visit levels for patients with special needs/disabilities. This will be an issue for all settings, including both hospitals and physicians' offices.

There are several types of cases that involve increased time and resource consumption for all types of medical conditions (i.e. emotional, physical, and mental) that could fall into this situation. Many examples could be listed here, which highlight the need to develop some type of standard for addressing the different types of needs for services that play a large part in resource consumption and intensity of service. Just as one example, culturally diverse locations require interpreters in the emergency care areas or outpatient departments/clinics for coordination of care.

For this reason, the PRT emphasizes the need for CMS to consider "time" as a factor to be included in the guideline interventions when "counseling and coordination of care" consume more than 50% of the patient visit. To alleviate CMS' concern about additional financial liability for the beneficiary who takes more time due to special needs or disabilities and therefore owes more in co-payment, the PRT encourages CMS to establish equal co-payment amounts across the five levels of hospital outpatient visit and five levels of Emergency Room APCs. The PRT encourages CMS to establish a co-payment for all hospital outpatient levels and a separate co-payment for all emergency room visit levels. The PRT believes that, if the co-payment is consistent within the visit guidelines across all levels, it will eliminate any potential violation of the law. This methodology would also eliminate any increased financial liability based on an individual disability or other medical conditions.

G. Differentiation Between New and Established Patients, and Between Standard Visits and Consultations.

The PRT is pleased that CMS elected to remove the distinction between new versus established versus consult patient types, as we believe any differences among these types of patients are best addressed by the actual visit levels assigned, assuming those are constructed in a manner to capture hospital resource intensity rather than clinical acuity, as these are different things. We do believe that there is often additional expense for new patients, but we suggest that this can be listed as a contributory factor to visits rather than have distinct visit types for new and established patients.

H. Type A & B facilities

The PRT believes that CMS has already established the distinction between type A and B emergency facilities. Type A facilities are hospital emergency departments that are open 24 hours per day, 7 days per week. Type B facilities are NOT open 24/7, but rather have designated hours of operation (i.e., an off-site urgent care facility that is open Monday through Friday, 8am – 5pm).

Type A facilities have significantly higher resource costs than Type B facilities, mostly due to the staffing requirements associated with staying open 24-hours-a-day, 7-days-a-week, and being available to care for patients at any hour. Type B facilities expend fewer resources, since they are open fewer hours, treat fewer patients, and may not offer some of the critical services that hospital-based Emergency Departments offer.

CMS stated in the OPPS Proposed Rule (*Federal Register* page 49608, second column) that it has no way to distinguish the cost of visits provided in Type B (DED's) facilities verses Type A facilities from the hospital claims data. The PRT supports CMS' proposal to implement one set of five G-codes for use by a Type A facility and a second set of five G-codes for use by a Type B facility. Reporting separate code sets will improve data reporting and enable CMS to gather the appropriate claims data for establishing appropriate APC payments for both types of facilities.

The PRT also supports CMS' proposal that separate payment be established for Type B facilities due to the lower resource cost in comparison with Type A facilities.

8. Observation services

The PRT asks CMS to provide specific and definitive guidance concerning observation cases that exceed 48 hours. We note that, on page 65830 of the November 15, 2005 *Federal Register*, CMS states (in the Final OPPS Rule) that it would "not adopt as final its proposal to exclude claims with G0244 that reported more than 48 hours from the median cost calculation." This was after PRT comment to CMS which noted that claims with more than 48 hours are accepted into the CMS data base only after Fiscal Intermediary (FI) scrutiny. CMS released Change Request 3311, which allowed FIs to override the Medicare CWF edit on claims with units of observation hours greater than 48. This Change Request was subsequently rescinded. Change Request 4259 (released on December 16, 2005) for 2006 OPPS indicates that, "in only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours." Section 290.1.4 states that the 2006 changes to observation billing were made so that "hospitals are able to provide consistent coding and billing under all circumstances in which they deliver observation care... the units of service [for G0378] should equal the number of hours the patient is in observation status."

Fiscal Intermediaries continue to reject claims for observation when the units of service are greater than 48. This means that a hospital which believes it has a case that qualifies as rare and exceptional -- and that can withstand FI scrutiny -- is unable to get the claim into the FI for review, much less into the CMS claims database. The hospital must arbitrarily reduce the hours to equal 48 hours and place the remaining hours as non-covered hours. Yet, according to the CMS definition of "observation", these hours should be covered and either packaged (if the case does not qualify for separate observation payment) or be included in the median cost calculation for APC 0339.

CMS must make a definitive decision and communicate this decision to both hospitals and FIs alike. CMS must clarify if all hours of observation care beyond 48 hours are non-covered. If they are not, CMS needs to release a clear transmittal to both hospitals and FIs regarding acceptance and review of observation claims with more than 48 units on G0378. In addition, the PRT seeks clarification on whether the 2007 OPPS median cost calculation for APC 0339 includes claims with more than 48 hours of observation.

The second issue the PRT would like to raise with respect to observation is CMS' proposal to use midnight as a defining measure of an overnight stay for ASC facility services. We believe that this suggestion makes sense not only for a freestanding ASC, but for outpatient hospital patients as well.

We note that an ASC would not be able to keep a patient at its facility if it becomes apparent that overnight monitoring is medically necessary. In such a case, the ASC would follow its required hospital transfer agreement and transfer the patient to a hospital. These patients are unlikely to meet acuity and severity of illness requirements to qualify as hospital inpatients, therefore, their admission status would be "observation". The hospital would be able to bill HCPCS code G0379 for a direct admission (assuming the patient did not arrive through the ED) to observation. The hospital would bill each hour of observation under HCPCS code G0378. The only payable APC (assuming no other interventions than medically necessary monitoring) in this case would be APC 0604 for HCPCS code G0379, assuming the patient's complications did not meet the clinical criteria for the separately payable observation APC conditions of chest pain, CHF, or asthma.

The PRT raises the above issue because we are concerned about the payment inequity in the above case and the case in which the patient receives the exact same surgery at a hospital as an outpatient and develops the same complication requiring an overnight stay with the hospital transferring the patient to a floor for observation. In this case, the hospital would not be able to bill HCPCS code G0379, because an *internal* transfer case does not qualify as a direct admission to observation. Even if CMS changes the description on G0379 and allows the hospital to bill this code for post-surgical direct admission to observation, there would be no APC payment under the current outpatient code editor logic since APC 0604 is not payable if there is a procedure (status indicator "T" or "S") on the same day or the day before the observation service.

The PRT is not only concerned about this payment disparity, but also about the ASCs' ability to transfer cases to hospitals when payment is limited because hourly observation qualifies for payment in limited clinical cases. The vast majority of

transferred ASC cases will not have chest pain, CHF, or asthma. We therefore urge CMS to consider midnight a defining criteria and instruct hospitals to report any medically necessary time beyond midnight on the day of hospital outpatient surgery as hourly observation with code G0378. We further ask CMS to once again consider separate APC payment for observation regardless of the clinical condition. This is particularly important now with the expansion of allowable procedures in ASCs and the resulting fact that ASCs may have to transfer more cases to the hospital. Additionally, the PRT asks CMS to stress that ASCs should not transfer cases for routine recovery, nor should they begin cases late in the day when routine recovery could extend beyond midnight thinking that they can simply transfer the case to the hospital.

Finally, for quality of care monitoring, CMS should consider a new source of admission code for "transfer from an ASC" to be used by hospitals when reporting cases transferred in from an ASC. This will allow hospitals and CMS to capture useful data.

9. Outpatient Quality Initiative

The PRT believes the Quality Initiative is an important and laudable project, however, we are concerned about the significant increase in hospital resources that will be required to collect additional data if Medicare implements separate outpatient quality measures. We ask CMS to bear in mind that the volume of outpatient cases is much higher when compared to inpatient volume. Based on the current model of 100% data collection, we believe hospitals will need to hire additional staff and/or increase vendor workload resulting in increased cost simply to meet the additional data demands. Moreover, this issue will be further compounded by the projected increase in Medicare beneficiaries over the next decade.

Now that CMS is linking hospital outpatient department payments to the submission of quality indicators and expects to expand this in the future, we believe the timing is appropriate to now require physicians to participate in a similar Quality Initiative program so that their payments are also linked to quality indicators. We believe the upcoming completion of the MAC project is an excellent opportunity to link physician reimbursement to quality indicators where their actions directly impact patient outcomes. This will allow CMS to tie both physician and hospital reimbursement to quality indicators. Finally, the PRT encourages CMS to calculate an outpatient case-mix index for each hospital as part of its Quality Initiative program.

10. OPPS Payment Status Indicators and Comment Indicators

CMS has made yearly refinements to the Status Indicators (SIs) used under OPPS as well as the Comment Indicators. The PRT thanks CMS for these efforts and notes that the refinements help providers tremendously in the implementation of OPPS changes and in the ongoing management of systems and processes necessary for complete and accurate billing and appropriate OPPS payment. Providers use the SIs assigned to HCPCS codes to better understand Medicare payment policy. With the ASC proposal to move towards payment policy based on OPPS, the importance of SIs becomes even more crucial for understanding CMS' payment policy for different services.

In the spirit of providing suggestions and ideas for continued refinements, the PRT would

like to propose that the current SI "B" be split into two different SIs because the current definition of SI "B" means two different things. The current definition is:

> "B" = Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x). Not paid under OPPS [because]
>
> - Code may be paid by intermediaries when submitted on a different bill type, for example, 75x (CORF), but not paid under OPPS.
>
> - An alternate code that is recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x) may be available.

From the above, it is clear that SI "B" means the HCPCS code is not paid either because (1) the code is not paid under OPPS, but may be paid when submitted on a different bill type, or (2) an alternative code will be paid under OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x).

As a general rule, we believe each SI definition should be "pure" and have only one meaning. Therefore, we propose CMS change the definition of SI B so that it only means the first item above, (1) the code is not paid under OPPS, but may be paid when submitted on a different bill type and create a new, separate SI "Z" to mean the second item from above (2) an alternative code will be paid under OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x). These changes will facilitate an understanding of what each SI means for both hospitals and ASCs.

Furthermore, the PRT requests that CMS publish a separate addendum as part of the OPPS rule that lists the alternative HCPCS Level II codes for OPPS that should be used for all codes that are assigned the newly proposed SI "Z" as described above. This supplemental information will be very helpful to hospitals and ASCs as they will not have to search for the alternate code if CMS simply provides it as part of the final OPPS rule each year. This will also facilitate improved accuracy of the claims data CMS receives under OPPS.

11. Medicare Contracting Reform and Establishment of MACs

The PRT supports CMS' current effort to replace the current fiscal intermediary (FI) and carrier structure by creating Medicare Administrative Contractors (MAC's). PRT members are aware of significant inconsistencies in payment policy across FIs throughout the country and have brought these to CMS' attention via e-mail and through the Hospital and Quality Open Door Forum calls. The most egregious inconsistencies are the ones where an FI simply misinterprets official national guidance released by CMS and releases contradictory instructions to its providers. This causes a great deal of confusion and results in CMS receiving poor, inconsistent, and incorrect data not to mention the harm done to Medicare beneficiaries who are charged differently across the country even though national guidance exists. In addition, when different fiscal intermediaries govern two hospitals in the same geographic area, even more confusion results.

By consolidating intermediaries and carriers into single MAC's, we expect to see more consistency in payment policy over time. Inconsistencies within a geographic area should also be eliminated as a result of assigning MAC's by region. Finally, we anticipate that CMS will instruct MACs to review LCD and other policies to ensure consistency in coverage between settings of care and to align payment policy and incentives between physicians and hospitals within the discretionary boundaries of the MACs.

12. **Transparency Initiative**

The PRT agrees that health care consumers should have access to information on the price and quality of healthcare items and services. We are in firm support of publishing geographically-based Medicare payment information on the CMS website. We are, however, concerned about publishing facility-specific pricing for services without specific guidelines to facilities instructing us on exactly what to include in describing the price for a service. Facilities should be provided with and expected to follow a standard definition and description of a "price" for an item are a service to allow beneficiaries to adequately compare prices – particularly for outpatient services as hospitals have discretion about whether to "package" certain services/charges together and report a single line item or to separately report each item. It is not clear to us how CMS will be able to provide price comparisons of like services. Consumers cannot be expected to sort through concepts of packaging or sum together prices for several line items in order to come up with an equivalent "apples to apples" comparison of similar services. In other words, for outpatient services, if providers are including different items in the price of a single service (represented by a line item), accurate comparison cannot occur. We ask CMS to carefully review this issue and determine how best to proceed so that consumers are able to achieve what is expected from the transparency initiative.

Conclusion

The Provider Roundtable would sincerely like to thank CMS and its staff for reviewing and considering our comments. Although we are still a relatively new group, 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 spokesperson Valerie Rinkle, listed in Appendix A below.

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

Jennifer L. Artigue, RHIT, CCS
Dir. Revenue Mmgt, CDM & Medical Records
Our Lady of Lourdes Regional Medical Center
Lafayette, LA

Kathi L Austin, CPC, CPC-H, CCP
Corporate Director Revenue Integrity
Sisters of Mercy Health System
St. Louis, MO

Barbara Bunge, RHIA, CCS, CCS-P
Coding Quality Specialist, HIM
Mercy Medical Center
Cedar Rapids, IA

Kathy Dorale, RHIA, CCS, CCS-P
Director of Health Information Management
Avera Health
Sioux Falls, SD

Janet V. Gallaspy, BS, RN, CPUR, CPC-H
Director of Patient Care Services, Outpatient Services
Forrest General Hospital
Hattiesburg, MS

Jerry Hill, MA
ChargeMaster Coordinator
University Health System
San Antonio, TX

Marion G. Kruse, BSN, RN, MBA
Columbus, OH

Monica Lenahan, CCS
Coding Manager
University of Colorado Hospital
Denver, CO

Bonnie Malterer, RHIT, BA
APC Coordinator, Outpatient Coding Supervisor
St. Mary's Hospital
Duluth, MN

Yvette Marcan, RN, MA, RHIA, CCS
Clinical reimbursement specialist
Health First, Inc.
Melbourne, FL

Terri Rinker, MT(ASCP), DLM. MHA
Reimbursement Manager
Community Hospital Anderson
Anderson, IN

Valerie A. Rinkle, MPA
Revenue Cycle Director
Asante Health System
Medford, OR

Julie Rodda, RHIT
Reimbursement Coordinator
St. Joseph's Hospital
Marshfield, WI

John Settlemyer, MBA/MHA
Director, Financial Services/CDM
Carolinas Healthcare System
Charlotte, NC

Denise Williams, RN, CPC-H
Corporate CDM Manager
Vanguard, Health Systems
Nashville, TN

CUTLASS CAPITAL, LLC

60-D
(4)

84 State Street, Suite 1040
Boston, MA 02109
(617) 624-0159 (Tel)
(617) 624-9669 (Fax)

1750 Montgomery Street
San Francisco, CA 94111
(415) 954-7163 (Tel)
(415) 954-7164 (Fax)

September 22, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate HOPPS payment. By excluding new and innovative brachytherapy

radiation sources from separate HOPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT

Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical *brachytherapy*. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity *brachytherapy*. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year's proposed rule. Should you have any questions please do not hesitate to email me at jonosgood@cutlasscapital.com

Respectfully,

Jon Osgood

Jonathan W. Osgood (JO)
Managing Member